Oracle® Life Sciences Clinical One Cloud Service and Oracle® Life Sciences Clinical One Digital Gateway

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Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support
- Additional copyright information

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- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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What should I use this guide for?

About this guide

This *Change Log* is a user guide that contains Release Notes content from previous releases. This includes but may not be limited to the following:

- **Patch log** content: includes details about patches applied to a minor release.
- **What's new** content: includes details about new features and enhancements.
- **Fixed issues** content: includes details about the issues that were fixed in each release, whether it is a minor release, a patchset, or a patch.
- **Rest API Updates**: includes details about API services that are updated for each release.
- **Release impact for other applications**: includes details about downstream impact on other applications for specific new features introduced in a release.

For example, when the current Production version is 22.2, the Change Log includes the Release Note content for versions 22.1 and lower. If you are looking for this content for the current release, visit the Oracle Help Center (OHC).

How far back does the Change Log content go?

The *Change Log* user guide stores historical Release Notes content up to two years back from the current year. If you require content from older Release Notes, send us an email at *clinical_one_doc_feedback_us_grp@oracle.com*.

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Clinical One Cloud Service and Clinical One Digital Gateway 26.1

- Patch log
  This page briefly describes the history of fixed issues and any new functionality delivered in patches on top of the 26.1 release.
- What's new in 26.1
- Fixed issues in 26.1

Patch log

This page briefly describes the history of fixed issues and any new functionality delivered in patches on top of the 26.1 release.

Release Number	Release Date	Details
26.1.0.4	21 May 2026	In this patch release, we fixed several issues, see the following: • Issues **38436750**, **38653482**, and **39029323** in Forms, visits, and rules. • Issue **39220752** in Randomization and kits. • Issue **39280942**, **38618793**, and **39246256** in Reports, archives, extracts, and notifications. • Issue **39123163** and **39219318** in Site users and subject data. • Issue **39260429** in Facilities, settings, and user management.
26.1.0.3	08 May 2026	This version was republished to move the mention of issue 39219300 into the Fixed Issues section of the patch log for release 26.1.0.2.
26.1.0.3	02 May 2026	In this patch release, we fixed bug **39294968**. For more information, see All users.

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Release Number	Release Date	Details
26.1.0.2	28 April 2026	In this patch release, we fixed several issues, see the following: • Issues **39039938**, **38690545**, and **39114558**, **39233418**, and **39239493** in Forms, visits, and rules. • Issue **39173547** in Oracle Clinical One Analytics. • Issues **38873886** and **39165655** in Integrations. • Issue **39131935** in Randomization and kits. • Issue **39175694** in Site users and subject data. Enhancements to subject screening and subject number assignment were introduced. For more information, see Enhancements to subject screening and number assignment.
26.1.0.1	07 April 2026	In this patch release, we fixed several issues, see the following: • Issue **37762573** in Code lists. • Issues **38097324** and **38936132** in Integrations. • Issues **36028851**, **38927690**, and **38937068** in Oracle Clinical One Analytics. • Issues **38991660**, **38982049**, **38997236**, **39064298**, **37610864**, **38833657**, **36619590**, **36857253**, **36216445**, **37919137**, and **39089068** in Forms, visits, and rules . • Issues **37646263**, **38993461**, and **38965549** in Reports, archives, extracts, and notifications . • Issue **36862807** in Site users and subject data .

What's new in 26.1

- Documentation update: Name updated to Oracle Life Sciences Clinical One Cloud Service
- Data Collection
- Data review
- Integrations
- Randomization and Trial Supply Management
- Reporting, archives and analytics

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- Study design
- User experience
- REST API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 26.1.
- Release impact on downstream systems
  This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 26.1 may have on downstream systems, specifically Oracle Clinical One Analytics, Clinical One Digital Gateway integrations, Oracle CRF Submit, and Oracle Life Sciences Data Management Workbench.

Documentation update: Name updated to Oracle Life Sciences Clinical One Cloud Service

We updated our product name from *Oracle Life Sciences Clinical One Platform* to the officially trademarked name of *Oracle Life Sciences Clinical One Cloud Service*. This change is for name alignment only. Expect to see references to Oracle Life Sciences Clinical One Cloud Service in materials and documentation in all future releases.

Data Collection

- Highlight Missing Questions View
  To ensure the timely input of data, site users can now switch to the Highlight Missing Questions view while completing visits.
- Enhanced analytics visibility of missing data across visit types
  To ensure that reports, dashboards, and downstream integrations accurately reflect the current status of a study, Oracle Clinical One Analytics now persists all scheduled and expected visits and forms, including dynamically triggered visits, visit branches, cyclic visits, and associated forms. In addition, the logic of forms and visits that are considered missing has been updated to consider static and dynamic forms, as well as visit schedules that include dynamic visits, cycles, and branching.

Highlight Missing Questions View

To ensure the timely input of data, site users can now switch to the Highlight Missing Questions view while completing visits.

Details for site users

Site users can now highlight questions with incomplete or missing data by selecting **Highlight Missing Questions** in the upper right corner of the data entry area. Questions with missing data are outlined in red and are accompanied by the message `Value is required`.

Once you select **Highlight Missing Questions**, the page automatically takes you to the first question with missing data.

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> **Note**
>
> Questions marked by users as **Not Done**, **Not Applicable**, and **Unknown** are not highlighted when you press the **Highlight Missing Questions** button, as they are not considered missing. However, question that have automatically been marked as **Not Answered** are highlighted by this view.

As a site user, you should also be aware of the following:

- The **Highlight Missing Questions** button also displays the count of questions with missing data once you select it. This count is updated every time you save the visit data.
- Whenever the response to a triggering question triggers a dynamic question or the dynamic flat form that includes required fields, those missing required questions are highlighted only after you save your subject data.
- For repeating or two-section forms, questions are only considered missing once the form or row has been started. As such, questions on forms and rows that have not been started are not highlighted.
- Questions that are visible only to specific roles are highlighted as missing only for users in those roles.

You can find additional information on using this feature in the *Site User Guide* after the assessment environment upgrade finishes.

Enhanced analytics visibility of missing data across visit types

To ensure that reports, dashboards, and downstream integrations accurately reflect the current status of a study, Oracle Clinical One Analytics now persists all scheduled and expected visits and forms, including dynamically triggered visits, visit branches, cyclic visits, and associated forms. In addition, the logic of forms and visits that are considered missing has been updated to consider static and dynamic forms, as well as visit schedules that include dynamic visits, cycles, and branching.

Details for sponsor users

As a data manager, you can now leverage the following changes to Oracle Clinical One Analytics to perform data review and issue resolution at the appropriate time:

- The system now persists records for upcoming, scheduled, and dynamically triggered visits, including visit branches, cyclic visits, and their associated forms. These records are associated with the subject.
- • Dynamic visits, visit branches, cyclic visits, and their associated forms are now included in missing data evaluation.
- A form or a visit is referred to as missing whenever it should have been completed, but is not yet started.

Details about changes to visits, forms, and questions

As a data manager, you should be aware that the system now creates and stores records of upcoming or scheduled visits. Such records are associated with the subject those visits pertain to.

You should also be aware of the following changes to the way visit statuses are determined:

- Future visits now keep the status of SCHEDULED until they are started. Once a visit is started, the status changes to IN_PROGRESS.

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- Visits inserted in the study design as part of Advanced Study Versioning (ASV) are now considered missing (IS_MISSING=Y) and have a status of NEW.

The behavior of forms has also been adjusted as follows:

- Forms associated with visits with a status of SCHEDULED also have a status of SCHEDULED.
- When a visit transitions to IN_PROGRESS, its forms transition to NEW or OPTIONAL, as applicable.
- Once a form is started, it receives a status of IN PROGRESS.
- If a form is triggered, but the condition that led to its triggering changes, it receives a status of DELETED.
- Forms associated with a visit that is identified as missing are also considered missing.

Impact on reports, extracts, archives, or datasets

Oracle Clinical One Analytics users can now generate reports and dashboards that include the following new elements:

Dataset	Type of change	Description
Blinded Subject Events dataset	Changes to existing data elements	• The IS_MISSING_VISIT element now receives a value of Y only when the visit includes: – the status of either SCHEDULED or NEW. – an associated PROJECTED_VISIT_END_DATE element, containing a value older than that of SYSTEM_DATE. – not skipped. – the IS_CURRENT element with a value of Y. • The VISIT_STATUS element can now also receive a value of NEW whenever the visit was either dynamically triggered or added as part of ASV.

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Dataset	Type of change	Description
Unblinded Subject Events dataset	Changes to existing data elements	• The IS_MISSING_VISIT element now receives a value of Y only when the visit includes: – the status of either SCHEDULED or NEW. – an associated PROJECTED_VISIT_END_DATE element, containing a value older than that of SYSTEM_DATE. – not skipped. – the IS_CURRENT element with a value of Y. • The VISIT_STATUS element can now also receive a value of NEW whenever the visit was either dynamically triggered or added as part of ASV.
Subject Forms dataset	Changes to existing data elements	• The IS_MISSING_FORM element now receives a value of Y only when the following conditions are met: – the form has a status of either SCHEDULED or NEW. – the value contained in the parent visit's PROJECTED_VISIT_END_DATE must be older than that of SYSTEM_DATE. – the form has not been skipped. – the form's associated IS_CURRENT element has a value of Y. • The FORM_STATUS element can now also receive the following values: – OPTIONAL: the form does not have any required or completed items – NEW: none of the items of the form have been completed yet. A form can only received this status if it is triggered by a question with a show form rule or if it is added as part of ASV.

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You can find additional information regarding these changes in the *Analytics User Guide* after the assessment environment upgrade.

Data review

- Sign, verify, and freeze visit dates
  The signing, verifying, and freezing of visit dates is now supported for visit dates, aligning with other data items in the visit.

Sign, verify, and freeze visit dates

The signing, verifying, and freezing of visit dates is now supported for visit dates, aligning with other data items in the visit.

Details for sponsor users

As a sponsor user, you can now verify, unverify, freeze, and unfreeze visit dates.

- These actions can still be performed even if the study settings prevent the user from entering or editing the visit date.
- **Targeted SDV** toggles are included in the user interface (UI) for the Create Visit dialog and Edit Visit dialog for Source Data Verification (SDV) for Critical Variables (Targeted SDV) and All Subjects.

> **Note**
>
> These toggles are set to **Off** by default. These toggles are present for any Scheduled or Unscheduled visit that include a visit date.

More information and step-by-step instructions can be found in the *Sponsor and CRO User Guide* after the upgrade.

Details for site users

When it comes to your workflow as a site user, you can now sign a visit date at both the subject and visit level. All visit date modifications are reflected in the **Answer & Visit History**.

In order for the visit date to be eligible for signing at the visit level, at least one question in the study must be entered or updated. This action applies the signature to the visit date associated with the signed visit.

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Impact on reports, extracts, archives, or datasets

Report, extract, archive, or dataset	Type of change	Description
Subject Events report	Modified column data	This report now indicates when a visit date is Signed, Verified, or Frozen. The following values have been introduced for the **Event Type** column when applicable: • Visit Date Signed - Subject Level • Visit Date Signed - Visit Level • Visit Date Unsigned • Visit Date Verified • Visit Date Unverified • Visit Date Frozen • Visit Date Unfrozen
Annotated Case report	Modified column data	This report now includes SDV settings for visit dates in the **Forms by Visit** section.
Study Design report	Modified column data	This report now includes SDV settings for visit dates in the **Visit Details** section.
Study Design dataset (Events folder)	New column field	The new **SDV_VISIT_START** column is introduced to this dataset to capture SDV settings for visit dates with the following possible values: • NULL • ALL SUBJECTS • TARGETED SDV
Blinded Subject Event Dataset	New column field	The new **SDV_SELECTION_VISIT_DATE** element is introduced to this dataset with the following possible values: • OBLIGATORY • OPTIONAL • OPTIONAL_CRITICAL • IRRELEVANT This element tracks visit dates for visits associated with the record that's part of the targeted SDV pool for a subject tied to the record.

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Report, extract, archive, or dataset	Type of change	Description
Unblinded Subject Event dataset	New column field	The new **SDV_SELECTION_VISIT_DATE** element is introduced to this dataset with the following possible values: • OBLIGATORY • OPTIONAL • OPTIONAL_CRITICAL • IRRELEVANT This element tracks visit dates for visits associated with the record that's part of the targeted SDV pool for a subject tied to the record.
Subject Event SVFL dataset	Modified data element	The OBJECT_TYPE element allows you to track visit date actions, such as VERIFY, FREEZE, SIGN, and LOCK.

More information and specific descriptions on modified report values can be found in the *Reporting Guide* and the *Analytics User Guide* after the upgrade completes.

Impact on integrations

Integration	Details
Oracle Siebel CTMS Source Data Verification (SDV)	If the visit date is configured as SDV-required, the SDV integration marks the visit as SDV complete in CTMS only after the entire visit—including the visit date—has been verified. If the visit date is not SDV-required, it is ignored when updating the SDV complete status in CTMS. **Already using this integration with a live study?** For existing integrations, visits previously verified and integrated with CTMS retain their SDV-complete status. ***Note**: No template updates are required to implement this feature*.

Already working in a live study?

Once the upgrade completes, visit dates in new and existing studies can be signed, verified, and frozen.

Sponsor users working in an existing study:

- If all questions in the visit are frozen at the time of the upgrade, a newly created event moves the visit date to a *Frozen* status. This allows the visit date to be unfrozen. Furthermore, the entry is logged in the Answer & Visit History and attributed to the system user.
- If any questions in the visit are unfrozen or never frozen at the time of the upgrade, the visit date continues to be available for editing and must be frozen by a sponsor user. This results in the visit date no longer being implicitly frozen when the remainder of the questions on the visit are frozen.
- If the visit was verified prior to the upgrade, the visit remains verified. However, if another question in the visit requires verification, the visit requires verification whether or not the visit date does.

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Site users working in an existing study:

- If a visit was signed before the upgrade, the visit is required to be re-signed in order to sign the visit date.
- Signature status is not impacted for visits that were signed at the casebook or visit level prior to the upgrade. However, if the visit or casebook is signed after the upgrade, the visit date is also signed.

Integrations

- Enhancements to the Master User List (MUL) integrations

Enhancements to the Master User List (MUL) integrations

Use a colon in the site field to assign multiple sites to a user

The MUL - User integration now supports a colon as a site separator in the site field when assigning a user to multiple sites; previously, only a semicolon was supported. The use of a colon as a separator also applies to the depot field.

> **Note**
>
> This integration supports only one separator type per configuration—either a colon or a semicolon.

Already using this integration with a live study?

- There is no impact to live integrations using a semicolon as the separator.
- To implement the new site separator for existing integrations, reach out to your Oracle point of contact.

MUL integrations now support importing data using Excel (.xlsx) files.

The MUL - User and MUL - Site Tenant integrations now support the use of files with an .xlsx extension; previously, only files with an .xml extension were supported.

> **Note**
>
> This feature only extends support for an additional file extension type. The requirements for the structure and content of the data within the file remain unchanged.

Already using this integration with a live study?

- Your current .xml imports will continue to work without impact.
- To change the file extension type for existing integrations, reach out to your Oracle point of contact.

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Randomization and Trial Supply Management

- Enhancements for forced randomization
  Sponsor users can now set forced randomization limits at multiple levels and create custom enrollment groups using questions from the randomization visit.
- Manage kits from the same lot
  Sponsor users can now manage kits from the same lot for sites and subjects.
- Unblinded Drug Order Form for Quantum integrated studies
  Unblinded Drug Order Forms (DOF) for shipment requests, fulfillment, and manual requests can now be generated for Quantum-integrated studies, supporting regional regulatory requirements.

Enhancements for forced randomization

Sponsor users can now set forced randomization limits at multiple levels and create custom enrollment groups using questions from the randomization visit.

Details for sponsor users

- You can now set a maximum number of forced randomizations that can occur in a study.
  - To set a forced randomization limit, use the new **Forced Randomization Limits** setting in Enrollment Settings on the Study Settings tab.

    > **Note**
    >
    > Subjects force-randomized prior to enabling this feature are excluded from the limit count.

  - Limits can be set at the Study Total, Site Total, Country, and Cohort levels. For more information about these levels, see Specify enrollment settings.

    > **Note**
    >
    > It is not possible to define a forced randomization limit at the individual-site level.

  - Setting a limit defines how many subjects can be force-randomized. For example, if the **Randomization Limit** is 100 and the **Forced Randomization Limit** is 10, then up to 10 of the 100 subjects can be force-randomized.
  - Notifications are governed by two settings: **Forced Randomization Limits** and the **Notification** percentage. The system displays a notification when the count defined for forced randomizations reaches the specified percentage of that limit. For example, with a limit of six and a notification percentage of 50%, a notification is triggered after the third subject is force-randomized.
- Additionally, the Randomization visit is now available under **Select a Visit** when creating custom enrollment groups. This allows you to create a group using questions on forms in the randomization visit.
  As with screening groups, the subject limit is recalculated for randomization groups after a group is created. This ensures that previously randomized subjects are taken into account

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when calculating the subject limit for a group. You may notice a brief delay before the change appears in the interface—updates are usually complete within about ten minutes.

You can use questions on forms from both the Screening and Randomization visits when creating groups.

- If the same data is collected at both visits, like weight at screening and randomization, you can only use one question in the group.
- If a group contains only screening-visit questions and the subject limit is reached, you cannot screen additional subjects. Likewise, if a group contains only randomization-visit questions and the defined limit is reached, you cannot randomize additional subjects.
- If a group is created using questions from both screening and randomization forms that are part of the screening visit, and the subject limit is met, you cannot screen or randomize additional subjects.
- If a group is created using questions from both screening and randomization forms that are part of different visits, and the subject limit is met, you cannot randomize additional subjects.

Details for site users

If a forced randomization limit is met, you are presented with a message informing you of that and to reach out to your clinical research associate (CRA) for assistance.

Impact on reports, extracts, archives, or datasets

More information and specific descriptions on modified report values can be found in the *Reporting Guide* after the assessment environment upgrade completes.

Report	Type of change	Description
Study Design report	Column name change	The setting **Restrict Randomization to Available Kit Types** (on the Treatment Arms page in Randomization Design) has been renamed to **Restrict Randomization to Available Kit Types (Forced Randomization)**. This updated label now appears in the **Randomizations** section of the Study Design report.
Study Settings Report	New column fields	The **Enrollment Settings** tab now displays the following columns when a forced randomization limit is configured at that level: • Forced Randomized Study Total • Forced Randomized Site Total • Forced Randomized Country Total The **Cohort Limits by Cohort** tab now displays the following column when a forced randomization limit is configured for a cohort: • Forced Randomization Limit

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Report	Type of change	Description
Study Enrollment report	New column fields	A **Forced Randomization Limit** column now appears in the following sections: • General Enrollment ***Note**: Forced Randomization Limit**s** is displayed here.* • General Enrollment Audit Trail • Cohort Enrollment • Cohort Enrollment Audit Trail • Country Enrollment • Country Enrollment Audit Trail

Manage kits from the same lot

Sponsor users can now manage kits from the same lot for sites and subjects.

Details for sponsor users

Sponsor users now see two new fields on the Supply Settings tab under Shipment Settings:

- **Ship Kits from Same Lot to Site**: Ensures that all kits shipped from the depot to a site are from the same lot, updating site inventory without assigning kits to subjects.
- **Dispense from Same Lot to Subject at Site**: Assigns and dispenses kits to a subject at the site, ensuring all kits come from the same lot. Kits are removed from site inventory and linked to the subject.

Depot-to-site shipment

- In a depot-to-site shipment, the system searches until it successfully locates lots according to expiry dates (first-expiry-first-out) and sufficient kits from the same lot to send them in one shipment. The shipment fails if there are not enough kits in the same lot.
- The system displays a warning if the selected lot does not contain enough kits, so you can adjust your plan before proceeding.
- For blinded kits, the system ships all kits from the same blinded lot (across manufacturing lots) or the same manufacturing lot if the study does not use blinded lots. For unblinded kits, you can ship kits from any lot.

Dispensation at sites

- The system uses first-expiry-first-outame (FEFO) and checks for enough kits from the same lot before dispensing. The system prevents dispensing if it cannot find enough kits in a single lot.
- When dispensation is completed at a site, all blinded kits come from the same lot. If the study uses blinded lots, the selected blinded kits may come from different manufacturing lots, but they belong to the same blinded lot. If the study does not use blinded lots, the selected blinded kits all come from the same manufacturing lot. When you switch to a new lot, the system disables kits from the previous lot.
- When you replace a kit, the system provides a replacement from the same lot as the original dispensation.
- If your study has forced randomization active, the dispensed kits come from the same lot.
- For partial dispensation, the system ensures the initial and subsequent kits each come from the same lot, but they do not need to match each other. If a single shipment request

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includes multiple shipments to complete, such as when one request involves multiple shipping addresses, the blinded kits in all the shipments have the same blinded lot number.

- When a subject is removed from a dose hold, the dispensed kit comes from the same lot.
- Manual shipments fail if you select multiple lots for blinded kit types.
- During randomization, the system assigns kits from the same lot when all are available.
- If a shipment request results in multiple shipments, for example, when the request includes several shipping addresses, all blinded kits in those shipments use the same blinded lot number.
- You can include up to 999 kits in a manual shipment request.

> **Note**
>
> If the **Dispense reusable kits** option is enabled, the lot is not rechecked during the dispensing process.

More information and step-by-step instructions about configuring locally sourced kits can be found in the *Sponsor and CRO User Guide* after the assessment environment upgrade.

Impact on reports, extracts, archives, or datasets

These reports now include details of the new kit management options you select:

Report	Type of change	Description of enhancements
Study Settings Report	New columns	**Ship Kits from Same Lot to Site** and **Dispense from Same Lot to Subject at Site** columns in the Supplies Settings section display the status (enabled/disabled) for new lot management options.
Study Design report	New columns	**Ship Kits from Same Lot to Site** and **Dispense from Same Lot to Subject at Site** columns display the status (enabled/disabled) for new lot management options.

You can find additional information in the *Reporting Guide* after the assessment environment upgrade.

Already working in a live study?

As soon as the upgrade for this release completes, you can begin shipping and dispensing kits from the same lot in existing studies.

Unblinded Drug Order Form for Quantum integrated studies

Unblinded Drug Order Forms (DOF) for shipment requests, fulfillment, and manual requests can now be generated for Quantum-integrated studies, supporting regional regulatory requirements.

The Unblinded DOF provides kit details and, when fulfilled, kit and lot numbers for your Quantum-integrated study, supporting shipment activities. The DOF is generated on demand for initial, resupply, and manual pooling kit shipments for users with the appropriate permissions.

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Before you work with this feature

Sponsor users assigned the *Receive Notification of Quantum Drug Order Form (Unblinded)* permission receive the **Kit Order Form [Requested/Fulfilled] notification**.

Additionally, sponsor users assigned the *View the Quantum Drug Order Form* permission are able to view and download generated DOFs.

More information on these permissions can be found in the *Add Users Guide* and *Notifications and Permissions Guide* after the assessment environment upgrade completes.

Details for sponsor users

As a sponsor user, you can generate an Unblinded Drug Order Form (DOF) for your Quantum-integrated studies when an initial, resupply, or manual shipment is created.

- The Unblinded DOF includes the following details:
  - Kit ID
  - Kit description
  - Minimum expiration date (for initial and resupply shipments)
  - Lot number (for manual shipments)
  - Quantity requested
- Once the shipment request is fulfilled, the DOF is updated to display kit and lot numbers, where applicable.
- The Unblinded Drug Order Form can be downloaded in HTML format. Users with the appropriate permissions can regenerate, resend, and download the form.

> **Note**
>
> Blinded users who are not assigned the *View Quantum Drug Order Form* permission will not see the option to download the Drug Order Form.

Step-by-step instructions and additional information can be found in the *Sponsor and CRO User Guide* after the assessment environment upgrade completes.

Impact on reports, extracts, archives, or datasets

Report, extract, archive, or dataset	Type of change	Description
Global Study Roles report	Modified column data	The **Permissions** column includes details on newly created **unblinded** permissions for *Receive Notification of Quantum Drug Order Form* and *View the Quantum Drug Order Form* when applicable.

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Report, extract, archive, or dataset	Type of change	Description
Study Roles report (by study)	Modified column data	The **Permissions** column includes details on newly created **unblinded** permissions for *Receive Notification of Quantum Drug Order Form* and *View the Quantum Drug Order Form* when applicable.

Already working in a live study?

Once the assessment environment upgrade completes, Drug Order Forms can be generated for existing Production studies that use Quantum integrations.

Reporting, archives and analytics

- Enhancements to Oracle CRF Submit archives and reports

Enhancements to Oracle CRF Submit archives and reports

Blank form PDFs are now more easily identifiable

By default, Submission requests include blank form PDFs. For all other request types, including Archival (sponsor and site) and Custom, the setting **Include Blank Forms** must be set to **Yes** to include blank form PDFs with the request.

To help differentiate blank form PDFs from other files, the default file name for the blank form PDFs has been updated to include "blankforms," for example, `<studyname>-<blankforms>-<study version> (abc123-blankforms-1.0.0.1)`.

Changes to the PDF security settings for Custom PDF requests

Currently, the Advanced Settings page for Custom PDF requests includes a **Prevent Form Changes** setting with Yes and No options. If Yes is selected, a password must be manually entered. This password is required to unlock the PDF and introduce changes to it.

The security settings on the Advanced Settings page for Custom PDF requests have been updated in this release as follows:

- The current **Yes** option has been updated to **Yes, user-provided password** for greater clarity.
- A new option, **Yes, irretrievable password**, is now available. When enabled, a system-generated password is created that cannot be retrieved by Oracle. This provides additional protection against unauthorized PDF changes or accidental use of a manually entered password.

> ⚠ **Caution**
>
> Neither the user-provided nor the system-generated passwords are retrievable by Oracle.

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Video file links now open correctly

Video files imported at the question level can now be opened directly via links embedded in a subject PDF. Previously, embedded links did not work, requiring users to navigate to the Uploaded Files folder in the relevant site folder.

Study design

- Manage dynamic code lists
  Now, dynamic code list types allow study designers to add code list options without requiring a Study Version or an Advanced Study Version change, while also being able to control which values in a code list are visible to a user based on the site.

Manage dynamic code lists

Now, dynamic code list types allow study designers to add code list options without requiring a Study Version or an Advanced Study Version change, while also being able to control which values in a code list are visible to a user based on the site.

Before you work with this feature

Study designers assigned the new *Manage Dynamic Study Code Lists* permission can create, update, and apply dynamic code lists to a question. Additionally, users with this permission can select any site in any mode while creating the code list.

More information on this permission can be found in the *Notifications and Permissions Guide* after the upgrade.

Details for study designers and other sponsor users

As a study designer, here's what's new for you:

- You can now associate a dynamic code list to a choice question and see the changes reflected on the form immediately once the question has been moved to the respective mode. Any changes made to the code list are applied to it in all modes once saved.
- By default, all values are shown in the code list. If one or more sites are specified for a particular mode, the code list is filtered so that the option is available only for subjects at the specified site(s) for that mode.

> **Note**
>
> Site specifications apply only to dynamic code lists.

  - Any changes you make to the code list row is applied to all associated sites.
  - A site must be created in the required mode (Training, Testing, or Production) before code list values can be mapped to it.
  - A selected site that is later retired still displays in the code list, but cannot be selected once retired.

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> **Note**
>
> The system generates the following warning when a retired site is selected and additional code list values are changed, as well:
>
> `Site [ID] is retired and will be removed where it was previously selected. If no other sites have been selected for the code list option, it will be set to "All Sites."`

- Dynamic code lists can be used in studies and libraries.
- You can copy dynamic code lists from one study to another by using download and import.
  - To copy a study that includes one or more dynamic code lists, the user's role in the source study must include the *Manage Dynamic Study Code Lists* permission.
- You can copy forms from one study to another that contain dynamic code lists.
  - The user's role in the targeted study must be assigned the *Manage Dynamic Study Code Lists* permission to copy a form from another study or library that includes one or more dynamic code lists.
- All values of the dynamic code list are passed to a signature configuration, regardless of any site associations that may be specified for the code list option.
- A value that is later hidden in the code list that was previously selected by the site remains stored as the selection by the site until the site updates the question value and the changes are saved; the value is then faded, moved to the top of the list, and removed from their selection.
- This functionality does not apply to Safety and Test tagged code lists, custom enrollment groups, reconciliation forms, and Electronic Health Records (EHR).
- The new **Last Modified Date (UTC)** column on the Code List page provides details on when the code list was last updated.

> **Note**
>
> When working with dynamic code lists in integrated studies, be aware that some systems may not support this feature.

More information and step-by-step instructions on managing dynamic code lists can be found in the *Study Designer User Guide* after the upgrade completes.

Impact on reports, extracts, archives, or datasets

Report or archive	Type of change	Description
Study Design report	Modified column data	The **List of Values** column now indicates when a code list is dynamic, with a value of **Dynamic Code List**.
Annotated Case Report Forms	Modified column data	The **Answer** column now indicates when a code list is dynamic, with a value of **Dynamic Code List**.

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Report or archive	Type of change	Description
Study Codelist dataset (Codelists folder)	New and modified column data	The following updates have been made to this dataset for dynamic code lists: • The new column, **CODELIST_MODE**, indicates the mode in which the associated site was created (Training, Testing, Active). • The new column, **SITE_ASSOCIATION**, indicates which sites in that mode the code list option is mapped to with a value of either **ALL SITES** or an alphabetical list of the sites based on site ID. ***Note**: This field only populates for CODELIST_LEVEL = study.* • The new column, **LOCALE**, indicates the selected code list language. ***Note**: This value displays as **NULL** for static code lists.* • The CODE_LEVEL column indicates whether a code list is dynamic or static with either a value of **DYNAMIC** or **STATIC**.
Study Design dataset (Items folder)	New and modified column data	The following updates have been made to this dataset for dynamic code lists: • The new column, **CODELIST_LINK_TYPE**, indicates whether choice questions are **DYNAMIC** or **STATIC**. ***Note**: This value displays as **NULL** for non-choice questions.* • The **CODELIST_VALUES** and **ITEM_VALUES** fields populate as **NULL** because no code list values are stored in the form for dynamic code lists.

More information can be found in the *Analytics User Guide* and *Reporting Guide* after the upgrade completes.

Already working in a live study?

Once the upgrade completes, you can begin creating and using dynamic code list options in new and existing studies. Existing code lists are defaulted to a Static type, requiring a study version change to make updates. The initial creation of the question and code list association

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to the question requires a Study Version or ASV change; once the question - with the associated code list - exists in the respective mode, changes can be made to the code list options.

User experience

- New deep link pages
  Sponsor users can now create and share deep links that navigate study team members directly to specific Clinical One Cloud Service pages, including the newly supported Query Management and Site & Labs study configuration pages.
- Updated login experience for Clinical One Cloud Service
  You'll still access Clinical One Cloud Service the same way, but now you'll see a more prominent, full-screen login page when you sign in.

New deep link pages

Sponsor users can now create and share deep links that navigate study team members directly to specific Clinical One Cloud Service pages, including the newly supported Query Management and Site & Labs study configuration pages.

When sponsor users create and share deep links with users, they can avoid the need to drill down into pages to locate data. Instead, they select one link to open the exact page they need right away. If unauthorized users attempt to open pages, the application redirects them to the Home page.

A deep link is a web address (or URL) that leads directly to the Queries page within a web application. In the context of Clinical One Cloud Service, a deep link includes parameters that define the study, mode, and status of training or live study.

A training study is a dedicated study environment in Clinical One Cloud Service used solely for training purposes, not for real clinical trial data or study management. In contrast, training mode is an operational setting that lets users practice protocols and study design with mock data, without affecting the live clinical trial.

These deep links enable you to quickly locate a specific query or change the SDV strategy assigned to a site when referenced from an external application.

Access pages through deep links

Site users can access pages through deep links the following ways:

- Navigate directly to a page using a shared deep link from various locations, such as within an application, a document, or any other compatible source.
- Sign in with your credentials before selecting deep links to open pages immediately. Otherwise, the system will prompt you to sign in before opening pages from a deep link.
- If you cannot access certain pages, your account may not have the appropriate permissions. Contact your administrator to request access privileges.

Details for sponsor users who create deep links:

The following Clinical One Cloud Service study pages are now accessible through deep links:

- **Sites & Labs** (tab in a study's settings): Opens the URL to the Settings Sites & Labs tab and enables you to adjust the Study Version, Resupply Strategy or SDV Strategy.
- **Queries** (also known as the Query List page): Opens the URL to the Queries page and enables you to view and filter the list of queries.

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> **Note**
>
> User administrators must grant viewing permissions for the relevant page. Access can be specified for each mode individually (such as test, training, or production). Users will only be able to view the page in the modes where both page and mode-specific permissions have been granted.

To create a deep link, sponsor users need to:

1. Copy the base URL from the **Queries** or **Sites & Labs** page.
2. Add the required parameters:

Parameter	Description	Pages
`studyId`	Study identifier	**Queries**, **Sites & Labs**
`mode`	Study mode (e.g., production/ test)	**Queries**, **Sites & Labs**
`isTraining`	Specify if it's a training study	**Queries**, **Sites & Labs**

3. Check all parameters for accuracy and correct formatting.
4. Share the deep link using your preferred method (for example, in a browser window for testing, a third-party application, an email, a document, or a messaging platform).

> **Note**
>
> Users without access permissions will be redirected to the Home page.

For example, here's how a URL pointing to a Sites & Labs page would look like:

```
{BaseURL}

?ojr=clinicalone/settings/sites&studyId={studyId}&mode={mode}
```

You can find additional information about this new feature in the *Sponsor and CRO User Guide* after the assessment environment upgrade.

Updated login experience for Clinical One Cloud Service

You'll still access Clinical One Cloud Service the same way, but now you'll see a more prominent, full-screen login page when you sign in.

What's new:

- The login and authentication steps you follow remain unchanged.
- The Oracle Life Sciences IAMS login screen now appears in an improved full screen, instead of a dialog box.
- The content and layout of the login screens, including your organization's identity provider if you use one, stay the same.

When you access Clinical One Cloud Service, you'll be redirected to the IAMS login page as before. If you use another identity provider, you'll continue to follow your usual sign-in process.

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REST API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 26.1.

> **Note**
>
> To ensure you can easily access all the information that you need, we are working on restructuring the REST API guide. As a result, some of the categories listed under the **Tasks** section of this guide now follow a slightly different hierarchy, to which all categories will eventually conform. For example:
>
> From:
>
> - Tasks > Data Capture > Data Elements > v4.0 > Clear data elements scope by study ID and mode
>
> To:
>
> - Tasks > Data Capture > Data Elements > Clear data elements scope by study ID and mode>V4.0
>
> This documentation update will be completed in future releases.

Permissions

For this release, no new services or permissions have been added. Only existing services have been updated.

Service updates

The following services are updated:

- Codelist
- Data Action
- Data Hub
- Data Capture
- Designer EDC
- Designer
- Randomization & Supplies
- Site

Codelist

Change	Endpoint
New	• POST /v1.0/codelist/dynamic/copy • GET /v1.0/codelist/values/asOfDate/{id} • GET /v4.0/codelist/values/{fieldName} • POST /v5.0/codelist/code • PUT /v5.0/codelist/code/{codeId}

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Data Action

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/unfreeze/vsd • GET /v1.0/studies/{studyId}/{mode}/visit/sdv • PUT /v2.0/studies/{studyId}/{mode}/unsign-unverifyforitem

Data Hub

Change	Endpoint
New	• GET /v10.0/studies/{studyId}/{mode}/odm/metadata • POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v12.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v13.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v14.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v3.0/tenant/{tenantId}/studies/{studyId}/codelists • POST /v9.0/tenant/{tenantId}/studies/{studyId}/dataCollection
Deprecated	• POST /v1.0/tenant/{tenantId}/studies/{studyId}/codelists • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v12.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • GET /v8.0/studies/{studyId}/{mode}/odm/metadata • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits

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Data Capture

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/visit/freeze • POST /v1.0/studies/{studyId}/{mode}/visit/verify • PUT /v11.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId} • GET /v12.0/studies/{studyId}/{mode}/visitstatus • GET /v5.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata • GET /v8.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
Deleted	• PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/randomizationnumber/{randNumber} • PUT /v1/studies/{studyId}/{mode}/dataelements • GET /v6.0/studies/{studyId}/{mode}/eventsCount

Designer EDC

Change	Endpoint
New	• POST /v20.0/studies/{studyId}/versions/{version}/forms • GET /v20.0/studies/{studyId}/versions/{version}/forms • GET /v20.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v20.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v20.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v20.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v20.0/studies/{studyId}/versions/{version}/forms/{formId} • GET /v20.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms • GET /v3.0/studies/{studyId}/forms/{formId}/formitems • POST /v5.0/studies/{studyId}/lockObjectDetails

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Designer

Change	Endpoint
New	• POST /v10.0/studies/{studyId}/versions/{version}/visits • GET /v10.0/studies/{studyId}/versions/{version}/visits/{visitid} • PUT /v10.0/studies/{studyId}/versions/{version}/visits/{visitid} • DELETE /v10.0/studies/{studyId}/versions/{version}/visits/{visitid}

Randomization & Supplies

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/randlists • GET /v11.0/studies/{studyId}/{mode}/supply/settings • PUT /v11.0/studies/{studyId}/{mode}/supply/settings • GET /v3.0/studies/{studyId}/{mode}/settings/cohortlimits • PUT /v3.0/studies/{studyId}/{mode}/settings/cohortlimits • POST /v3.0/studies/{studyId}/{mode}/sites/{siteId}/resupply/manual • POST /v4.0/studies/{studyId}/{mode}/resupply/manual

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Change	Endpoint
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/events/codebreak/{eventId} • PUT /v1.0/studies/{studyId}/{mode}/inventory/kits • GET /v1.0/studies/{studyId}/{mode}/inventorystatuses • GET /v1.0/studies/{studyId}/{mode}/kits/{sourceId}/export • POST /v1.0/studies/{studyId}/{mode}/lots/blinded-lots • GET /v1.0/studies/{studyId}/{mode}/lots/blinded-lots • POST /v1.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v1.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v1.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • PUT /v1.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • GET /v1.0/studies/{studyId}/{mode}/randlistdesigns • POST /v1.0/studies/{studyId}/{mode}/reports/supplysettingsaudit • POST /v1.0/studies/{studyId}/{mode}/resupplies • GET /v1.0/studies/{studyId}/{mode}/resupplies • GET /v1.0/studies/{studyId}/{mode}/resupplies/{resupplyId} • PUT /v1.0/studies/{studyId}/{mode}/resupplies/{resupplyId} • GET /v1.0/studies/{studyId}/{mode}/settings/cohortlimits • PUT /v1.0/studies/{studyId}/{mode}/settings/cohortlimits • GET /v1.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits • GET /v1.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits • POST /v1.0/studies/{studyId}/{mode}/shipments/{shipmentId}/received • GET /v1.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits • POST /v1.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codebreak • POST /v1.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codeview • POST /v1.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/allowed-doseholds • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/dosehe ld • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/reuse-kits

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Change	Endpoint
	• GET /v1.0/studies/{studyId}/{mode}/unblinded-disp-history • POST /v1.0/studies/{studyId}/{mode}/{studyVersion}/randlist/generate • GET /v15.0/studies/{studyId}/{mode}/visits/subjectvisit • PUT /v2.0/studies/{studyId}/{mode}/inventory/kits • GET /v2.0/studies/{studyId}/{mode}/inventorystatuses • GET /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • GET /v2.0/studies/{studyId}/{mode}/randlists • GET /v2.0/studies/{studyId}/{mode}/randlists/{rndlistid} • GET /v2.0/studies/{studyId}/{mode}/randlists/{rndlistid}/randnumbers • POST /v2.0/studies/{studyId}/{mode}/resupply/manual • GET /v2.0/studies/{studyId}/{mode}/shipment-statuses • GET /v2.0/studies/{studyId}/{mode}/shipments • GET /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId} • GET /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits • GET /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits • PUT /v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits • PUT /v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId} • GET /v2.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId} • GET /v2.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits • POST /v2.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits • POST /v2.0/studies/{studyId}/{mode}/subjects/{subjectId}/reuse-kits • GET /v2.0/studies/{studyId}/{mode}/unblinded-disp-history • GET /v3.0/studies/{studyId}/{mode}/randlists • GET /v3.0/studies/{studyId}/{mode}/randlists/{rndlistid} • GET /v3.0/studies/{studyId}/{mode}/randlists/{rndlistid}/randnumbers • GET /v3.0/studies/{studyId}/{mode}/shipments • GET /v3.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits • PUT /v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits

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Change	Endpoint
	• PUT /v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId} • GET /v3.0/studies/{studyId}/{mode}/unblinded-disp-history • GET /v4.0/studies/{studyId}/{mode}/randlists • GET /v4.0/studies/{studyId}/{mode}/shipments • GET /v4.0/studies/{studyId}/{mode}/supply/settings • PUT /v4.0/studies/{studyId}/{mode}/supply/settings • GET /v5.0/studies/{studyId}/{mode}/randlists • GET /v5.0/studies/{studyId}/{mode}/shipments • GET /v5.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits • GET /v5.0/studies/{studyId}/{mode}/supply/settings • PUT /v5.0/studies/{studyId}/{mode}/supply/settings • GET /v6.0/studies/{studyId}/{mode}/shipments • GET /v6.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits • GET /v6.0/studies/{studyId}/{mode}/supply/settings • PUT /v6.0/studies/{studyId}/{mode}/supply/settings • GET /v7.0/studies/{studyId}/{mode}/orders • GET /v7.0/studies/{studyId}/{mode}/orders/{shipmentId} • PUT /v7.0/studies/{studyId}/{mode}/supply/settings • GET /v8.0/studies/{studyId}/{mode}/orders • GET /v8.0/studies/{studyId}/{mode}/orders/{shipmentId} • PUT /v8.0/studies/{studyId}/{mode}/supply/settings • GET /v9.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • PUT /v9.0/studies/{studyId}/{mode}/supply/settings

Site

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/site/all • PUT /v3.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals

Release impact on downstream systems

This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 26.1 may have on downstream systems, specifically Oracle Clinical

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One Analytics, Clinical One Digital Gateway integrations, Oracle CRF Submit, and Oracle Life Sciences Data Management Workbench.

For additional information about the features in this release and the potential impact on your studies, Download the Release Implementation Assessment document.

Oracle Clinical One Analytics also known as Data Hub

Release feature	Analytics impact
Manage dynamic code lists	The newly added support for dynamic code lists is reflected in Oracle Clinical One Analytics, but existing ongoing study data remains unchanged.
Enhanced analytics visibility of missing data across visit types	Oracle Clinical One Analytics now automatically creates and persists records for scheduled or expected visits and forms, even when no data has been entered. This includes dynamically triggered visits. As such, users can now see additional visits and form rows in Oracle Clinical One Analytics, but existing ongoing study data remains unchanged.

Clinical One Digital Gateway configured integrations

Release feature	Digital Gateway impact
Manage dynamic code lists	The inbound Data Intake and Multi-IWR integrations do not currently support dynamic code lists. For outbound integrations, the integration configuration files must be updated if any new values are added or changed through dynamic code lists.

Oracle Life Sciences Data Management Workbench (DMW)

Release feature	DMW impact
Enhanced analytics visibility of missing data across visit types	As part of the enhancements to improve visibility of missing data across visit types, updates have been made to several existing clinical datasets, with new view versions created. These updated views are already reflected in Oracle Analytics. The newly introduced view for missing items is not currently available in Oracle DMW. However, Oracle DMW's supplemental views for the Unblinded Events dataset may show new records for expected visits. Some existing event records may also have their status or various attributed updated.
Manage dynamic code lists	The newly introduced dynamic code lists are not currently supported in Oracle DMW and are not reflected in any datasets in existing studies.

Oracle Life Sciences InForm CRF Submit

The features introduced with this Clinical One Cloud Service release do not impact Oracle Life Sciences InForm CRF Submit integrations.

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Fixed issues in 26.1

- All users
- Code lists
- Integrations
- Oracle Clinical One Analytics
- Facilities, settings, and user management
- Forms, visits, and rules
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data
- Documentation corrections
  Lists documentation issues corrected in this release, including clarifications, fixes, and updates to improve accuracy and usability.

All users

Users no longer experience workflow disruption or data loss due to authentication failures

Users no longer encounter a generic UI error that disrupts ongoing work when authentication fails. Previously, if an authentication failure occurred while a user was actively entering or managing study data, a generic error message would appear with no actionable response when selected. Users were required to close the application and log back in before resuming their work, resulting in the loss of any unsaved data due to this interruption.

(Issue **39294968**)

Code lists

Codelist item labels now display correctly after ASV on copied forms

If you update a codelist associated with a question on a copied form and apply Advanced Study Versioning (ASV), the Study Design Report now correctly displays the label value for each codelist item instead of a NULL value. Annotated CRF/Clinical One Reports and the UnblindedGetForms API now also return the correct label values.

(Issue **37762573**)

Integrations

Clearing codes in Oracle Central Coding now clears values in Clinical One Cloud Service

Now, when codes are cleared in Oracle Central Coding the action is reflected in Clinical One Cloud Service and the coded values are properly cleared.

(Issue **39293196**)

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Enrollment integration files use the correct naming convention

Now, enrollment integration files use the correct "IORQ_AE" naming convention (or configured filename), ensuring compliance with integration specifications.

(Issue **39165655**)

Clinical One Digital Gateway properly handles integration files including the "/" character

Now, Clinical One Digital Gateway processes integration files that include the "/" character in incoming values without failing, preventing job errors and ensuring data loads properly in Clinical One Cloud Service.

(Issue **38873886**)

Data Intake integrations are successful after performing Undo Add Subject

Data Intake integrations now run successfully after performing Undo Add Subject, ensuring integrations no longer fail due to previously removed subjects.

(Issue **37174912**)

Oracle Siebel CTMS imports blank and duplicate shipping attention contacts

Oracle Siebel CTMS now imports shipping attention contacts even if the shipping attention field is blank or if multiple contacts share the same address. This improvement ensures site integration in Clinical One Cloud Service no longer fails in these scenarios, making data transfer seamless and more reliable.

(Issue **38097324**)

Shipping attention contacts support duplicates with the same address

The system handles duplicate-address scenarios correctly, streamlining site setup and eliminating errors when multiple contacts point to the same address.

(Issue **38936132**)

Oracle Clinical One Analytics

Oracle Clinical One Analytics correctly displays the form title and reference name in the Subject Forms records

Now, Oracle Clinical One Analytics displays the correct form title in the FORM_NAME column in the Subject Forms records, including cases where forms are missing for future visits, ultimately preventing the two fields from showing the same value and making form identification in reports consistent and accurate.

(Issue **39173547**)

Oracle Clinical One Analytics correctly displays the Subject ID

Datasets in Oracle Clinical One Analytics now correctly displays the Subject ID for all rows. Records from older or previously hidden/cleared forms are properly tracking, ensuring that subject information appears consistently, even for legacy or dynamic form data.

(Issue **38584123**)

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Oracle Clinical One Analytics dataset includes query age

You can now view information for query age in the Oracle Clinical One Analytics Queries Dataset and Query Management Detail Report.

(Issue **36028851**)

Subject Form Items Dataset displays SDV_SELECTION_STATUS for repeating items

The Subject Form Items dataset now shows SDV_SELECTION_STATUS for repeating sections (INNER_REPEAT) and repeating forms (OUTER_REPEAT).

(Issue **38927690**)

Clinical One Cloud Service updates repeat values for repeating forms with label questions

Clinical One Cloud Service now correctly identifies repeating forms that have a label question defined and calculates the INNER_REPEAT and OUTER_REPEAT values accurately. This ensures that the SDV_SELECTION_STATUS row in the Subject Form Items Dataset reflects the correct repeat values for these form types.

(Issue **38937068**)

Facilities, settings, and user management

The *Edit Study Settings* permission no longer grants the ability to create regions

The ability to create or edit regions is now only controlled by the *Edit Regions* permission. Users assigned with the *Edit Study Settings* permission no longer have the ability to create regions, unless they are also assigned with the *Edit Regions* permission.

Previously, the *Edit Study Settings* permission allowed users to also edit regions.

(Issue **39260429**)

Lab range values in all study modes are visible even when the study language is changed

Lab ranges entered in one language now display correctly under the Sites & Labs tab, even after changing the application's language settings.

(Issue **36817536**)

Study settings option is visible when assigned the View Study Settings permission

Users assigned the *View Study Settings* permission can now see the **Study Settings** button as expected, and access to this option is no longer dependent on having assigned global level roles.

(Issue **37791202**)

Edit Organization dialog displays the correct organization's information

When editing an organization in the Global Settings, the window now opens with the correct, currently selected organization's details, ensuring that you modify the correct information.

(Issue **38491660**)

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Forms, visits, and rules

Repeating forms are now accurately marked as complete when cleared mandatory questions use data flags

When repeating forms are cleared and data flags are inserted in empty questions, the form status is now properly recalculated. In the case of all mandatory questions either answered or using data flags, the form now accurately shows as complete.

Previously, cleared values remained cleared regardless of the use of data flags, preventing the form to be completed when this happened on mandatory questions.

(Issue **38436750**)

Show visit rule now works properly for radio button questions

When a show visit rule is designed so that two radio button options trigger the same visit, the show visit rule now works properly and shows the visit when any of those options are selected. Previously, the visit would only show for one of those options and fail to display for the other valid option.

(Issue **38653482**)

Form details updated via Advanced Study Versioning now display correctly in Testing mode

After updating a form using advanced study versioning, the following updated details now display correctly in Testing mode:

- The study version in the **Apply Change to Study Version** field.
- The order of the items within a form.

Previously, both, the study version in the **Apply Change to Study Version** field and the order of the items, displayed in Testing mode as currently in Production mode, instead of preserving the changes previously applied on Draft mode.

(Issue **39029323**)

Form status update correctly and consistently

Now, form statuses update correctly upon completion of required items, ensuring subjects can progress to the next visit without delays, even during transient system issues.

(Issue **39239493**)

Visit Date updates properly save and display in the system

Now, Visit Date updates save and display correctly without User Interface (UI) errors, ensuring consistent behavior across concurrent user actions.

(Issue **39233418**)

Advanced Dispensation setup functions properly

Now, Advanced Dispensation is stable and consistent, handling each dispensation group independently with unique identifiers, and preventing data from being overwritten or lost. Updates to visits, kit settings, and dispensation groups also retain configurations correctly, and criteria displays reliably without shifting or disappearing.

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(Issue **39039938**)

Data entry and saving functions properly across study version changes

Now, data entry saves work smoothly across study version changes, even when Not Answered flags or label records exist, preventing validation errors and allowing users to continue to enter and save data without interruption.

(Issue **38690545**)

Visit statuses display correctly for casebook signatures

Now, after removing form and visit level signature configurations, casebook signing correctly results in a fully signed status while residual signature data is properly cleared, ensuring visits no longer appear as partially signed, and signature status reflects the current configuration accurately.

(Issue **39114558**)

Clinical One Cloud Service applies the correct status when automatically generating a follow-up visit

If you (as a site user) completed a parent visit and the form included an answer that triggered a follow-up (dynamic) visit, Clinical One Cloud Service incorrectly labeled the visit with a status of NEW instead of PROJECTED. This incorrect status caused the information to not show up in downstream reports. It now applies the correct status to a dynamic visit and the details appear in reports generated with Clinical One Cloud Service 26.1.0.1 or later. This fix causes dynamic visits to show a status of VISIT_STATUS = SCHEDULED in the Unblinded Subject Events and Blinded Subject Events data sets and in the following APIs: Get unblinded subject data details (V12.0) and Get blinded visit details (V11.0).

(Issue **38991660**, **38982049**)

Clinical One Cloud Service successfully creates missing item records for unanswered child questions

If you (as a site user) delete a repeating form with unanswered child questions and then restore it, you now see a missing item record for the unanswered questions in the appropriate reports as expected. This fix causes additional items on restored forms to show as missing form items in the Subject Form Items data set. If you need to see the missing item records for unanswered child questions from earlier versions, you need to repeat the action of deleting the repeating form and restoring it using Clinical One Cloud Service 26.1.0.1 or later.

(Issue **38997236**)

Two rules with the same target now compare across all visits

When you set up two rules with the same target, for example comparing a weight value between visits, the system now references all previous visits for comparison, ensuring comprehensive rule evaluation.

(Issue **39064298**)

Associated Form rows in repeating forms display correctly

When opening a repeating for through Query Management then selecting **View in Form**, previously linked Associated Form rows now appear correctly checked for repeating forms.

(Issue **38703070**)

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Repeating form questions in a reopened skipped visit can be edited

When a skipped visit is reopened, now repeating form questions are able to be modified as expected.

(Issue **35975766**)

Auto-lock rule triggers as expected in test mode after renaming an approved study version

Auto-lock rules on randomization visits now trigger properly in the test container, even if the study version was first moved to the approved container and then renamed.

(Issue **37610864**)

Removed repeating and 2-section forms correctly excluded after sign, verify and freeze

When you verify or freeze a visit, removed repeating forms, including 2-section forms are now handled correctly, by applying he NA flag only to current records, not to removed forms. As a result, removed forms are properly excluded from the Subject Data Extract, ensuring accurate output.

(Issue **38833657**)

Withdrawing, completing or screen failing a subject auto-hides the next scheduled New visit

When you withdraw, complete or screen-fail a subject, the system automatically hides any next scheduled visit with New status from the user interface, keeping your visit records organized and clear, and makes subject management more efficient.

(Issue **36619590**)

Rule-referenced question data clears without errors

You can now clear data from rule-referenced questions without encountering errors or red outlines, streamlining data entry and correction processes.

(Issue **36857253**)

Calculation result will not be updated if there is no change in the resulting value

If a calculation rule runs, and returns the same value as is already saved for the target question, now the value will not be updated and no additional records will be saved in the Answer History, preventing duplicate entries.

(Issue **36216445**)

Verification required displays correctly after data entry

The Verification Required checkmark now appears immediately after a subject is enrolled by running the verification check across all active visits, ensuring the checkmark is shown as expected for your SDV configuration, when SDV is set to 100% and Include Screen Failures is set to No, without any additional actions.

(Issue **37919137**)

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Screening visit now triggers rules immediately after generating subject number

After you press the Screen button in a screening visit and the subject number is generated, the system now processes and triggers the rule right away, ensuring next visit restrictions are applied as intended.

(Issue **39089068**)

Randomization and kits

Resupply is now calculated correctly for studies with branch visits

Projected visit dates are now calculated correctly for branch visits, which results in correct resupply calculations for studies with branch visits. Also, these projected dates now populate and display correctly in the **Projected Visit/Event Date** column of the Subject Visits and Subject Visits (Unblinded) reports.

Previously, the system was incorrectly calculating projected dates for branch visits, returning the same date for all future branch visits and causing errors in the resupply calculations.

(Issue **39220752**)

Blinded groups can be created and modified using a single kit type

Now, blinded groups can be created and updated using a single kit type, enabling shipments to include an additional kit of the same type when needed, without requiring selection of a second kit type or sending extra kits unintentionally.

(Issue **39131935**)

Reports, archives, extracts, and notifications

The Kit Dispensation report no longer shows intermittent duplicate rows

The Kit Dispensation report no longer shows duplicate rows. Previously, the Kit Dispensation report included intermittent duplicate rows in the report output caused by the way the projected dispensation date was calculated.

(Issue **38618793**)

The security setting Prevent Form Changes selection is now preserved in the UI for the Custom PDF archive

When generating the Custom PDF archive, the selection of the security setting **Prevent Form Changes** (in the Advanced Settings) is now preserved in the User Interface (UI). Previously, when selecting *Yes, irretrievable password* for this field, and navigating out and then back to the Advanced settings, the choice would automatically change to *Yes, user-provided password*.

This was an UI display issue only. The Custom PDF has always been generated using the correct selected option.

(Issue **39246256**)

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First Subject Screened at Site notification is now sent in studies that assign subject number at screening

For studies that assign the subject number when the subject is screened, the *First Subject Screened at Site* notification is now properly sent. This notification is sent when the first subject is screened at a site, along with the normal *Subject Screened* notification that is sent for every screened subject.

Previously, only for studies that assign the subject number when the subject is screened (and not for studies where the subject number is assigned when the subject is added), the *First Subject Screened at Site* notification was not being sent for first subjects and only the normal *Subject Screened* notification was sent.

(Issue **39280942**)

Site and depot creation notifications send as expected

Email notifications are now sent when a site or depot is created, in addition to status updates.

(Issue **37264765**)

Shipment ID in the Kit Chain of Custody (Blinded and Unblinded) reports lists all shipments

Shipment ID in the Kit Chain of Custody (Blinded and Unblinded) reports now lists all shipments in the study, allowing you to search and select any shipment, including older ones.

(Issue **37638227**)

Lab Normal Data report provides correct data

Lab Normal Data report now correctly shows the associated site(s) for each lab, even when no lab normal ranges are defined. Instead of displaying N/A or listing incorrect sites, the report accurately reflects only the site(s) the lab is actually assigned to.

(Issue **37085331**)

Subject Archival PDF ZIP correctly includes the Uploaded Files folder

Subject Archival PDF ZIP now correctly includes the Uploaded Files folder. Any files uploaded through file-upload questions are packaged in the archive and available in the subject's site folder, ensuring all subject documents are included in the download.

(Issue **38748924**)

Accurate site activation and retirement dates in Site and Depot report

Site and Depot report now accurately shows activation and retirement dates for sites managed on the last day of the year in Clinical One Cloud Service. In addition, the Annotated Case Report Form generation date is now correctly captured when the report is generated on the last day of the year.

(Issue **37646263**)

Archival and Custom PDF requests generate with control characters in query comments

Archival and Custom PDF requests now generate successfully even when query comments contain control characters such as the null character (\u0000).

(Issue **38993461**)

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Clinical One Cloud Service standardizes display of decimal values display across all reports and integrations

When you enter a value with a decimal in a form (such as .9), Clinical One Cloud Service, the system now automatically adds the leading zero, displaying it as 0.9 throughout the application. This standardization ensures decimal values appear consistently and clearly in the Subject Data Extract report, as well as in Data Hub, Oracle Clinical One Analytics, and all downstream integrations. Values must still match the defined precision for each field to be accepted. This update helps prevent errors in report generation and data processing across all connected systems.

(Issue **38965549**)

Site users and subject data

Subject number is not assigned if there are open validation errors

For studies that assign subject number when subject is screened, that use the screen candidate workflow, the subject number is no longer assigned whenever there are open validation errors. With this fix, the screening action is disabled if validation errors are encountered or query rules are triggered upon screening data submission.

Previously, rules and validations were evaluated after the subject was added and the subject number was created.

(Issue **39219318**)

Data can now be properly saved for dynamic repeating forms in adverse events

Now, data is properly saved in dynamic repeating forms, added to adverse events, configured to show on current and future visits. Previously, when a site user tried to save data in the mentioned situation, the following error message displayed and didn't save any data:

The answer you provided for the determining question of this dynamic form is not yet saved. Make sure the saving process has started and wait a couple of minutes before you attempt to save the changes to the dynamic form again.

(Issue **39123163**)

Unit of measure values save and populate correctly

Now, unit of measure values for number-type questions, number questions within a Question Group, and age-type questions are saved and displayed correctly in the Answer History, ensuring complete and accurate data during subject screening.

(Issue **39175694**)

Verify, Freeze, and Lock options remain disabled until the repeating form dialog loads completely

When navigating to a repeating form instance using the view in form button on the query list page, the verify, freeze, and lock options now are remain disabled until the repeating form fully loads.

(Issue **37212352**)

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Queries are only triggered for non-deleted repeating form instances

Queries are now triggered only for non-deleted repeating form instances, ensuring that there are no unnecessary auto-queries created that require manual closing.

(Issue **37771932**)

Subject number assignment at screening reliability improved

For studies using the Assign Subject Number at Screening setting, Clinical One Cloud Service now ensures subject number assignment happens only after all designer-level rule validations pass.

- When you click Submit during screening, the system automatically confirms there are no designer-level rule validation errors.
- If any validation errors are found, the system guides you to resolve them first—screening is paused until corrections are made.
- A subject number is generated and assigned only after the validation errors are corrected, helping maintain clean and consistent subject identification.
- An informative message at the top of the page highlights that validation errors must be addressed before screening can be completed and a subject number assigned.
  This fix helps promote higher data quality and reduces rework by keeping screening and subject number assignment aligned with your study's configured rules.

(Issue **39219300**)

API query updates validate the visit instance correctly

The system keeps queries specific to each visit instance, so if there are two unscheduled visits and you open a query on the Date of Assessment , as an example, for the first visit, updating the Date of Assessment for the second visit will not impact the query on the first visit. This behavior was only applies with API-driven updates.

(Issue **36862807**)

Documentation corrections

Lists documentation issues corrected in this release, including clarifications, fixes, and updates to improve accuracy and usability.

Table 2-1 ***Add Users Guide***

Issue ID	Details
39056628	Added a note about user setup requirements for adding users to a study. Specifically, when a user is assigned the User Administrator (template) role in Design mode and a custom role in other modes (Testing, Production, or Training), the custom role must include certain permissions to support this action. The note includes a table outlining the required permissions. For more information, see Assignments for user administrators.

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Table 2-2 ***Analytics User Guide***

Issue ID	Details
38697392	Added a note to the **IS_CURRENT** element description (for applicable datasets) clarifying that for repeating, two-section, and lab forms, **IS_CURRENT** is populated for both form-level records and repeating-row records.
38837638	Added a note to the **SUBJECT_NUMBER** description (in the **Subject Folder**) for the Subject Forms dataset, clarifying that NULL is displayed when a subject is removed using the Undo Add Subject feature. ***Note**: See the Site User Guide table for the additional change included in this fix*.
39034588	Moved **FORM_RESTORED** in the Subject Forms dataset from the **FORM_STATUS** data element description (in the **Form (Required)** folder) to its own row in the Audit folder.
38956950	Updated the **ITEM_ORDER** item's description clarifying it is study-version specific, and may appear as decimals when items are inserted without renumbering, and may be re-sequenced to consecutive integers in later/latest versions. Also clarified it reflects form sequence only (no completion/clinical meaning), provided an example and added a note. For more information see the Study Design Dataset, Item folder.
38996677	Added a new **Filter Settings** section with a tip explaining default cascading filter behavior and how to disable it. For more information, see Select a dataset and create a workbook.

Table 2-3 ***Release Notes***

Issue ID	Details
38680914	The fixed issue description for bug **37578138** (resolved in 25.3) has been updated to include previously omitted data element names for the **Subject dataset**. For more information, see Fixed issues for Oracle Clinical One Analytics.

Table 2-4 ***Reporting Guide***

Issue ID	Details
38699759	Corrected the **Fields in General Enrollment** table to clarify that **Screened Subject** includes Completed and Withdrawn (in addition to New, Screened, and Screen Failed). For more information, see Study Enrollment report.
38512003	Added clarifying notes to the **User Name** and **Location** filters to explain the scope of included training data: filtering by a specific user includes all associated training regardless of user status, while filtering by a specific site includes training data only for active users at that site. For more information, see Clinical One Training report.
38981090	Added a concept note to clarify that predicted kit quantities for calculated doses are shown only when the dosing form is completed and the same calculated-dose form is used across visits; otherwise predictions may not be generated. For more information, see Subject Visits (Unblinded) report.

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Table 2-5 ***Rules Developer Guide***

Issue ID	Details
38384443	Added a note in the **Parameters** section for the findMinDateIn2SForm( ) and findMaxDateIn2SForm( ) helper functions, clarifying that they do not support being passed variables that reference unscheduled visits.

Table 2-6 ***Site User Guide***

Issue ID	Details
38837638	Added a note in **Step 6.** of the Cancel a subject procedure clarifying that NULL is displayed when a subject is removed using the **Undo Add Subject** feature.
38878742	Added a tip to the first bullet in the *Before you mark a visit that a subject missed, consider the following* section of Mark a visit that a subject misses as skipped, explaining how to correctly clear data.
38993250	Updated the first bullet under **Step 6. Enter data in a form** to clarify that users should open each repeating form row in full view by selecting the row number, rather than entering data cell-by-cell directly in the table. Added a note describing potential impacts of cell-by-cell entry, including incomplete saves (especially for **date fields**) and **dynamic questions** not appearing. For more information, see Enter data in a repeating form.

Table 2-7 ***Sponsor and CRO User Guide***

Issue ID	Details
38695345	Added a tip to the **Notification** setting describing recommended configuration for the **Subject Limit** and **Notification** settings when creating or editing custom enrollment groups.
38948566	Added guidance to clarify how to create an initial shipment in a min/max resupply strategy, namely to enter a value greater than 0 for at least one kit type in the Initial Shipment section so the system can generate the shipment when the study's initial-shipment trigger occurs (for example, site activation or after the first subject visit). For more information, see Create a min/max resupply strategy.

Table 2-8 ***Study Designer User Guide***

Issue ID	Details
38979089	Added a note to the **Restart Cycle Numbering** setting, clarifying that it appears only when creating a second or subsequent cycling branch. For more information, see Create a visit branch.
36695307	Added a bullet explaining that instructional text can only be updated using Advanced Study Versioning (ASV), along with a note describing how to delete the text box and its contents. For more information, see Add instructional text to a form.

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3

Clinical One Cloud Service and Clinical One Digital Gateway 26.0.1

- Patch log
  This page briefly describes the history of fixed issues and any new functionality delivered in patches on top of the 26.0.1 release.
- What's new in 26.0.1
- Fixed issues in 26.0.1

Patch log

This page briefly describes the history of fixed issues and any new functionality delivered in patches on top of the 26.0.1 release.

Table 3-1 Patch log

Release Number	Release Date	Details
26.0.1.2	25 February 2026	In this patch release, we fixed several issues, see the following: • Issues **38852976**, **38634114**, **38913506**, and **38953803** in Reports, archives, extracts, and notifications. • Issue **37700629** in Site users and subject data. • Issue **38725708** in Facilities, settings, and user management. • Issue **36394532** in Forms, visits, and rules. • Issue **38921650** in Integrations.
26.0.1.1	09 February 2026	In this patch release, we fixed an issue where a long-running SQL query could impact generation of the Subject Data Extract. For details, see Bug **38924524** in Reports, archives, extracts, and notifications.

What's new in 26.0.1

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

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> **Note**
>
> The Release Notes available for the release assessment environment represent a draft version and are subject to change before the General Availability.

- Data collection
- Integrations
- Reports, archives, and analytics
- REST API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 26.0.1.
- Release impact on downstream systems
  This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 26.0.1 may have on downstream systems, specifically Oracle Clinical One Analytics, Clinical One Digital Gateway integrations, Oracle CRF Submit, and Oracle Life Sciences Data Management Workbench.

Data collection

- Upload video files to form questions
  Sponsor users can now allow sites to upload video files to form questions.

Upload video files to form questions

Sponsor users can now allow sites to upload video files to form questions.

In some cases, it's necessary to upload video files to help serve as objective evidence in documenting and tracking changes in a targeted system throughout the course of the study. These uploaded files are sourced through a clinically validated platform that aids in referencing the material from that specific system.

Details for sponsor and site users

Uploading video files of **10 MB or less** to form questions are now supported in the following formats:

- **mp4**
- **mov**
- **AVI**

> **Note**
>
> The system displays an error message if you upload a video file in an unsupported format or a file size larger than 10 MB.

Preview and playback of a video file is not available within Clinical One Cloud Service. You must download the video file locally to your computer to view it.

More information can be found in the *Study Designer Guide* and *Site User Guide* after the Release Assessment Environment (RAE) upgrade completes.

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Impact on extracts and reports

The following extracts and reports now include information on these new video formats, as they do with existing formats when applicable:

- **Subject Data Extract**
- **Subject Data report**
- **Subject Queries report**

Already working in a live study?

Once the RAE upgrade completes, you can upload video format files in new and existing document upload type questions.

Integrations

- Clinical One Digital Gateway integrations support rescreen visits
  Integrations that process screening data now support the use of rescreen visits if configured in your Clinical One Cloud Service studies.

Clinical One Digital Gateway integrations support rescreen visits

Integrations that process screening data now support the use of rescreen visits if configured in your Clinical One Cloud Service studies.

Rescreen refers to the ability to screen subjects who initially did not meet protocol requirements but then qualified at a later date. This process is different from the Undo Screen Failure action, which occurs when a subject is incorrectly marked as screen failed. For more information about this feature, see Limit subject rescreening.

Supported inbound to Clinical One Cloud Service integrations

You can find additional information in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

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Table 3-2 Impact to inbound integrations

Integration	Details
• Multi-IWR • ObvioHealth • Medrio	These integrations can now send rescreening data to Clinical One Cloud Service studies for subjects in a screen-failed status and trigger events if applicable. • After the rescreen data is successfully processed, the vendor can make another API call instructing the integration to trigger the appropriate event—Screen or Screen Fail—based on the submitted data. ***Note**: The ObvioHealth integration can import rescreening data, but it does not make additional API calls to trigger events*. • Previous screen failure instances cannot be updated. Only the most recent instance of Screen Fail Date and Screen Fail Reason can be modified. ***Note**: The ability to update these values is only applicable to the Multi-IWR and Medrio integrations. The ObvioHealth integration cannot update these values*. There is no impact to existing integrations. If you want to take advantage of this enhancement: • Reach out to your Oracle point of contact to request a change to the integration template. • Contact your integration vendor to request that they update the integration to send rescreen data and to make an additional API call to trigger the events after the rescreening data has been successfully integrated.

Supported outbound from Clinical One Cloud Service integrations

You can find additional information in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

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Table 3-3 Impact to outbound integrations

Integrations	Details
• Outbound subject data integration • Oracle Clinical One Platform to Oracle InForm	The following details are relevant for the Outbound subject data and Clinical One Cloud Service to Oracle InForm integrations. • Multiple instances of rescreening are supported. • Screen and screen failure events triggered by a rescreen visit are propagated downstream to the configured target, which includes third-party EDC systems or Oracle InForm studies. – Data sent by the Outbound subject data integration to a third-party system can be mapped to update initial screening data or as individual scheduled visits. Unscheduled visit mapping is not supported. – Data transmitted to Oracle InForm studies can be mapped to update initial screening information on a flat form within an existing visit or added as unscheduled visits. • Updates to the Screen Fail Date or Reason for Screen Fail overwrite the corresponding values in the target system. • The audit trail in the target system captures changes made to the visit date, form items, screen fail date, and screen fail reason and includes the rescreening instance number if multiple instances are triggered. • Updates are integrated downstream in the order in which they occur in Clinical One Cloud Service. ***Note**: There is no impact to existing integrations. If you want to integrate data from a rescreen visit with a third-party EDC system or with Oracle InForm studies, reach out to your Oracle point of contact and request that they update the integration template to support this.*

Reports, archives, and analytics

- Enhancements to reports
  The Study Enrollment report and the Randomization List (Blinded and Unblinded) reports now include additional information related to stratified adaptive cohort randomization options.
- Enhancements to Subject Data Extract with visit data
  A new dataset, VISIT_SYS, has been added to the Subject Data Extract to consolidate visit information, making user review, reporting, and analysis easier and more efficient.
- Enhancements to the Subject Forms dataset
  Oracle Clinical One Analytics now contains more comprehensive Audit folder details for forms that are in a SCHEDULED status. New data elements have also been introduced for better audit trails.
- Enhancements to the Study Design dataset
  The dataset now includes new elements allowing users to view and sort details based on the ordering of visits, forms, and items. The dataset also includes new elements that detail data classification applied to items, additional information when changes are implemented using Advanced Study Versioning, and details at a version level that inform users of the justification/reason for a new version and if the new version has ever been applied to the active mode container.
- Enhancements to the Dh Metrics dataset
  You can now view record count and versioning metrics for queries in the Dh Metrics dataset in Oracle Clinical One Analytics.

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- Clinical One Cloud Service now stores formatted text values without non-printable characters
  Text responses are now stored both in their original format as entered by the site user, and as a formatted value with all non-printable characters removed. The formatted value is used in the Subject Data Extract, Oracle Clinical One Analytics, and downstream integrations; ensuring consistent data integration and minimizing the risk of errors.

Enhancements to reports

The Study Enrollment report and the Randomization List (Blinded and Unblinded) reports now include additional information related to stratified adaptive cohort randomization options.

The following enhancements have been added to these reports:

Report	Type of change	Description of enhancements
Study Enrollment report	New columns	New **Stratum** and **Randomization limits** columns have been added in the Cohort Enrollment tab to provide stratum group titles and randomized subject limits.
Randomization List reports (Blinded and Unblinded)	New column	The new **Stratum** column displays the stratum title and details within a cohort for all adaptive randomization schemas.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to Subject Data Extract with visit data

A new dataset, VISIT_SYS, has been added to the Subject Data Extract to consolidate visit information, making user review, reporting, and analysis easier and more efficient.

The VISIT_SYS dataset provides Data Managers and Statisticians with a consolidated view of all visits across all subjects. Centralizing visit data in one place can speed up the post processing time for analysis and the Study Data Tabulation Model (SDTM) standard by providing current visit statuses, dates, details, disposition terms, or reasons for specific actions. This approach enhances programming accuracy and accelerates SDTM dataset creation, leading to more efficient development timelines and enabling clinical trial data to be quickly prepared, organized, and submitted for compliance, analysis, and reporting.

The Subject Data Extract now includes a new dataset, VISIT_SYS, which contains the following new fields VISSTAT, SKIPYN, DSDECOD, DSSTDAT, and REASON, that are only present in this dataset.

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New data fields

New data field	Description
VISSTAT	Indicates the visit status. The following statuses are available: • INPROGRESS • INCOMPLETE • INCOMPLETE_ERROR • COMPLETE • COMPLETE_ERROR • NOT_STARTED For more information about the visit statuses, see Visit status and icon descriptions
SKIPYN	Indicates if a visit is skipped. The following values are available: • **Y** for visits that were skipped. • **N** for visits that were not skipped.
DSDECOD	Indicates the Disposition Term. The following values are available: • Screened • Screen Failure • Randomized • Completed • Withdrawal For more information about the subject statuses, see Available subject statuses.
DSSTDAT	Indicates the Disposition Date for the corresponding event, following the YYYY-MM-DD format.
REASON	Indicates the Reason for a specific action, such as a skipped visit or withdrawal. The Adverse Event event will not be included in the new dataset since it does not include a visit date.

You can find additional information about this feature in the *Reporting Guide*, after the Release Assessment Environment (RAE) upgrade.

Enhancements to the Subject Forms dataset

Oracle Clinical One Analytics now contains more comprehensive Audit folder details for forms that are in a SCHEDULED status. New data elements have also been introduced for better audit trails.

Full audit details for SCHEDULED forms

Forms that are not yet In Progress are included in the Subject Forms dataset as SCHEDULED form records. Such records are created based on the expected forms from the study design and visit schedule.

Previously, these records did not include details such as VERSION_START or VERSION_END in the Audit folder, as these records were not part of the subject's captured data.

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> **Note**
>
> VERSION_START indicates the first timestamp in the system where it is known that a subject should be completing that form. For dynamic forms, this would be when the form is triggered. For forms in scheduled visits, this matches the audit information of the visit containing the form.

New audit data elements for the Forms folder

Additionally, for better audit trails, the following data elements have been introduced in the Form folder:

> **Note**
>
> These two elements provide additional context for the current record with the latest revision (IS_CURRENT=Y or VERSION_END = 31-12-3099) but cannot be used to investigate modifications that occurred in the past. The values contained in these data elements change independently of form status versioning.

Data element	Type of change	Description
LAST_UPDATED_DATE	New element	This new element provides the time of the most recent clinical data change within a particular form. This includes entering data, clearing data, or restoring data. If no clinical data has been entered in a form, this data element displays a value of `null`. ***Note:*** Data contained within this element does not change as a result of *Sign*, *Freeze*, *Verify*, and *Lock* (SVFL) actions, nor does it change as a result of form associations or site transfers.
LAST_UPDATED_BY	New element	Whenever a user performs a clinical data change that triggers a change in the data stored in LAST_UPDATED_DATE, the user's information is stored in LAST_UPDATED_BY.

You can find additional information regarding this dataset and its data elements in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to the Study Design dataset

The dataset now includes new elements allowing users to view and sort details based on the ordering of visits, forms, and items. The dataset also includes new elements that detail data classification applied to items, additional information when changes are implemented using Advanced Study Versioning, and details at a version level that inform users of the justification/

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reason for a new version and if the new version has ever been applied to the active mode container.

New data elements to view ordinal values for visits, forms, and questions

Ordinal values are integers that indicate the order of visits in the visit schedule, the sequence of forms within visits, and the placement of questions on forms for a selected study version. They are study design attributes only and do not reflect a subject's progress through a study or carry clinical significance. You can find additional information about the following new data elements in the *Analytics User Guide* after the assessment environment upgrade.

Table 3-4 New dataset elements

Data element	Folder	Description
VISIT_ORDER	Event	Indicates a visit's ordinal position (order) within the visit schedule for the selected study version. These values may change across versions; for example, a visit that is in position 3 in version 1.0.0.1 may shift to position 4 in a later version if a new visit is inserted at position 3. • VISIT_ORDER values won't appear in the dataset for a draft study version until you either move the draft to the test container or choose **Send to Analytics** from the draft container menu. • **Scheduled non-branch visits** (for example, a screening visit) are listed first, followed by scheduled branch visits, and finally unscheduled visits when the VISIT_ORDER is sorted in ascending order. • **Scheduled branch visits** are assigned an ordinal value that reflects their position in a branch. When sorted in ascending order, visits from earlier tiers appear before those in later ones. ***Note**: A tier—the highest level in visit branch design—is used to organize parallel branches, also called arms or cohorts. Each branch consists of a group of visits*. For instance, a study includes two tiers (Tier1 and Tier2); each consists of two branches (BranchA and BranchB), and each branch contains a set of visits (Day1 and Day15). When sorted in ascending order, they appear as follows in the output. – Tier1.BranchA.Day1 – Tier1.BranchA.Day15 – Tier1.BranchB.Day1 – Tier1.BranchB.Day15 – Tier2.BranchA.Day1 – Tier2.BranchA.Day15 – Tier2.BranchB.Day1 – Tier2.BranchB.Day15 • **Unscheduled visits**, which include Withdrawal, Screen Fail, Rescreen, and Study Completion visits, are assigned an ordinal value based on the sequence defined on the **Unscheduled Visit or Event** sidebar and appear after scheduled branch visits when VISIT_ORDER is sorted in ascending order.

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Table 3-4 New dataset elements

<table>
<tr><th>Data element</th><th>Folder</th><th>Description</th></tr>
<tr><td>FORM_ORDER</td><td>Form</td><td>Indicates a form's ordinal position (order) within a visit for the selected study version. These values may change across versions; for example, a form that is in position 3 in version 1.0.0.1 may shift to position 4 in a later version if a new form is inserted at position 3.
Duplicate FORM_ORDER values appear in the output when a new form is added using Advanced Study Versioning (ASV) and the dataset is generated for a previous study version. For example, study version 1.0.0.1 includes three forms, and study version 1.0.0.2 introduces a new form (Vitals). The output appears as follows when the dataset is generated for version 1.0.0.1. However, if the dataset is generated for version 1.0.0.2, no duplicate values appear and the order is sequentially correct.
<table>
<tr><th>FORM_NAME</th><th>FORM_ORDER</th></tr>
<tr><td>Screening</td><td>1</td></tr>
<tr><td>Baseline</td><td>2</td></tr>
<tr><td>Vitals</td><td>2 (3 when generated for 1.0.0.2)</td></tr>
<tr><td>Study Completion</td><td>3 (4 when generated for 1.0.0.2)</td></tr>
</table></td></tr>
<tr><td>ITEM_ORDER</td><td>Item</td><td>Indicates a question's ordinal position (order) on a form for the selected study version. These values may change across versions; for example, a question that is in position 3 in version 1.0.0.1 may shift to position 4 in a later version if a new question is inserted at position 3.
When an Age item is added to a form, the system also adds a Date of Birth field and displays them together, making it appear as a single question in the study design. In the study design dataset, however, Age (a calculated item) and Date of Birth are recorded as two distinct items, each on its own row with a unique ordinal value.</td></tr>
<tr><td>ITEM_GROUP_ORDER</td><td>Item</td><td>Indicates the order of items on two-section forms and in question group type questions.
For example, a study's design includes a question group labeled Scan 1 with two questions: Scan Date and Upload Scan. In the output, the ITEM_GROUP is repeated for each question in the group, and ITEM_GROUP_ORDER reflects each question’s position within the group. In the design, the group is treated as a single question, so if ITEM_ORDER is present, it is the same for all items.
<table>
<tr><th>ITEM_GROUP</th><th>ITEM_NAME</th><th>ITEM_GROUP_ORDER</th><th>ITEM_ORDER</th></tr>
<tr><td>Scan 1</td><td>Scan Date</td><td>1</td><td>1</td></tr>
<tr><td>Scan 1</td><td>Upload Scan</td><td>2</td><td>1</td></tr>
</table>
Note: For any other form or question types, ITEM_GROUP_ORDER is NULL.</td></tr>
</table>

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New data elements to view data classification and design details

Now, the same information visible in the user interface (UI) is accessible in the Study Design dataset when retrieving data through APIs and when working in Oracle Clinical One Analytics. These updates apply only to design data and do not impact runtime.

The following new data elements are included in the Study Design dataset:

Data element	Folder	Description
REASON_FOR_REVISION	Study	Indicates the user provided reason for revising the study version. This reason is provided when moving a study version from Test to Active container.
VERSION_TITLE	Study	Indicates the title of the study version.
IS_APPROVED	Study	Indicates whether or not (**Y** or **N**) the study version was ever in the Approved container, which is especially useful for archived study versions.
EARLIEST_VISIT_TO_COMPLETE	Event	When setting up a study completion visit, you can designate an earlier visit that must be completed before the option to mark the subject as Complete becomes available. The reference name of the required scheduled visit is specified in this field. This data element is added for each event. However, it is only specified when the record is for a Subject Completion event, while all other records display as a `NULL` value.
DATA_CLASSIFICATION	Item	This data element populates with a comma separated list of all the selected data classification groups of a hidden item. Possible values for this element include: • Adjudication data • Blinded data • PII data • Public data • Sponsor data
DATA_TYPE	Item	Indicates the data format of the collected data. For example: • VARCHAR • NUMBER • DATETIME
APPLY_CHANGE_VERSION	Item	Indicates the version in which changes to the form item apply. This data element refers to the lowest study version in which the change occurs; all study versions inclusive of the APPLY_CHANGE_VERSION and current study version are included in the change.

You can find additional information about this dataset and the new data elements in the *Analytics User Guide* after the assessment environment upgrade.

Enhancements to the Dh Metrics dataset

You can now view record count and versioning metrics for queries in the Dh Metrics dataset in Oracle Clinical One Analytics.

The Dh Metrics dataset now includes four new data elements to verify query data completeness. This allows for more efficient data validation. The new data elements are:

- C1_SUBJ_QUERIES_ROWCNT

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- DH_SUBJ_QUERIES_ROWCNT
- C1_SUBJ_QUERIES_MAX_VER_START
- DH_SUBJ_QUERIES_MAX_VER_START

These new data elements combined, allow you to review query total counts in both the core Clinical One Cloud Service system and the data model in the Oracle Clinical One Analytics system. As well as the last versioning change in both tables. This enables users to verify existing data, comparing data in one system against the other, just as you can with other existing metrics: Randomization and Trial Supply Management (RTSM) inventories, study versions, and data collected in form items.

You can find additional information about this dataset and its new data elements in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Additionally, there is a new Data Hub API that allows users to retrieve Dh Metrics from an endpoint instead of through Oracle Clinical One Analytics. This provides Data Hub APIs users the same operational details as users working with the Dh Metrics dataset in Oracle Clinical One Analytics. For more information on the specific endpoint refer to *Rest API updates* section in this guide and the *REST API for Clinical One Platform* guide after the RAE upgrade.

Clinical One Cloud Service now stores formatted text values without non-printable characters

Text responses are now stored both in their original format as entered by the site user, and as a formatted value with all non-printable characters removed. The formatted value is used in the Subject Data Extract, Oracle Clinical One Analytics, and downstream integrations; ensuring consistent data integration and minimizing the risk of errors.

Text responses entered by site users may contain non-printable characters, which are invisible symbols that control text formatting. These characters include tabs, carriage returns, newline characters, and leading or trailing white spaces. However, these require additional downstream processing when consumed by downstream systems. Now, this burden is reduced by providing pre-formatted data without these non-printable characters.

As clinical data is extracted from Clinical One Cloud Service for use in Oracle Clinical One Analytics and downstream integrations, form items get represented in four different columns:

- Raw (ITEM_R)
- Formatted (ITEM_F)
- Decode (ITEM_D)
- The item itself (ITEM)

The Clinical One Cloud Service system stores the original site entered text in the main ITEM column, for accurate rendering and display within the application. The formatted value, excluding all non-printable characters, is stored in the ITEM_F column.

> **Note**
>
> This applies to values coming from text questions only.

This change does not impact the data entered or displayed in the application, and it is intended solely to improve data quality and downstream Oracle Clinical One Analytics compatibility. To achieve this, the ITEM_F column now serves as the standardized, analytics-ready version for downstream integrations, exports, and data pipelines.

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You can find additional information in Form item output mapping in data extracts, in the *Analytics User Guide*, after the Release Assessment Environment (RAE) upgrade.

Impact on integrations

There would be no impact if you are working with Clinical One Digital Gateway or Oracle CRF Submit.

However, if you are working with Oracle Central Coding, you must consider that after the upgrade to 26.0.1, Clinical One Cloud Service will send the formatted text value (without non-printable characters) to Oracle Central Coding for all newly entered verbatim terms (VTs) and any VTs that were coded before the upgrade and edited after. Users may be required to manually code new and edited VTs.

> **Note**
>
> Keep in mind manual re-coding is only needed if the VT and its associated context items in fact include non-printable characters. This can sometimes happen if a user pastes text into one of the text fields in the study, resulting in the introduction of non-printable characters into the field.

If VTs were entered before the upgrade but coded afterward, Oracle Central Coding codes them using the pre-upgrade 'raw' text, and subsequent matching VTs auto-code based on the same text.

Already working in a live study?

For existing text responses, the original data stored in the ITEM_R column (and displayed in the application) remains unchanged. Clinical One Cloud Service will only generate and populate the corresponding ITEM_F data by processing the stored values and removing all non-printable characters:

- These updates to the ITEM_F column will be performed as a post-upgrade activity.
- Data will be updated irrespective of the current data status (locked, frozen, signed, read-only, hidden, etc.), and will not trigger any actions, such as unsign, unverify, auto-lock or other rules.
- After the upgrade, the first incremental load may take several hours to complete as it pushes these updates into Data Hub and Oracle Clinical One Analytics. This is part of the Oracle Clinical One Analytics data pause, which will be announced as it ends.

Any future updates or edits to existing responses will continue to automatically update in all four ITEM, ITEM_R, ITEM_F, and ITEM_D columns.

REST API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 26.0.1.

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> **Note**
>
> To ensure you can easily access all the information that you need, we are working on restructuring the REST API guide. As a result, some of the categories listed under the **Tasks** section of this guide now follow a slightly different hierarchy, to which all categories will eventually conform. For example:
>
> From:
>
> - Tasks > Data Capture > Data Elements > v4.0 > Clear data elements scope by study ID and mode
>
> To:
>
> - Tasks > Data Capture > Data Elements > Clear data elements scope by study ID and mode>V4.0
>
> This documentation update will be completed in future releases.

Permissions

For this release, no new services or permissions have been added. Only existing services have been updated.

Service updates

The following services are updated:

- Data Hub
- Data Integration
- Notifications
- Randomization and supplies
- Query management
- Rule designer
- Rules

Data Hub

Change	Endpoint
New	• GET /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/metrics • GET /v1.0/tenant/{tenantId}/{mode}/dhSynchupTime • POST /v13.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v8.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v9.0/studies/{studyId}/{mode}/odm/metadata
Deprecated	• POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v6.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v7.0/studies/{studyId}/{mode}/odm/metadata

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Data Integration

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/subjects
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v1.0/studies/{studyId}/{mode}/subjects/history/all • GET /v1.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v2.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v2.0/studies/{studyId}/{mode}/subjects/history/all • GET /v2.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v3.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Notifications

Change	Endpoint
Deleted	• DELETE /v1.0/studies/{studyId}/{mode}/notificationsbroadcast/{id} • GET /v1.0/studies/{studyId}/{mode}/{rightname}

Randomization and supplies

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/allShipments

Query management

Change	Endpoint
Deleted	• POST /v1.0/studies/{studyId}/{mode}/queries/subjectsitetransfer • GET /v1.0/studies/{studyId}/{mode}/querymgmt/filteredList • PUT /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/bulkCloseDelete
Deprecated	• POST /v1.0/studies/{studyId}/{mode}/querymgmt/openQueryList • POST /v1.0/studies/{studyId}/{mode}/querymgmt/queryList • GET /v10.0/studies/{studyId}/{mode}/openQueryDetails • GET /v10.0/studies/{studyId}/{mode}/queryDetails • GET /v8.0/studies/{studyId}/{mode}/openQueryDetails • POST /v8.0/studies/{studyId}/{mode}/queries/candidate • POST /v8.0/studies/{studyId}/{mode}/queries/open • GET /v8.0/studies/{studyId}/{mode}/queries/{queryId} • PUT /v8.0/studies/{studyId}/{mode}/queries/{queryId}/answer • PUT /v8.0/studies/{studyId}/{mode}/queries/{queryId}/close • PUT /v8.0/studies/{studyId}/{mode}/queries/{queryId}/delete • PUT /v8.0/studies/{studyId}/{mode}/queries/{queryId}/open • GET /v8.0/studies/{studyId}/{mode}/queryDetails • GET /v9.0/studies/{studyId}/{mode}/openQueryDetails • PUT /v9.0/studies/{studyId}/{mode}/queries/{queryId}/close • GET /v9.0/studies/{studyId}/{mode}/queryDetails • POST /v9.0/studies/{studyId}/{mode}/report/{reportName}

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Rule designer

> **Note**
>
> Rule Designer endpoints are listed under the Rules category.

Change	Endpoint
New	• PUT /v5.0/rule/studies/{studyId}/{mode}/bulkupdate • GET /v5.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId} • PUT /v6.0/rule/studies/{studyId}/{mode}/bulkupdate • GET /v6.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId} • PUT /v7.0/rule/studies/{studyId}/{mode}/bulkupdate
Deleted	• POST /v1.0/rule/studies/{studyId}/{mode}/copy • PUT /v1.0/rule/studies/{studyId}/{mode}/from/{fromState}/to/{toState}/bulkstateupdate • POST /v1.0/rulemgt/studies/{studyId}/{mode}/filteredlist
Deprecated	• POST /v1.0/rule/studies/{studyId}/{mode}/ruleIds/operands • GET /v3.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId} • PUT /v4.0/rule/studies/{studyId}/{mode}/bulkupdate

Rules

Change	Endpoint
Deleted	• PUT /v1.0/studies/{studyId}/{mode}/debugRule • PUT /v2.0/studies/{studyId}/{mode}/deleteform

Release impact on downstream systems

This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 26.0.1 may have on downstream systems, specifically Oracle Clinical One Analytics, Clinical One Digital Gateway integrations, Oracle CRF Submit, and Oracle Life Sciences Data Management Workbench.

For additional information about the features in this release and the potential impact on your studies, Download the Release Implementation Assessment document.

Oracle Clinical One Analytics also known as Data Hub

Release feature	Analytics impact
Enhancements to the Subject Forms dataset	The audit details included in the Subject Forms dataset for forms with a status of SCHEDULED are reflected in Data Hub and all Data Hub-related integrations.

Clinical One Digital Gateway configured integrations

The features introduced with this Clinical One Cloud Service release do not impact Clinical One Digital Gateway integrations.

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Oracle Life Sciences Data Management Workbench (DMW)

Release feature	DMW impact
Enhancements to the Study Design dataset	• The new elements allowing users to view and sort details based on the ordering of visits, forms, and items will be available in Oracle DMW as part of a future release. • The newly added elements to the Study Design Dataset, which ensure that the same information presented in the UI is also present in the dataset, will be implemented in Oracle DMW in a future release.

Oracle Life Sciences InForm CRF Submit

Release feature	CRF Submit impact
Upload video files to form questions	Video files imported at the question level are included in the ZIP file generated by Oracle CRF Submit, and a link appears on the question where the import occurred. However, these links will not be active until a future release. To download and view imported video files, open the ZIP folder, locate and open the applicable site folder, and then open the Uploaded Files folder.

Fixed issues in 26.0.1

- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

Site IDs are created without trailing or leading spaces

Now, when a site ID is created, any entered trailing or leading spaces are automatically trimmed, preventing the creation of duplicate site IDs (e.g. 'Site-A123 ' and 'Site-A123'), and preventing subjects from being incorrectly assigned to the wrong site during integrations.

(Issue **36687489**)

Edit Kit dialog appears even when the Units Per Kit field is empty

Now, the Edit Kit dialog displays for all kit types. Kits can no longer be saved if the Units Per Kit field is left empty, preventing any invalid configurations.

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(Issue **38716381**)

Visits with outstanding queries display an accurate color in the user interface (UI) in the visit train after opening the next visit

Now, visits with outstanding queries consistently display red tiles in the visit train, even after opening subsequent visits. The visit colors accurately reflect query status and ensure the UI reliably shows which visit requires attention.

(Issue **38641592**)

Screening Visit Verification status remains consistent

Now, the Screening Visit Verification status remains consistent for all users, irrespective of their data classification permissions. The status does not change based on whether a user has data classification view or edit permissions, ensuring the verification status accurately reflects the visit's actual state.

(Issue **38593700**)

Undo Withdrawal button is disabled immediately after the first click

Now, the UI disables the “Undo Withdrawal” button immediately after the first click, ensuring only one DELETE request is sent. This prevents duplicate calls and correctly restores the subject to an Active status.

(Issue **37809799**)

Assign Lab dialog window can be closed

Now, the Assign Lab dialog window, which pops up after selecting Assign/Manage Labs on the Sites & Labs tab, successfully closes after selecting **Cancel** or clicking the X icon in the upper right corner of the window.

(Issue **35975881**)

Users can view the Assign Lab and Add Lab options when their screen zoom is greater than 100%

Now, users are able to use the new scroll bar to scroll down to access the **Assign Lab** and **Add Lab** options when adding labs to a site, even if their screen zoom is greater than 100%.

(Issue **37121295**)

Facilities, settings, and user management

The Study Version drop-down now displays values on the Sites & Labs tab

Users with the required permissions can now select a study version from the **Study Version** drop-down on the **Sites & Labs** tab even if they don’t have a global design role assigned.

Previously, the drop-down appeared blank for users without a global design role, preventing updates despite having the necessary permissions.

(Issue **38725708**)

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Forms, visits, and rules

Answer & Visit History updates correctly when selecting any radio button other than the first

Now, the Answer & Visit History correctly displays the history for all radio button questions, regardless of which answer is selected, for users with permission to edit or add data.

(Issue **36534645**)

Error message appears only when a parent question containing a frozen, locked, hidden, or read-only child question item is updated

Now, an error message dialog is prompted only when the answer of a parent question of a frozen, locked, hidden, or read-only child question item has been changed.

(Issue **36844592**)

Rules execute properly for date items included in newer study versions

Now, rules that use **isStudyVersion** and reference date items introduced in newer study versions execute correctly for subjects in older study versions. The system detects and handles missing date data properly, preventing unexpected rule execution errors and ensuring proper rule processing across study versions.

(Issue **37752614**)

Form data is saved once the parent question item has been completed

Now, child question data can no longer be entered or saved unless the parent question is fully valid and saved first. If a required parent validation (such as **Reason for Change**) is missing, the system prevents the save, generates a validation error, and prevents child data from being saved or entered.

(Issue **38594822**)

Freezing individual items in a repeating form row freezes the entire row

Now, freezing all items within a repeating form instance - either individually or by freezing the entire row - consistently records a row-level freeze in the system.

(Issue **38692755**)

Signatures are applied correctly to all forms and questions

Now, for skipped visits, signatures are correctly applied to all forms and questions, including new forms or questions added in later study versions. Whether the visit is frozen first or signed first, all eligible items in the latest study version are included to ensure complete and accurate subject signing.

(Issue **37745313**)

Creation of Future-Only visits is prevented in earlier study versions

Now, the system prevents the creation of Future-Only visits for subjects associated with an earlier study version (e.g. V1). If a subject from V1 triggers a rule to create a visit that was designed only in V2 and marked as Future-Only, no record for that visit is created.

(Issue **38710698**)

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Parent questions are updated successfully when child forms and visits are frozen without data

Now, users can successfully clear, reset, or update parent questions, even when associated child forms or visits have been frozen without data, ensuring that the dynamic triggering and un-triggering of forms and visits works as expected.

(Issue **37278583**)

Users can save form changes after manually entered options are replaced with a code list

Now, study designers no longer encounter errors when saving form changes if the previously approved study version included a choice-type question that was initially created with manually added options and replaced with a code list before the draft study version was moved to the Approved container.

(Issue **38473860**)

Error message is not prompted when attempting to select a new study role in the Rule Editor

Rule designers can now successfully update the study role associated with a rule that triggers an assigned query when the study role that was initially selected is retired.

(Issue **38148943**)

Cyclic visits are created correctly in a previous branch

Now, the next required visit is created after the current one is completed, ensuring correct visit order and preventing any missing or extra visits for sites.

In Release 26.0.1, we suppressed visits that were displayed incorrectly due to this big; if a subject later reaches one of these visits as part of the normal schedule, the visit will automatically reappear in the user interface (UI).

(Issue **38717686**)

Integrations

Study version retrieval includes deleted data elements

Now, deleted data elements are correctly included when determining the study version for a subject event, ensuring consistent and accurate version handling, preventing validation errors during import, and supporting edge cases where deleted elements are involved.

(Issue **38451978**)

Integrations are not available after being retired

Now, integrations remain disabled when its integration group is retired, even after the study is taken out of maintenance, ensuring consistent management of integrations during study maintenance and retirement.

(Issue **38581061**)

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Data processes correctly for CTMS integrations

Now, the system no longer triggers unnecessary data reprocessing when performing locking, freezing, verifying, or signing actions on subject visits, also allowing integration jobs to process data correctly and efficiently.

(Issue **38155037**)

CTMS subject visit integration jobs complete successfully

Now, the system uses the correct visit study version, rather than the subject study version, to determine visit branch information, ensuring accuracy in visit schedules and branch assignments.

(Issue **38418928**)

MUL integration now properly assigns users to appropriate sites based on compounding site logic

Now, the Master User List (MUL)—User Integration can process site numbers that include a trailing alpha character (for example, **1004A**) by ignoring the alpha suffix and assigning the user to the corresponding primary numeric site (**1004**).

For existing integrations: To apply this fix, update your MUL integration configuration to set ProcessCompoundSite to true.

(Issue **38921650**)

Oracle Clinical One Analytics

Deleted repeated forms prevent additional data entry in Oracle Clinical One Analytics

Now, users can no longer enter data for deleted records in repeating forms, ensuring that deleted forms do not resurface and avoiding potential discrepancies in data, PDFs, and Analytics.

(Issue **36658531**)

IS NULL and NOT NULL operations function properly in Data Hub Dataset API framework

Now, users can successfully use **IS NULL** and **NOT NULL** operations in their Data Hub Dataset API requests.

(Issue **38653653**)

Sign, verify, freeze, and lock (SVFL) datatsets complete properly and in adequate time

Now, queries for Sign, Verify, Freeze, and Lock (SVFL) datasets in Oracle Clinical One Analytics return subject data reliably and complete within expected timeframes.

(Issue **38487962**)

Subject Form Items dataset API completes incremental loads successfully

Now, the Subject Form Items dataset Data Hub API completes incremental loads successfully without timing out, delivering an improved and more reliable performance when fetching data.

(Issue **38665136**)

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Randomization and kits

Create Shipment dialog updates correctly when switching sites with different kit availability

Now, the Create Shipment dialog correctly updates when switching sites. If a site with no available kits is selected, the Select Lot drop-down is disabled. Additionally, when switching to a site with available kits, the drop-down is enabled and works as expected.

(Issue **37734929**)

Reconciliation shipment can be created when all kits are selected using the Kit Status filter

Now, site users can use **Select All** to update multiple kits to *Pending Destruction* without errors. The system correctly processes all selected kits - regardless of subject or kit status - and creates the appropriate destruction shipment.

(Issue **37804099**)

Predictive Resupply considers randomization and dispensation visits correctly

Now, resupply calculations correctly ignore randomization and dispensation visits that are not fully completed. Only completed visits are used for accurate resupply prediction without requiring changes to study design or visit completion rules.

(Issue **38696263**)

Predictive resupply shipments are created with the correct number of kits

Now, the system correctly calculates the scheduled date for the first visit in the next cycle, using the last completed visit from the previous cycle before any skipped visits, ensuring that scheduling and kits requirements are accurate.

(Issue **36323779**)

Projected schedule date is correct for cyclic branch visits

Now, the system correctly calculates the projected scheduled date for cyclic visits, even when visits in earlier cycles are skipped, ensuring that the scheduled date is calculated from the last completed visit before the skipped visit in the cycle, and that this behavior is consistent across the user interface (UI) subject visit cards and the Subject Visits (Unblinded) report.

(Issue **37500371**)

Reports, archives, extracts, and notifications

Email notifications are sent for CRF Submit downloads for specific browser settings

Now, email notifications for CRF Submit and Confirm actions are sent correctly regardless of browser language and settings.

(Issue **37452854**)

Clinical One reports display correct user roles

Now, reports in Clinical One display the current, updated study role for each user.

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(Issue **37377107**)

Country enrollment counts in the Study Enrollment report are correct when subjects are transferred

Now, the Study Enrollment report correctly includes subjects who were screened at a site, even if they were transferred to another site in a different country after randomization. The counts for *Screened* and *Active* subjects are correctly reflected at both the Site and Country levels, and transferred subjects are accurately represented in the Country Enrollment section of the report.

(Issue **36440859**)

User Assignment report shows accurate site and user details

Now, the User Assignment report correctly processes historical role and site assignments without generating duplicate, invalid, or misleading information.

(Issue **38154927**)

The Subject Data Extract is now successfully generated

The Subject Data Extract now completes successfully, and users no longer receive failure notifications.

Previously, a long-running SQL query that performed a full table scan degraded performance and caused the Reporting Service API to time out.

(Issue **38924524**)

The Subject Data report now generates successfully for CSV format

The Subject Data report now generates successfully in CSV format when all filters—**Study Version**, **User Name**, **Location**, and **Subject Number**—are set to All, regardless of whether **Include Cleared Data** is **Yes** or **No**.

Previously, a discrepancy between the total record count and the report query caused the report to fail.

(Issue **38852976**)

The Subject Data report now displays the correct Date & Time values

The Date & Time column now shows the correct Date & Time data. Previously, The Date & Time column for some records intermittently showed an incorrect date or time value.

(Issue **38634114**)

Oracle CRF Submit Archival PDF requests are generated successfully for transferred subjects

Oracle CRF Submit now successfully generates Archival PDF requests for transferred subjects, even when the requesting user does not have access to both sites.

Previously, Oracle CRF Submit blocked request generation for transferred subjects unless the user had access to both the originating site and the destination site.

(Issue **38913506**)

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The Kit Dispensation report now includes the correct columns in the output

The column **Return Depot Name** now appears only once, and **Return Depot ID** is present in the report output.

Previously, Return Depot Name appeared twice, and Return Depot ID did not appear at all. This occurred because both were mapped to the same anchor ID. To address this, the anchor ID for Return Depot ID was updated, ensuring uniqueness.

(Issue **38953803**)

Site users and subject data

Child questions now clear successfully when the parent is cleared

When a user clears a parent question, any hidden child question targeted by a rule that invokes the clearValue() function now clears successfully without error. The Clear Item API (v2.0) has been updated to handle hidden items by supplying the appropriate data classification during validation. As a result, rule-driven clear actions complete as expected, and the UI no longer displays an error.

(Issue **37700629**)

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4

Clinical One Cloud Service and Clinical One Digital Gateway 25.3

- Patch log
  This page briefly describes the history of fixed issues and new functionality applied on top of the 25.2 release.
- What's new
- Fixed issues
- Release impact on downstream systems
  This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 25.3 may have on downstream systems, specifically Oracle Clinical One Analytics and Clinical One Digital Gateway integrations.
- Rest API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.3.

Patch log

This page briefly describes the history of fixed issues and new functionality applied on top of the 25.2 release.

Release number	Release date	Notes
25.2.1.5	24 November 2025	For this release, we fixed several issues. For more information see the following: • Issues **37816125** and **38198217** in Facilities, settings, and user management • Issues **38504328**, **37246186**, **38540346**, **38553728**, **38198138**, **38528093**, **36122564**, and **38552905** in Forms, visits, and rules • Issues **38461830** and **38353201** in Integrations • Issue **38478524** in Randomization and kits • Issue **38193558** in Reports, archives, extracts, and notifications • Issue **36230101** in Site users and subject data

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Release number	Release date	Notes
25.2.1.4	29 October 2025	For this release, we fixed several issues. For more information, see the following: • Issues **38285107** and **38511005** in Reports, archives, extracts, and notifications • Issues **38489911**, **38515304**, **38469837**, **38055482**, and **38359126** in Oracle Clinical One Analytics • Issue **37507918** in Site users and subject data • Issues **37700629** and **38371717** in Forms, visits, and rules • Issue **38430197** in Facilities, settings, and user management
25.2.1.3	29 September 2025	For this release, we fixed an issue related to branching. For more information, see issue **38437568** in Forms, visits, and rules.
25.2.1.2	25-September-2025	For this release, we fixed several issues. For more information, see the following issues: • Issues **37999017**, **38331231**, and **38274625** in Oracle Clinical One Analytics. • Issues **38284857**, **38315906**, and **38330398** in Integrations • Issue **38336630** in Facilities, settings, and user management • Issue **37669804** in Forms, visits, and rules • Issues **38245796** in Reports, archives, extracts, and notifications • Issues **38198276**, **38255228**, **38316955**, **37669804** in Site users and subject data
25.2.1.1	16 September 2025	For this release, we fixed an issue related to the Subject Data Extract. For more information, see issue **38372054** in Reports, archives, extracts, and notifications.

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Release number	Release date	Notes
25.2.1	29 August 2025	For this release, we introduced new enhancements in the What's new section. For more details, see: • Lock and unlock multiple subjects simultaneously • Update multiple study users simultaneously • Randomization replacement • Include a form preview in the Annotated Case Report Forms report • New datasets to track sign, verify, freeze, and lock actions • New data element to track visit, form, and item level locks • Enhancements to Oracle Clinical One Analytics datasets • Enhancements to Oracle DMW clinical data extracts • File-based integrations now support file name format changes (enhancement **37810447**) • A fresh new Redwood look • For REST API updates, see Rest API patch updates. • For more information on downstream impact, see Patch set release impact for other applications. For a detailed list of fixed issues, look for the following issues in the Fixed issues section: • Issue **37259277** in All users • Issues **38120683**, **38278228**, **38219969**, and **38239994** in Oracle Clinical One Analytics • Issues **37331039** and **36212384** in Facilities, settings, and user management • Issues **38267486**, **36465916**, **38209696**, and **36496392** in Forms, visits, and rules • Issue **37010117**, **38278228**, **38120683**, and **37566193** in Integrations • Issues **36343281** and **38272631** in Reports, archives, extracts, and notifications • Issues **36400347**, **38209696**, **36505556**,**37845829**,

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Release number	Release date	Notes
		38193545 in Site users and subject data
25.2.0.3	19-August-2025	For this release, we fixed issues related to the visit schedule. For more information, see issue **38260677** in Site users and subject data.
25.2.0.2	13-August-2025	For this release, we fixed issues related to visits and data collection. For more information, see the following issues: • Issues **37110046**, **38247383**, and **38235953** in Site users and subject data. • Issue **38259231** in Integrations. • Issue **38288851** in Reports, archives, extracts, and notifications.
25.2.0.1	31-July-2025	For this release, we fixed issues related to randomization, integrations, and more. For more information, see the following: • **38166723** in Facilities, settings, and user management • **38172469** in Integrations • **37914482** in Site users and subject data

What's new

- Data Collection
- Integrations
- Reporting, archives and analytics
- Randomization and Trial Supply Management
- Rules management
- User experience
- Data collection
- Data review
- Integrations
- Notifications
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management
- Study design

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- User experience
- User management
- Study design
- Data collection
- Randomization and trial supply management
- Integrations
- Reporting, archives, and analytics
- Notifications
- Other enhancements

Data Collection

- Limit the number of times a subject can be rescreened
  Sponsor users can now limit the amount of times site users can rescreen a subject.
- Choose when subject numbers are assigned
  With the new **Assign Subject Number** study-level setting, study managers can choose when subject numbers are assigned, either when the subject is added or after screening.
- Subject data can now be unverified
  Sponsor users can now unverify data at the visit, form, and question level that may have been verified in error. This removes the need to manually track verification errors, ensures verification is conducted on the required visits, forms, and questions, and ultimately improves overall data quality.

Limit the number of times a subject can be rescreened

Sponsor users can now limit the amount of times site users can rescreen a subject.

In some cases, your study's protocol may call for allowing subjects to be rescreened a specific or an unlimited amount of times. This feature allows for data collection specific to each rescreen attempt, making it available for review and analysis. Controlling and tracking the number of rescreen attempts can help facilitate site compliance to the protocol and reduce data review responsibilities for sponsors.

Before you work with this feature

Users assigned to a study role with the *Receive the Subject Rescreening Notification* permission receive the new **Rescreening [Success/Failure]** text format notification, informing them whether a subject has been successfully rescreened or not.

Additionally, users assigned the *Receive the Rescreening Limit Notification* permission receive the **Subject has reached rescreening limit** text format notification that informs them when a site has reached the rescreening limit for a subject.

More details about these notifications can be found in the *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade completes.

Details for study designers

As a study designer, here's what's new for you when creating an event type:

- You can now select the new unscheduled event type, **Rescreening Event**.
  - If a screening visit is not present, the option to create a rescreening visit is unavailable.

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  - While defining a rescreening event, when **Use Screening Visit as Template** is selected, the screening visit is copied, including all forms and their sequence defined in the screening visit.
  - When you choose to use the screening visit as the template for the rescreening visit, any kits assigned to the screening visit are also copied to the newly created rescreening visit.
  - You *cannot* create a rescreening visit if randomization is included in the original screening visit.
  - You can assign kits to the rescreening visit and dispense from it during the study conduct period.
- Like other unscheduled visits, rescreening visits *cannot* be a dynamic visit, *cannot* be marked as *Required*, and *cannot* trigger a branch visit.

More information can be found in the *Study Designer User Guide* after the RAE upgrade completes.

Details for sponsor users

As a sponsor user, here's what's new for you when defining rescreen settings for subjects:

- On the Study Settings tab, under the Subject Management section, the new **Allow Rescreening** setting allows you to determine whether or not a subject can be rescreened.

  > **Note**
  >
  > The **Allow Rescreening** setting is set to **No** by default.

  When a rescreen visit is present and this setting is set to **Yes**, the following settings appear:

  - **Maximum Rescreening Attempts**: This setting prompts you to enter the amount of times a subject can be rescreened. If left blank, then the subject can be rescreened an unlimited number of times.
  - **Lock All Screening/Rescreening Data after Screen Failure**: When the checkbox for this setting is selected, all questions in the visit are locked in the Screening/ Rescreening visit if the subject is auto or manually screen failed.

More information and step-by-step instructions on limiting a subject's rescreening can be found in the *Sponsor and CRO User Guide* after the RAE upgrade completes.

Details for site users

As a site user, here's what's new for you in your workflow:

- In the **Manage** drop-down menu, the **Rescreen** option is available for subjects that have been auto or manually screen failed when at least one rescreening event is permitted.
- The **Rescreen** option does not appear in the **Manage** drop-down for the following scenarios:
  - A rescreen visit has not been created in the study's design.
  - The subject has reached the maximum number of rescreen attempts.
  - The subject is successfully screened, randomized, or enrolled.
  - The screen fail event is started.

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– The subject has been withdrawn from the study.

> **Note**
>
> If all data is cleared during the screen fail event or an undo withdrawal is performed, if additional rescreen attempts remain, the **Rescreen** option becomes available again in the **Manage** drop-down.

- You are able to undo manual screen failures or update data that generated an auto-screen fail, as long as you have not moved on to another rescreen visit.

More information can be found in the *Site User Guide* after the RAE upgrade completes.

Impact on rule design

As a rule designer, be aware that when you are referencing a rescreening visit, the event type property value returns `UnScheduleAbleVisit` as opposed to `ScreeningVisit`. `ScreeningVisit` is reserved for the first occurrence of a screening event.

More information can be found in the *Rules Developer Guide* after the RAE upgrade completes.

Impact on reports, archives, and datasets

Report, archive, or dataset	Type of change	Description
Annotated Case Report Forms	Modified column data	The following report details include rescreening data when applicable: • **Visit** filter • **Include in Report**
Study Design report	Modified column data *and* new column fields	The following report fields are updated to include rescreening details when applicable: • **Visit/Event Title** • **Visit/Event ID** • **Visit/Event Type** The following settings and their respective values are included in the **Study Settings** section of this report when configured in a study's settings: • **Allow Rescreen** • **Maximum Rescreening Attempts** • **Lock All Screening/ Rescreening Data after Screen Failure**

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Report, archive, or dataset	Type of change	Description
Study Settings report (Study Settings tab)	New column fields	The following settings and their respective values are included in this report when the **Allow Rescreen** setting is set to **Yes** in a study's settings: • **Allow Rescreening** • **Maximum Rescreening Attempts** • **Lock All Screening/ Rescreen Data after Screen Failure**
Study Settings Report (Visit Settings tab)	Modified column data	The **Visit Type** field reflects rescreening data when applicable.
CRF Submit Archives	Modified column data	When applicable, the **by Visit** section in the left sidebar displays the rescreen visit. The result of the rescreen visit, either *Screened* or *Screen Failed*, appears in the **Subject Event History** table.
Subject dataset	Modified data element	When applicable, rescreening visit data is included in either Screened or Screen Failure records.

More information and specific descriptions on modified report values can be found in the *Reporting Guide* and the *Analytics User Guide* after the RAE upgrade completes.

Impact on integrations

If your study is integrated with Clinical One Digital Gateway, see Clinical One Digital Gateway integrations support rescreen visits.

Already working in a live study?

Once the RAE upgrade completes, this functionality is applied to all studies. By default, the **Allow Rescreen** setting is set to **No**, having no impact on the study conduct for live studies. If there is no rescreen window included in the study design, site and sponsor users do not see any change.

Choose when subject numbers are assigned

With the new **Assign Subject Number** study-level setting, study managers can choose when subject numbers are assigned, either when the subject is added or after screening.

Sponsors can now configure how subject numbers are assigned, choosing between assignment at the time of subject addition or after the completion of the Screening visit. This enhances alignment with operational requirements and strengthens control over subject data.

Before you work with this feature

No new permission or role is introduced along with this feature. However, as a user manager in your study, you must ensure that the sponsor user configuring this setting is assigned the *View Study Settings* and *Edit Study Settings* permissions.

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Details for study managers or other sponsor users

If you're a study manager or any other sponsor user who's in charge of configuring your study's settings, here's what's new for you:

- On the **Study Settings** tab, there's a new setting available called **Assign Subject Number**.

  > **Note**
  >
  > This setting is set to **When subject is added** by default.

  You can only set it to **When subject is screened** if your study has a Screening visit as the first visit in the study's schedule.
- The **Assign Subject Number** setting is only displayed if the setting **Allow Subjects to be Manually Added** is set to **Yes**.
- If the **Assign Subject Number** setting is set to **When subject is screened**, the **Allow Screen Fail before Screening** option - for the Screen Failed Subjects setting - is unavailable.
- The **Apply to All Modes** button is unavailable for use due to the setting's mode-specific nature. This means that you must configure the setting in each mode (Testing, Training, or Production) separately.
- The **Assign Subject Number** setting can be updated for a specific study mode when the study version and design at the site support it. However, if prerequisites aren't met, the setting cannot be changed.

  For example, if the study version associated with sites in Testing mode lacks a screening visit as the first scheduled and required visit in the schedule, you cannot switch from **When subject is added** to **When subject is screened**.

You can find additional information about this new setting in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for study designers

There's nothing new in your workflow. However, remember to always work with your study manager to ensure that you align the study's design with the way the **Assign Subject Number** setting is configured. If this setting must be set to **When subject is screened**, you need to include a required screening visit as the first visit in the schedule and follow specific requirements when designing forms.

You can find additional information about your design requirements for screening visits in the *Study Designer User Guide* after the RAE upgrade.

Details for site users

If subject number assignment during subject addition is enabled in your study, your workflow remains the same. The application assigns a subject number when you select **Add Subject** to add a new subject.

If subject number assignment is only allowed when screening has occurred, you'll first have to screen a subject before adding them to the study. Furthermore, you'll encounter the following User Interface (UI) and workflow changes:

- The **Add Subject** button label is updated to **Screen Candidate**.

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- Upon completing the Screening visit forms, you can select **Cancel** or **Submit**. Selecting **Submit** completes the screening process, assigns a new subject number, and adds the subject in the study with a *Screened* or *Screen Failed* status, as indicated by a new dialog that informs you of the screening state.
- If your study includes additional visits after the Screening visit, the new dialog displays a **Next Visit** button. You can click it to move to the next visit (if applicable). The **Return to All Subjects** button lets you return to the **Subjects** page.
- The **Manage Subjects** button isn't enabled until you complete the Screening visit and the subject is assigned a number in the application.

You can find additional information about this new feature in the *Site User Guide* after the RAE upgrade.

Impact on reports, archives, and Analytics datasets

> **Note**
>
> CRF Submit archives and Oracle Clinical One Analytics datasets include only subjects with assigned subject numbers, as expected, whether assigned at addition or after completing the Screening visit.

The following reporting changes are introduced for this new setting:

Report	Type of change	Description
Study Design report	New data point	The Study Settings section displays the name of the configured **Assign Subject Number** setting. It also displays the last update time, and the user who made the update.
Study Settings report	New column	The Study Settings tab now includes a new column: **Assign Subject Number**. The tab also displays the last update time, and the user who made the update.

You can find additional information about this new setting in the *Reporting Guide* after the RAE upgrade.

Impact on integrations

If your study includes integrations with Oracle Clinical One Analytics, Clinical One Digital Gateway, or Oracle DMW, no subject-specific data is sent to any of these downstream applications until a subject number is assigned.

If your study integrates with Oracle Central Coding and the **Code data for new and screen failed subjects** setting on the **Study Settings** tab is disabled, Oracle Central Coding data will not be sent until the subject is enrolled or randomized.

Already working in a live study?

You can update the new **Assign Subject Number** setting if the study version and design meet the prerequisites for the selected study mode (Testing, Training, Production). If the prerequisites aren't met, the setting cannot be changed.

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You can find additional information about these prerequisites in the *Sponsor and CRO User Guide* after the RAE upgrade.

Subject data can now be unverified

Sponsor users can now unverify data at the visit, form, and question level that may have been verified in error. This removes the need to manually track verification errors, ensures verification is conducted on the required visits, forms, and questions, and ultimately improves overall data quality.

Details for all users

At the visit level, the **Unverified** icon is no longer displayed. Instead, the Verification Required icon easily identifies visits with data requiring verification.

All questions with the status of **Unverified** and the related action are still displayed in the Answer History and Visit History sidebars, along with the user who performed them.

Details for sponsor users

As a Clinical Research Associate (CRA), you can now unverify data directly on a subject's visit page. This can be done at the visit, form, and question level.

To use this feature, you must have the permissions associated with verifying data assigned to your role.

To unverify data at the form and visit levels, the newly introduced **Unverify** option, accessible by selecting **Verify Visit Data** at the top, is only available if at least one question within the form or visit you are working on is verified.

- You can unverify visits whose data is partially verified.
- A reason for change is required for all actions of unverification.
- If you unverify a question in a visit that requires verification for that subject, the visit status is updated to **Verification Required** .
- If you unverify questions that do not require verification in a visit with a status of **Verified**, the visit retains its **Verified** status.
- If a question has been verified, but a change in study settings makes the question ineligible for verification, you can still unverify that question. For example, you can unverify a question with the status of **Verified** if SDV is turned off.

Impact on reports

As is the case with any other action that causes a visit, form, or question to become unverified, the new unverify feature is reflected in the following reports with no further changes:

- Subject Data report
- Subject Events Report

Integrations

- Oracle Siebel CTMS Subject Visit (SV) integration - improved error message
  Authentication error messages have been improved, providing a description that is easier to understand, clearer guidance for users, and more relevance to the encountered issue.

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- Clinical One Digital Gateway integrations support rescreen visits
  Integrations that process screening data now support the use of rescreening visits if configured in your Clinical One Cloud Service studies.
- Oracle DMW now includes full audit records for kits chain of custody and dispensation
  The coming version of Oracle DMW now includes full audit records coming from Clinical One Cloud Service, allowing you to replicate the kit chain of custody and kit dispensation reports.
- Shorter deprecation period for Clinical One Cloud Service Rest APIs
  The API deprecation period before complete removal from Clinical One Cloud Service is now reduced from 12-24 months to 6-12 months.

Oracle Siebel CTMS Subject Visit (SV) integration - improved error message

Authentication error messages have been improved, providing a description that is easier to understand, clearer guidance for users, and more relevance to the encountered issue.

For integration managers

Integration managers now see more descriptive error messages in both the User Interface (UI) and in email notifications when an authentication error is encountered. To learn more about the integration, see Oracle Siebel CTMS Subject Visit (SV).

Table 4-1 Authentication error details

Action resulting in error	Details
Authentication issues (401 error)	Previously, a nondescript error message was displayed in the Clinical One Digital Gateway user interface and was sent by email to configured users. **Previous error message**: Failure Message: Remote call failed with error: Integration Title: (integration title). Exception in TMMCS Subject Transporter: No content to map due to end-of-input at [Source: (String)""; line: 1, column: 0]null **New error message**: Failure Message: Remote call failed with error: Integration Title: (integration title). Exception in CTMS Subject Transporter: Error while performing an API call to CTMS system. Status code: 401|<>. Error occurred while connecting with the CTMS system. Please ensure you have the correct user credentials and target URL configured in the integration file.null Introduced to address enhancement request **36858344**.

Already working with this integration and a live study?

You do not need to take any actions. Going forward, the enhanced error message is used with all integrations, even those that are already active with a production study.

Clinical One Digital Gateway integrations support rescreen visits

Integrations that process screening data now support the use of rescreening visits if configured in your Clinical One Cloud Service studies.

Rescreen refers to the ability to screen subjects who initially did not meet protocol requirements but then qualified at a later date. For more information about this new feature, see Limit the number of times a subject can be rescreened.

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Supported inbound to Clinical One Cloud Service integrations

Integration	Details
Data Intake integration	This integration supports the import of data to a rescreen visit, provided that the visit is not locked. For existing integrations, a new mapping needs to be added to the **Visits** section in the integration template. ***Note**: If assistance is needed, reach out to your Oracle point of contact*.

Supported outbound from Clinical One Cloud Service integrations

Screening data is usually integrated after the completion of a screening visit, but now it can also be integrated following the completion of a rescreen visit. Once a rescreen visit is completed, Clinical One Cloud Service triggers either the screening event or the screen fail event, and the corresponding data is integrated into configured downstream systems.

Integration	Details
Oracle's Siebel CTMS Subject Visit (SV) integration	If the rescreen results in screening, the screening date and status are reflected in CTMS. If the rescreen results in a screen fail, the new screen fail date and reason are sent to CTMS. The screen fail date and reason for screen fail are overwritten if they were previously captured. ***Note**: Updates to the integration template are not required to support rescreen visits*.
CTMS Study Version Template (SVT) integration	For existing integrations, the *ReScreeningEvent* needs to be added to the **VisitType** codelist mappings in the SVT integration template, so that rescreening visits can be added to the CTMS system and marked as completed. `<Entry Source="ReScreeningEvent" Description="" Target="UnScheduleable"/>` For new studies, the newest version of the integration template should be used, as it includes this new mapping.
Oracle's Siebel CTMS Source Data Verification (SDV)	After source data verification (SDV) for a rescreening visit is complete, the data are integrated into the clinical trial management system (CTMS).

For a list of integrations that do not support this feature, see Release impact on downstream systems.

Additional information will be available in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Oracle DMW now includes full audit records for kits chain of custody and dispensation

The coming version of Oracle DMW now includes full audit records coming from Clinical One Cloud Service, allowing you to replicate the kit chain of custody and kit dispensation reports.

The Kit Chain of Custody report provides a row-by-row list of transactions that occur to each kit. For each kit, it provides details about where the kit started, what orders it was shipped in, when it was dispensed to a subject, and when it was returned and destroyed (if applicable).

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To support the full audit history for kits and Randomization and Trial Supply Management (RTSM) events, the following Data Hub views are included as a version with audits of existing integrated views that, instead of only containing the current status of subjects and kits, now contain their full audit history details:

- DHVW_SUBJECTS_AUDIT_V as a version with audits of DHVW_SUBJECTS_DATASET_V
- DHVW_RAND_KITS_AUDIT_V as a version with audits of DHVW_RAND_KITS_DESIGN_DATASET_V
- DHVW_UNBLD_KITS_AUDIT_V as a version with audits of DHVW_UNBLD_KITS_DATASET_V

As part of Clinical One Cloud Service 25.3, data provided by Clinical One Cloud Service in the integration with Oracle DMW includes the updates to the Data Hub views mentioned above. Users will be able to access this data in Oracle DMW once they upgrade to version 3.5.

You will find the dictionary for the new Oracle DMW version in the *Analytics User Guide* after Oracle DMW 3.5 is available.

Shorter deprecation period for Clinical One Cloud Service Rest APIs

The API deprecation period before complete removal from Clinical One Cloud Service is now reduced from 12-24 months to 6-12 months.

As new features are added to Clinical One Cloud Service, the APIs are enhanced to accommodate these additions, resulting in new API versions. As we add new API versions, existing versions become deprecated and subject to removal in future releases. All API versions, including deprecated ones, maintain backward compatibility. However, once an API version is removed from the product, you can no longer use it.

To avoid issues with your integration code, ensure you move to the newest supported version of an API (or an alternative supported API) as soon as possible, keeping in mind the new 6-to-12 months notice period. For each release, you can find the list of newly added, deprecated, and deleted APIs in the *Release Notes* dedicated section for *Rest API updates*.

Reporting, archives and analytics

- Enhancements to Oracle CRF Submit archives and reports

Enhancements to Oracle CRF Submit archives and reports

Study versions are now listed based on the study mode you're working in

The study versions presented to you under the **Study Versions—Select Versions** filter (on the Settings sidebar), when generating Blank Form PDF and Custom PDF archive requests, are now based on the mode you are working in.

Study versions with the status of Testing, Approved, or Archived can be selected when generating a request in Testing Mode, while only the Approved and Archived study versions are available in Production.

> **Note**
>
> Archived versions are those that were approved and then archived. Study versions that were moved from Testing directly to Archived are not included in Production.

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Archive file size is now displayed under Download Archives

Completed requests, available on the Download Archives sidebar, now include the size of the archive. For example, *Size: 1599 MB*. Such information can be useful when determining download and storage options for large archive requests. This information is especially helpful now that requests include uploaded files, such as images.

> **Note**
>
> The size of the file indicates the final size of the uncompressed (extracted) ZIP file. For failed requests, file size indicates the total zip size for the records that processed successfully.

Determine the forms and visits you want to include in a Custom PDF request

Use the new **Forms to Include** and **Visits to Include** filters, available on the Advanced Settings page, to determine which forms to include in a Custom PDF request.

You can select specific forms or choose one or more visits to include all forms associated with those visits.

Details for Archives users

- No new permissions are required to use the new filters.
- Selecting one filter disables the other.
- Form options are shown as Form Name (Reference Code), while visit options appear as Branch Name (Visit Name). If no branch exists, only the "Visit Name" is displayed.
- The options displayed under each filter are determined by the mode you're working in and the **As of Date** option you select.

Table 4-2 Mode and As of Date details

Mode & Date	Details
Mode	When you generate a Custom PDF archive in either Testing or Production mode, the options presented under each filter are based on the latest study version associated with your site for that specific mode.
As of Date	The latest study version is determined by the option selected. – When set to **Now**, the list of forms and visits corresponds to the most recent study version associated with your site. – When you select a specific date (using **Select Date/Time**), the list of forms and visits is based on the study version that was associated with your site on or before the date specified. For example, you are working in Testing mode and enter the As of Date of 04-June-2024. At that time, study version 1.1.0.8 was the last version associated with your testing site. In that case, the filters display the forms and visits from study version 1.1.0.8.

- If no data is present for a selected form, the subject PDF contains the following message. *There is no data present for this subject because either the subject add was undone or no data was found for the selection criteria in Request Settings.*

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> **Note**
>
> All forms associated with a study version are available. If you select a form that you do not have access to in the study, for example, due to data classification, the PDF for that form is blank, and the above message is displayed.

You can find additional information about these enhancements in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and Trial Supply Management

- Define dynamic resupply strategies
  Clinical supply managers can now define a resupply strategy to be dynamic, both when creating a Min/Max and Predictive resupply strategy.
- Support for compounding shipments
  Clinical One Cloud Service now supports the creation of compounding sites and the shipping of compounding kits, both manually and through an Clinical One Digital Gateway integration.
- New adaptive randomization schemas
  Clinical supply managers can now randomize at a stratum level using six new types of randomization for adaptive cohorts, ensuring a more balanced enrollment.
- Configure advanced dispensation for your study
  You can now create advanced dispensation definitions with different dispensation instructions and associated kit types for different groups of subjects.

Define dynamic resupply strategies

Clinical supply managers can now define a resupply strategy to be dynamic, both when creating a Min/Max and Predictive resupply strategy.

You can now configure a study's supply settings to dynamically resupply and dispense based on the number of active subjects at a site, without entering Oracle Clinical One Platform and manually changing the resupply settings for the site.

The resupply algorithm is enhanced to allow a more dynamic process when defining your study's resupply. This resupply approach:

- Considers subjects that have been either screened or randomized.
- Does not consider subjects assigned a current dose hold.
- Does not consider subjects that have skipped their most recent dispensation visit.
- Deducts from the resupply of subjects that are outside the window of a defined number of days.
- Ensures the site does not become overstocked.
- Minimizes the amount of time supplies require management.

Details for clinical supply managers

As a clinical supply manager, here's what's new for you when defining Min/Max and Predictive resupply strategies:

- The resupply strategy scope can be defined for sites and depots.

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> **Note**
>
> The default configuration is set to **Site**.

- You can choose to apply the predictive resupply rule to subjects once they have been screened or randomized.
- The **Subject Filtering Rules** setting allows you to exclude subjects from the predictive resupply rule that are on dose hold, have skipped their last dispensation visit, or fall outside of a specified dispensing visit window.
- You can now define and name up to 50 subject count ranges that are applied to different resupply strategies.
- Additionally, you are presented with the Initial Shipment page, where you specify kit types and quantities in one shipment that are sent before resupply begins.
- The Resupply Settings page allows you to set a buffer and manual shipment amount for each subject count range, letting you control the dynamic kit resupply.

> **Note**
>
> This must be defined for each subject count range. These settings can be defined individually for each range, or all together by selecting **Bulk Edit**.

- **Depot-to-depot shipments** can *only* be assigned a **Min/Max resupply strategy**.
- When defining a minimum and maximum buffer for a predictive resupply, on the Resupply Settings page, you must also specify:
  - **Trigger Weeks**: The number of weeks it takes for kits to be resupplied.
  - **Resupply Weeks**: The number of weeks when additional kits must be sent.

More information and step-by-step instructions can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Impact on reports

More information and specific descriptions on modified report values can be found in the *Reporting Guide* after the RAE upgrade completes.

Report	Type of change	Description
Projected Supply (Unblinded) report	New columns	The following columns have been added to this report: • **Group Name** • **Projected Subject Count**
Study Settings report	New and modified tabs	The **Resupply Group Configuration** tab has been added to this report. The following tabs have been updated in this report: • **Min/Max Resupply Strategy** • **Predictive Resupply Strategy**

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Report	Type of change	Description
Study Settings report	New filter	The **Min/Max Resupply Group Configuration** has been added to this report under **Include in this report** filters.

Already working in a live study?

If you're already working in a live study, consider the following notes that apply once this new feature is released:

- The automated resupply algorithm feature can be applied to existing studies.
- When configuring a resupply strategy, on the Resupply Scope page, the **Resupply Name** field has been updated to **Resupply Title**.
- Your previously defined resupply settings remain the same for existing studies.

Support for compounding shipments

Clinical One Cloud Service now supports the creation of compounding sites and the shipping of compounding kits, both manually and through an Clinical One Digital Gateway integration.

Before you work with this feature

As a user manager, be aware of the newly introduced permissions associated with this feature. You can assign these permissions to sponsor or site users depending on their responsibilities:

Permission	Details
Receive Compounding Shipments	Enables you to receive compounding shipments at the site you are associated with. User managers should assign this permission only when necessary. Can only be associated with custom roles. ***Note**: This permission only enables users to view compounding shipments. Visibility for regular shipments is not included with this permission.*
View Compounding Shipments to Sites	Enables you to view compounding shipments at the site you are associated with. Can only be associated with custom roles. User managers should assign this permission only when necessary.
Receive Notification of Compounding Sites	Enables you to receive a notification whenever a site administrator adds a compounding site. This permission is added to the following template roles: • Study Manager • Site Administrator • Clinical Supply Manager - Unblinded This permission can also be applied to any custom role.

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Permission	Details
Receive Notification of Compounding Shipments	Enables you to receive a notification once a compounding kit is shipped. This permission is added to the following template roles: • Clinical Supply Manager - Unblinded • Clinical Research Associate (CRA) • Pharmacy User - Unblinded • Site User • Unblinded Depot User This permission can also be applied to any custom role.

How it works

Compounding sites can be added to an Clinical One Cloud Service study either manually by study managers or automatically, using the Master User List (MUL) - Site Tenant Integration. Clinical supply managers or depot users then assign kits to the compounding sites. In turn, kits assigned to compounding sites are delivered through compounding shipments, either automatically via the SAP Shipment Request integration, or manually by the clinical supply manager. If your study is using the SAP Supply Management System Clinical One Digital Gateway integration, kits marked as compounding can be automatically sent to compounding sites.

Details for sponsor users

As a **clinical supply manager**, you can now configure the new **Select Shipping Address** setting in the study's **Supply Settings** tab, part of the Shipment Settings section. This setting defaults to the first shipment address. If it is set to Yes, a user with the appropriate permission, typically a **site administrator**, must select the shipping address on the **Kits** trainstop, in the **Sites & Labs** tab. Otherwise, the shipment will fail, whether it is a regular or a compounding shipment.

As a **site administrator**, you can designate sites as compounding sites. This means you can select the new Compounding Site checkbox as you configure a site's details on the **Address** trainstop, part of the **Sites & Labs** tab in a study's settings. This marks the site address as a compounding address.

When a compounding shipment is generated, the shipment is tagged as compounding. A user with permissions to receive compounding shipments is able to receive them at the compounding site. Once received, the kits are available for dispensation at the primary site.

You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for integration managers

> **Note**
>
> Sending compounding shipments to compounding sites through integrations is not mandatory. You can also send compounding shipments to compounding sites manually.

The following integrations are tied to this new feature:

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- SAP Shipment Request Integration: this integration processes shipment requests. Should the shipment be for a compounded kit, the SAP integration ships the kit to the compounding site.
- MUL - Site Tenant Integration: this integration can now distinguish between regular and compounding site addresses. As such, it can now create compounding sites as well.

You can find additional information in the *Digital Gateway User Guide* after the RAE upgrade.

Details for site users

As a site user at a compounding site, you can now receive kits for compounding, provided that a sponsor user has assigned the *Receive Compounding Shipments* and *Update Site Inventory* permission to your role.

Impact on reports and Analytics

The following reporting changes are introduced for this feature:

Report	Type of change	Description
Study settings report	New column	A new Select Shipping Address column is included on the Site Address tab.
Study design report	New data point	The Setting field in the Supply Settings section now displays details about the Select Shipping Address, if configured.
Unblinded Kits dataset	New data element	A new **COMPOUNDING_KITS** data element is now part of the Shipment folder. This new data element indicates whether a shipment was created as a compounding shipment, and can only accept a value of *Y* or *N*.

You can find additional information in the *Analytics User Guide* and the *Reporting Guide* after the RAE upgrade.

New adaptive randomization schemas

Clinical supply managers can now randomize at a stratum level using six new types of randomization for adaptive cohorts, ensuring a more balanced enrollment.

Details for study designers

As a study designer, when it comes to your workflow, here's what's new for you:

- In a study's draft, on the Create Randomization dialog, additional randomization options are available when you choose an adaptive cohort, letting you decide how the randomization is done at a stratum level:

Randomization type	Description
Central Stratified	Randomization balances at a global or central sequential level, from where the subjects are assigned to the next available stratum level.

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Randomization type	Description
Country Blocked Dynamic Stratified	Randomization balances at the country-level, from where a set number of blocks get filled based on the cohorts open and stratum limits met. Every country has at least one or multiple blocks bound to their country and the ability to configure the size of the block.
Country Blocked Fixed Stratified	Randomization balances at the country-level, from where the subjects are assigned to the next pre-allocated slot in each country-stratum block.
Site Blocked Dynamic Stratified	Randomization balances at each site level, from where a set number of blocks get filled based on the cohorts open and stratum limits met. Every country has at least one or multiple blocks bound to their site and the ability to configure the size of the block.
Region Blocked Fixed Stratified	Randomization balances at regional level, from where subjects are assigned to the next pre-allocated slot in the region-stratum block.
Site Blocked Dynamic Stratified	Randomization balances at site level, from where a set number of blocks get filled based on the cohorts open and stratum limits met. Every country has at least one or multiple blocks bound to their site and the ability to configure the size of the block. propagate

- When selecting an adaptive cohort method you will now be able to select a stratified randomization option.
- When uploading a randomization list, when mapping headers, there is a new option in the Mapped To column to map a specific header to **Stratum**.

Details for clinical supply managers and statisticians

- Users with the existing *Edit Study Settings* permission can determine the limit of strata allowed for each randomization scheme. In a study's setting, in the Enrollment Settings section, under the Cohort section, the new fields **Cap** and **Notification Percent %** are available for each Stratum Group you define.
- On the **Supply Settings** tab, you can enable or disable a stratum within a cohort, with all strata automatically disabled when the cohort itself is unchecked.
- You can enable or disable a stratum within a cohort, with all strata automatically disabled when the cohort itself is unchecked.
- You can update stratum caps for existing cohorts anytime during the study conduct period, without creating a new study version.
- The randomization lists now include two new columns: **Stratum** and **Cohort**.
- In the Generate Randomization List dialog, on the Select Randomization section, you can now choose **Number of Blocks** from the Length drop-down when using a stratified adaptive randomization design. Enter the block size you want for each treatment arm. The generated randomization list will create a separate list for each stratum, with balance maintained according to your chose strategy - central, regional, or site level, and dynamically or with fixed allocation.
- In the Upload the Randomization List dialog, on the **Map Headers** section, the **Stratum** and **Number of Blocks** fields are now available in the **Mapped To** drop-down. On the **Map Data Point** page, you must map both the cohort and stratum fields for the upload to succeed.
- When stratum limits in a cohort group reach the threshold defined in the study settings, a notification is sent.

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Impact on notifications

The **Randomization update notification** now includes information about the stratum limit within a cohort. It displays the percentage at which the notification was set and indicates when the limit of randomized subjects is reached. Once the limit is reached and subject assignment is no longer possible, a notification is sent to contact your Clinical Research Associate.

Impact on reports

Report	Type of change	Description
Study Settings Report, Cohort Limits by Cohort tab	New column	Now includes a Stratum Limit column next to each cohort. Shows "N/A" when displaying Cohort Limit details.
Study Design Report	New row	Now includes a new row about stratum limits, a new table about the Stratum Group design.
Subject Randomization Data Extract	New data points	Now includes details in the existing Stratum field.
Kits and Randomization Design dataset	New data element	The RANDOMIZATION_STRATEGY data element is now included in the Randomization folder. The following randomization types are available: • Central Stratified • Site Blocked Dynamic Stratified • Country Blocked Dynamic Stratified • Country Blocked Fixed Stratified • Region Blocked Dynamic Stratified • Region Blocked Fixed Stratified

More information can be found in the *Study Designer User Guide*, *Sponsor & CRO User Guide, Reporting Guide , Analytics User Guide* and *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade.

Configure advanced dispensation for your study

You can now create advanced dispensation definitions with different dispensation instructions and associated kit types for different groups of subjects.

When defining an advanced dispensation design, you can add as many groups as needed in your study. For each group, you specify the kit types and quantities to dispense to subjects within that group. You define a group by setting the criteria that subject must meet to be considered part of it. That criteria can come from a form question answer or from any other system variable, such as:

- Randomization date
- Screening date
- Current visit date

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- Cohort
- Treatment arm

For example, in a pediatric study you can configure different formulations of the investigational product (suspension, pills, and chewable tablets) based on the subject's age.

Details for study designers

If you want to start using the advanced dispensation feature, here's what's new for you, as a study designer:

> **Note**
>
> You still need to create the individual kit types to be used in the advanced dispensation. The process to create kit types, both simple and with calculated doses remains unchanged.

- In Draft mode, within the **Kits** tab in **Study Supplies**, there is a new button called **Create Advanced Dispensation**. Clicking it opens a dialog that guides you through the process of defining the advanced dispensation design.
- Within the advanced dispensation definition, you can add as many groups as needed. Each group constitutes a subset of subjects that meet specific criteria and that will have specific dispensation and dosing instructions. The group criteria can be set based on form question answers or other subject variables.
- You must define the criteria that qualify a subject for inclusion in each group. You can define as many criteria elements as needed, but you must define at least one.

> **Caution**
>
> When setting up the criteria for each group, you must consider the following:
>
> – If you add multiple criteria elements, all must be met for a subject to be included in the given group.
>
> – If a subject meets the criteria for multiple groups, then kits defined in all of those groups would be dispensed to the subject.
>
> – Consider all possible scenarios carefully to prevent assigning subjects to multiple groups that dispense the same kit. If dispensation of the same kit type is defined more than once in a visit for the same subject, dispensation will fail.

- For each group you must also define the specific kit types and quantity to be dispensed, as well as the dosing instructions that display to site users when dispensing to subjects in that group.
  You may select different kind of kit types, including Blinded, Unblinded, Unblinded Pharmacist kits and calculated doses, both serialized and non-serialized.
- After creating the advanced dispensation definition, you must add it to the required visits in the visit schedule. This step ensures its inclusion in the dispensation schedule of your study.

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> **⚠ Caution**
>
> - You must consider the defined criteria. If the advanced dispensation uses criteria that cannot be verified for a given visit, for example using the randomization date in the screening visit (prior randomization), dispensation will fail.
> - Avoid adding multiple dispensations of the same kit to a visit. This includes advanced dispensation, titration, and standalone kits. If dispensation of a same kit type is defined more than once in a visit, dispensation will fail.

You can find additional information in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for sponsor users

If your study begins using advanced dispensation, most of your workflows remain unchanged. However, there are a few things you must consider when it comes to partial dispensation and dose hold configuration:

- You define both partial dispensation and dose holds for the individual kit types, not for an entire advanced dispensation definition or for a group. This is because multiple kit types, in multiple combinations, can be defined for multiple groups.
- Partial dispensation is only possible when a visit requires dispensing multiple kits of the same type. This requires that you have at least one kit available of each kit type that is to be dispensed.

Details for site users

There are no changes in your workflow, as you should always dispense all of the kits indicated by the system.

Partial dispensation and dose holds are allowed in studies using advanced dispensation, with the same considerations as with standalone dispensation:

- Both partial dispensation and dose holds are defined for individual kit types and therefore must be performed on individual kit types.
- Partial dispensation is only possible when a visit requires dispensing multiple kits of the same type. This requires that you have at least one kit available of each kit type that is to be dispensed.

Impact on reports

The following reports have been updated to support advanced dispensation:

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Report	Type of change	Description
Study Design report	Modified tables	• The **Data Collection Design Summary** section, includes advanced dispensations in the **Kits Dispensed** column when associated with a given visit. • The main table in the **Kits** section includes details of the existing advanced dispensations. • The **Kit Dispensation** section includes details of the existing advanced dispensations when associated with a given visit.
Study Design report	New section	An **Advanced dispensation** section is added to this report, which includes the following information for each advanced dispensation definition: • Group name. • Group criteria for each group. • Kits to be dispensed for each group. • Dosing instructions for each group.
Kit dispensation report	New column	The **Dosing Instructions** column is added to display the dosing instructions for the group to which the subject belongs to, when using advanced dispensation.

You can find additional information and specific descriptions on modified report values in the *Reporting Guide* after the RAE upgrade.

Already working in a live study?

As soon as this release is available, you can start using advanced dispensation in your study. Create the advanced dispensation definition and update your dispensation schedule accordingly. To avoid dispensation failures, be careful not to add multiple dispensations of the same kit to the same visit. This considers kits in advanced dispensation, titration and standalone kits. You may need to remove the association between visits and existing kit types.

If you modify the dispensation schedule to use advanced dispensation in a live study, the updates will apply to all subjects for upcoming dispensations once the new study version with the updates is approved and assigned to the site. We highly recommend you properly test all possible dispensation scenarios in Testing mode.

Rules management

- New rule helper functions
  Rule designers can now retrieve dispensation information, visit windows and form submit dates, using the new rule helper functions available. These enable new Randomization and Trial Supply Management (RTSM) scenarios, as well as broader data collection use cases.

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New rule helper functions

Rule designers can now retrieve dispensation information, visit windows and form submit dates, using the new rule helper functions available. These enable new Randomization and Trial Supply Management (RTSM) scenarios, as well as broader data collection use cases.

New Visit Information variable

Before you work with new helper functions `getDispensationInfo()` and `getVisitWndw()`, you must become familiar with the new Visit Information variable. This is a new global variable that you can define to refer to a specific visit's information, instead of a specific form question. Using the Visit information variable with either of these two helper functions, allows you set the context of the rule to a specific visit, instead of using the visit from the rule target.

The `getDispensationInfo()` rule helper function

> ⚠ **Caution**
>
> This helper function may return unblinding information. Use the returned information carefully to preserve the study's blind.

The new `getDispensationInfo()` helper function supports the retrieval of dispensation details from different contexts:

- Last dispensation.
- All previous dispensations.
- Dispensation from a specific visit *(Requires using the Visit Information variable)*.

This new rule helper function is critical for titration studies, safety integrations, and advanced dispensation rules. For example, details of the last dose may be required to project the next kit type. In general, referencing detailed dispensation information with this helper function enables you to:

- Ensure protocol requirements are met by verifying dispensation transactions.
- Facilitate advanced strategies for dispensation, such as forced titration, by accessing last and all previous dose information.
- Provide necessary medication details for safety integrations.

The returned data is system-generated and recorded at the time of dispensation. This includes visit details, the kit type, kit description, dispensed date, dosage, quantity, and dose hold status. Additionally, rule designers can customize the returned output with optional parameters, as well as by specifying the context.

The `getVisitWndw()` rule helper function

The new `getVisitWndw()` helper function allows rule designers to evaluate visit scheduling windows and program other rules that require the visit window information. Key use cases include alerting site users when an unscheduled dispensation visit is needed or adjusting kit quantities when an unscheduled visit occurs. For example, if a subject is due for dispensation today and the next visit window is more than 21 days away, the site user should be notified that an unscheduled dispensation visit may be required before the next visit.

This rule helper function uses a parameter that allows you to specify which visit to reference. Rules can reference:

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- Current visit.
- Next visit.
- All previous visits.
- A specific visit *(Requires using the Visit Information variable)*.

The rule then returns the visit window for the specified visits, even if a visit was skipped. The returned data includes the visit's name, event instance number, scheduled visit date, window start and end dates, and whether the visit was skipped.

The `getFormSubmitDate()` rule helper function

With the new `getFormSubmitDate()` rule helper function, rule designers can now retrieve different dates associated with form updates. This new function uses a parameter that allows you to specify and retrieve the following:

- The date the form was started.
- The date the form was completed.
- The date the form was last updated.

These dates can then be used in your rule's logic for comparison with any other dates, such as dates captured by site users in the given forms and other system dates. For instance, to monitor site compliance when reporting adverse events, you can compare the form start date, when the form was initially submitted, with the date reported for a serious adverse event.

You can find additional information about these new rule helper functions in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

User experience

- Open Clinical One Cloud Service directly to the page you need
  Sponsor users can now create and share smart, context-aware hyperlinks that navigates other study team members directly to specific Clinical One Cloud Service pages.

Open Clinical One Cloud Service directly to the page you need

Sponsor users can now create and share smart, context-aware hyperlinks that navigates other study team members directly to specific Clinical One Cloud Service pages.

This reduces clicks and speeds up workflows, while still enforcing user authorization requirements: if a specific page is not available or you don't have access to it, you'll be redirected to the application's homepage.

Moreover, if you or another user accessing the direct links are already signed in, links open immediately; if not, you can sign in and be taken to the target page.

Details for creating direct links

Here's what's new for you if you need to create direct links to a study in Clinical One Cloud Service:

- The following Clinical One Cloud Service study pages can be accessed through direct links:
  - The **Subjects** page (also known as the Subject List page): open the URL to the Subjects page and see subjects for the specified study.
  - **General** tab in a study's settings: open the General settings tab and make adjustments for a specified study.

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- Both of these pages can be accessed in any mode: Testing, Training, and Production (Approved).
- To create a deep link, you need to copy the base URL from the application, replace the required parameters, and paste the modified URL where you need it: whether it's a browser window (for testing purposes) or embedded in a third-party application. The following path parameters are required for each deep link:
  - For the **Subjects** page, you must specify the Study ID (studyId) and study mode (mode).
  - For the **General** tab, you must specify the Study ID (studyId), study mode (mode), and whether the study would be available in Training study (isTraining);
- For example, here's how a URL pointing to a study's Subjects page would look like:

```
{BaseURL}?ojr=clinicalone/runtime&studyId={studyId}&mode={mode}
```

You can find additional information about this new feature in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Fixed issues

- All users
- Integrations
- Oracle Clinical One Analytics
- Facilities, settings, and user management
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data

All users

Not all kits are visible in the Add Shipment to Inventory dialog

Now, all kits are visible in the Add Shipment to Inventory dialog when receiving a shipment. Previously, some kits were not visible in the Damaged, Missing, or Review steps due to the dialog having a fixed height and no vertical scrollbar in the user interface (UI), resulting kits being hidden and inaccessible.

(Issue **38445550**)

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View in Form option is disabled

Now, in Production mode, when you access the Query Management list through the Queries icon, the **View in Form** option is available to select. Previously, when the Query Management list was accessed through the Queries Management list, the **View in Form** option was disabled.

(Issue **38447224**)

Integrations

Missing start time creates duplicate event processing in CTMS

Now, the system fetches only relevant data for the current specified time window specified in the integration payload for that specific integration run. Previously, because the start time was missing from the payload, data was fetched from Oracle Clinical One Platform to send to CTMS from an overly broad time range, which led to duplicate event processing and Bad Gateway Errors.

(Issue **37890401** and **38101163**)

Form fields create a status error in CTMS

Now, when integrating to CTMS, Informed Consent form date fields populate correctly. Previously, when an Informed Consent date was updated for a subject, the field would not integrate properly to CTMS and generated a system error message: `Status Date cannot be Null`.

> **Note**
>
> Applies only to integrations where the `ConvertDataUpdateToScreen` flag is set to true in the sub-integration template.

(Issue **37734776** and **37316545**)

The Clinical One Digital Gateway User Interface (UI) doesn't consistently render after login

Now, the Clinical One Digital Gateway consistently renders in the browser after entering valid login credentials when a study is undergoing maintenance. Previously, the home page loaded successfully for some users after logging in, but for others, the UI took longer than expected to load.

This issue only happened if a study was in maintenance mode. Performance for logging into Clinical One Digital Gateway went back to normal once the study maintenance period ended.

(Issue **38224043**)

Newly created study versions in CTMS lack previously recorded data

Now, newly added study versions are integrated properly. Previously, when a new study version was added in CTMS during an active integration job, the system implemented the study too soon, causing the study to start from the wrong time window and lack historical data.

(Issue **37384182**)

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Oracle Clinical One Analytics

Data Hub APIs retrieve data for the Data Collection dataset and code lists with delays

Now, Data Hub APIs take an adequate amount of time to respond for all Oracle Clinical One Analytics, including the Study Design dataset and code list data. Previously, users may have encountered delays in retrieving data, sometimes exceeding two (2) minutes.

(Issue **38602558**)

Columns are missing in Oracle Clinical One Analytics' Data Visualizer

Now, the **WITHDRAWAL_REASON**, **WITHDRAWAL_COMMENT**, **SCREEN_FAILURE_DATE**, and **SCREEN_FAILURE_COMMENT** are available in the Subject Dataset. Previously, these columns were missing in the dataset, preventing users from viewing or reporting on withdrawal and screen failure details.

(Issue **37578138**)

Facilities, settings, and user management

Screen Failed Subjects setting is marked as required

Now, the **Screen Failed Subjects** setting is options for sponsor users assigned the *Edit Study Settings* permission. Previously, a red asterisk (*) appeared next to the **Screen Failed Subjects** setting, indicating that it was a required field, although it is an optional field.

(Issue **37137040**)

Randomization and kits

Minimum expiry date displays incorrectly for automatic resupply shipments

Now, the Shipment Request File correctly includes the Minimum Expiry Date only for automatic resupply shipments. This date is calculated based on visit scheduling rules, using the highest Do-Not-Dispense (DND) value for the kit (for pooled kits, this is the current date plus the maximum DND). Manual shipments display Lot ID and Quantity, while resupply shipments display Minimum Expiry Date and Quantity as intended. Previously, the Shipment Request File defaulted the expiry date to the current day and occasionally populated it for other shipment types.

(Issue **38091110**)

Shipment Request File shows incorrect batch number data

Now, the batch number value for the Shipment Request File populates only for manual shipments, and remains blank (NULL) for automatic resupply shipments. Previously, the batch number value incorrectly populated for both manual and automatic resupply shipments.

(Issue **38038114**)

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Reports, archives, extracts, and notifications

User Assignment report generates successfully when Current Data is selected with default filters configured in the settings

Now, the User Assignment report generates successfully when **Current Data** is selected, regardless of the filter settings. Whether **Location** filter is set to **All** or filtered by a specific site, the report generates correctly, and users receive both the download and email notification that the report was successfully created.

(Issue **38584293**)

Email notifications are sent to unauthorized users

Now, notification emails are sent only to authorized users who have access to the specific site and study mode where the notification was triggered. Previously, the system considered user permissions across all study modes, which intermittently resulted in email notifications being sent to users who were not authorized for that site.

(Issue **37106839**)

The Subject Visit (Unblinded) report and Predictive Resupply report display incorrect projected kit counts

Now, the system correctly uses the most recent dispensation instance when projecting future kit needs, ensuring accurate projections for future visits. Previously, the Subject Visit (Unblinded) report was display an incorrect number of projected kits for future visits (Cycle 3 and beyond), while the Predictive Resupply report was also displaying an incorrect number of kits for future needs, due to the system incorrectly referencing the latest dispensation instance.

(Issue **38005388**)

Site users and subject data

Validation error occurs for Date/Time form items

Now, the system correctly validates Date/Time form items based on the site's defined time zone. Previously, the system considered the time zone set on the user's computer to validate Date/Time form entries, resulting in a validation error. If the time zone of the user's computer was set ahead of the site's time zone, a future date validation error would occur, even if the time was entered correctly.

(Issue **38377058**)

Code Break and Code View options are available for subjects prior to randomization

Now, the **Code Break** and **Code View** options are not available in the **Manage** drop-down before a subject has been randomized. Previously, these options appeared in the **Manage** drop-down for subject prior to randomization.

(Issue **38636049**)

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Release impact on downstream systems

This document describes the known impact and limitations that new features introduced in Clinical One Cloud Service 25.3 may have on downstream systems, specifically Oracle Clinical One Analytics and Clinical One Digital Gateway integrations.

For additional information about the features in this release and the potential impact on your studies, Download the Release Implementation Assessment document

Oracle Clinical One Analytics also known as Data Hub

Release feature	Analytics impact
Configure advanced dispensation for your study	This feature is not supported in Oracle Clinical One Analytics and will be implemented in a future release.
Support for compounding shipments	A new data element that helps differentiate shipments with compounding kits from shipments without compounding kits is now part of a Oracle Clinical One Analytics dataset.
Choose when subject numbers are assigned	When subject numbers are assigned upon screening, data related to subject numbers and subjects only flows to the applicable datasets as soon as a subject's screening forms are successfully submitted. This happens whether the subject fails or passes screening.
New adaptive randomization schemas	The new adaptive randomization feature is now reflected in Oracle Clinical One Analytics datasets.

Clinical One Digital Gateway configured integrations

Release feature	Impacted integration	Impact details
Subject data can now be unverified	CTMS Source Data Verification (SDV)	The ability to integrate unverified subject data is not supported.
Limit the number of times a subject can be rescreened	Multi-IWR Outbound subject data integration Oracle Clinical One Platform to Oracle InForm SAP Supply Management System—Actual Enrollment Integration ***Note**: For a list integrations that support this feature, see Clinical One Digital Gateway integrations support rescreen visits.*	**Multi-IWR** Does not support integrating data into rescreening visits and does not trigger any rescreen actions. Integrating rescreen data using the **Clinical One Cloud Service to Oracle InForm** integration and the **Outbound Subject Data integration** is not currently supported. Rescreen visits are not included in the extract for the **SAP Actual Enrollment Integration**.
Support for compounding shipments	Oracle Siebel CTMS Site Integration Supply Systems: Almac, Fisher, Catalent, SmartSupplies PMD, and Sharp ERP Shipment ***Note**: This feature is only supported by the Master User List (MUL) - Site Tenant Integration and the SAP Supply Management System integration.*	The Oracle Siebel CTMS Site integration cannot create compounding sites, and the following supply-management integrations cannot ship to them: Almac, Fisher, Catalent, SmartSupplies PMD, and Sharp ERP Shipment.

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Oracle Life Sciences Data Management Workbench (DMW)

Release feature	DMW impact
Configure advanced dispensation for your study	For the currently released versions of Clinical One Cloud Service and DMW, this feature introduces no changes to the data or records sent to DMW.
Support for compounding shipments	For the currently released versions of Clinical One Cloud Service and DMW, this feature introduces no changes to the data or records sent to DMW.
Choose when subject numbers are assigned	When subject numbers are assigned at screening, data flows to the applicable clinical and supplemental tables. This happens when the next DMW data load runs after a subject's screening forms are successfully submitted. This happens whether the subject passes or fails screening.
New adaptive randomization schemas	For the currently released versions of Clinical One Cloud Service and DMW, this feature introduces no changes to the data or records sent to DMW.

Rest API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.3.

Permissions

For this release, no new services or permissions have been added. Only existing services have been updated.

Services updates

The following services are updated:

- Data Capture
- Data Hub
- Data Integration
- Designer
- Designer ORS
- Randomization and Supplies
- Sites and Depots
- Users, Permissions and Roles

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Data Capture

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/subjects/screen • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/screenfaildates • POST /v10.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v10.0/studies/{studyId}/{mode}/subjects/{subjectId}/visitWindowInfo/{visitId} • POST /v17.0/studies/{studyId}/{mode}/visitstatus/subjects • GET /v2.0/studies/{studyId}/{mode}/subjects/{subjectId}/nextVisitAction • POST /v6.0/studies/{studyId}/{mode}/subjects/randomizeordispense • PUT /v6.0/studies/{studyId}/{mode}/subjects/{subjectId} • POST /v7.0/studies/{studyId}/{mode}/repeatSection/consolidatedRepeatInstanceNumbers

Data Hub

Change	Endpoint
New	• GET /v11.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v11.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v5.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v6.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits

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Change	Endpoint
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v1.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v1.0/studies/{studyId}/{mode}/odm/metadata • POST /v1.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v1.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • GET /v2.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v2.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v2.0/studies/{studyId}/{mode}/odm/metadata • POST /v2.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v2.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v3.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v3.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v3.0/studies/{studyId}/{mode}/odm/metadata • POST /v3.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v3.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • POST /v3.1/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • GET /v4.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v4.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v4.0/studies/{studyId}/{mode}/odm/metadata • POST /v4.0/tenant/{tenantId}/studies/{studyId}/dataCollection

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Change	Endpoint
	• POST /v4.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v5.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v5.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v5.0/studies/{studyId}/{mode}/odm/metadata • POST /v5.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v6.0/studies/{studyId}/{mode}/odm/metadata • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v8.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v8.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms

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Change	Endpoint
	• POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • GET /v9.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v9.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v2.0/studies/{studyId}/{mode}/dataelements • PUT /v2.0/studies/{studyId}/{mode}/subject/{subjectId}/formStatus • POST /v2.0/studies/{studyId}/{mode}/visitstatus/subjects • GET /v4.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v5.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Designer

Change	Endpoint
New	• POST /v10.0/studies/{studyId}/design • GET /v10.0/studies/{studyId}/versions/{version}/design • GET /v8.0/studies/{studyId}/statuses • GET /v8.0/studies/{studyId}/statuses/{version}

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Change	Endpoint
Deprecated	• PUT /v1.0/studies/{studyId}/versions/{version}/dispensings • POST /v10.0/studies/{studyId}/versions/{version}/forms • GET /v10.0/studies/{studyId}/versions/{version}/forms • GET /v10.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v10.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v10.0/studies/{studyId}/versions/{version}/forms/{formId} • POST /v11.0/studies/{studyId}/versions/{version}/forms • GET /v11.0/studies/{studyId}/versions/{version}/forms • GET /v11.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v11.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v11.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v11.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v11.0/studies/{studyId}/versions/{version}/forms/{formId} • POST /v12.0/studies/{studyId}/versions/{version}/forms • GET /v12.0/studies/{studyId}/versions/{version}/forms • GET /v12.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v12.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v12.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v12.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v12.0/studies/{studyId}/versions/{version}/forms/{formId} • POST /v14.0/studies/{studyId}/versions/{version}/forms • GET /v14.0/studies/{studyId}/versions/{version}/forms • GET /v14.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v14.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v14.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v14.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v14.0/studies/{studyId}/versions/{version}/forms/{formId} • POST /v15.0/studies/{studyId}/versions/{version}/forms • GET /v15.0/studies/{studyId}/versions/{version}/forms • GET /v15.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v15.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v15.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v15.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v15.0/studies/{studyId}/versions/{version}/forms/{formId} • GET /v16.0/studies/{studyId}/versions/{version}/forms/{formId} • POST /v17.0/studies/{studyId}/versions/{version}/forms • GET /v17.0/studies/{studyId}/versions/{version}/forms • GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v17.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v17.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v17.0/studies/{studyId}/versions/{version}/forms/{formId}

Designer ORS

> **Note**
>
> Designer ORS endpoints are listed in the Designer category.

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Change	Endpoint
New	• GET /v10.0/studies/{studyId}/versions/{version}/visits/{visitId}/kits/blindedInfo • GET /v10.0/studies/{studyId}/versions/{version}/visits/{visitid}/dispensings • GET /v13.0/studies/{studyId}/versions/{version}/forms/randomizationfactors • GET /v3.0/studies/{studyId}/randomizationfactors • POST /v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata/bulk • PUT /v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata/bulk • DELETE /v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata/bulk • GET /v4.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata • GET /v4.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata/{stratumId} • POST /v6.0/studies/{studyId}/versions/{version}/randomizations • PUT /v6.0/studies/{studyId}/versions/{version}/randomizations/{randomId} • GET /v7.0/studies/{studyId}/versions/{version}/dispensings • PUT /v7.0/studies/{studyId}/versions/{version}/dispensings

Randomization and Supplies

Change	Endpoint
New	• GET/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/visits/{visitId} • GET/v10.0/studies/{studyId}/{mode}/orders • GET/v10.0/studies/{studyId}/{mode}/orders/{shipmentId} • PUT/v10.0/studies/{studyId}/{mode}/supply/settings • GET /v11.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • GET /v17.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v2.0/studies/{studyId}/{mode}/settings/cohortlimits • PUT /v2.0/studies/{studyId}/{mode}/settings/cohortlimits • POST /v3.0/studies/{studyId}/{mode}/reports/projectedsupplies/countrycounts • POST /v3.0/studies/{studyId}/{mode}/reports/projectedsupplies/sitecounts • POST /v3.0/studies/{studyId}/{mode}/resupplies • GET /v3.0/studies/{studyId}/{mode}/resupplies • GET /v3.0/studies/{studyId}/{mode}/resupplies/{resupplyId} • PUT /v3.0/studies/{studyId}/{mode}/resupplies/{resupplyId} • GET /v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/allowed-doseholds • POST /v4.0/studies/{studyId}/{mode}/subjects/{subjectId}/reuse-kits • GET /v7.0/studies/{studyId}/{mode}/randlists • GET /v8.0/studies/{studyId}/{mode}/shipments

Sites and Depots

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/id/{sdfId}

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Users, Permissions and Roles

Change	Endpoint
New	• GET /v5.0/authusers/{userid}/studies/{studyId}
Deprecated	• GET /v1.0/authusers • GET /v1.0/authusers/{userid} • GET /v1.0/dataclassification • GET /v1.0/dataclassification/studyrole/{studyRoleId} • GET /v1.0/dataclassification/{studyId} • GET /v1.0/dataclassification/{studyId}/studyrole/{studyRoleId} • GET /v1.0/dataclassification/{studyId}/{mode}/user/{userId} • GET /v1.0/studyroles • GET /v1.0/studyroles/{studyId} • GET /v2.0/authroles • GET /v2.0/authroles/{studyId} • GET /v2.0/studyroles • GET /v2.0/studyroles/{studyId} • GET /v3.0/authstudies/{studyId}/users • GET /v3.0/authusers/{userid}/studies/{studyId} • GET /v3.0/globalroles/users

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5

Clinical One Cloud Service and Clinical One Digital Gateway 25.2

- Patch log
  This page briefly describes the history of fixed issues and new functionality applied on top of the 25.2 release.
- What's new
- Fixed issues
- Fixed issues in 25.2.1.5
- Release impact on other applications
  This document describes the known impact and limitations that new features and enhancements introduced in Clinical One Cloud Service 25.2 may have on downstream applications.
- Rest API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.2.

Patch log

This page briefly describes the history of fixed issues and new functionality applied on top of the 25.2 release.

Release number	Release date	Notes
25.2.1.5	24 November 2025	For this release, we fixed several issues. For more information see the following: • Issues **37816125** and **38198217** in Facilities, settings, and user management • Issues **38504328**, **37246186**, **38540346**, **38553728**, **38198138**, **38528093**, **36122564**, and **38552905** in Forms, visits, and rules • Issues **38461830** and **38353201** in Integrations • Issue **38478524** in Randomization and kits • Issue **38193558** in Reports, archives, extracts, and notifications • Issue **36230101** in Site users and subject data

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Release number	Release date	Notes
25.2.1.4	29 October 2025	For this release, we fixed several issues. For more information, see the following: • Issues **38285107** and **38511005** in Reports, archives, extracts, and notifications • Issues **38489911**, **38515304**, **38469837**, **38055482**, and **38359126** in Oracle Clinical One Analytics • Issue **37507918** in Site users and subject data • Issues **37700629** and **38371717** in Forms, visits, and rules • Issue **38430197** in Facilities, settings, and user management
25.2.1.3	29 September 2025	For this release, we fixed an issue related to branching. For more information, see issue **38437568** in Forms, visits, and rules.
25.2.1.2	25-September-2025	For this release, we fixed several issues. For more information, see the following issues: • Issues **37999017**, **38331231**, and **38274625** in Oracle Clinical One Analytics. • Issues **38284857**, **38315906**, and **38330398** in Integrations • Issue **38336630** in Facilities, settings, and user management • Issue **37669804** in Forms, visits, and rules • Issues **38245796** in Reports, archives, extracts, and notifications • Issues **38198276**, **38255228**, **38316955**, **37669804** in Site users and subject data
25.2.1.1	16 September 2025	For this release, we fixed an issue related to the Subject Data Extract. For more information, see issue **38372054** in Reports, archives, extracts, and notifications.

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Release number	Release date	Notes
25.2.1	29 August 2025	For this release, we introduced new enhancements in the What's new section. For more details, see: • Lock and unlock multiple subjects simultaneously • Update multiple study users simultaneously • Randomization replacement • Include a form preview in the Annotated Case Report Forms report • New datasets to track sign, verify, freeze, and lock actions • New data element to track visit, form, and item level locks • Enhancements to Oracle Clinical One Analytics datasets • Enhancements to Oracle DMW clinical data extracts • File-based integrations now support file name format changes (enhancement **37810447**) • A fresh new Redwood look • For REST API updates, see Rest API patch updates. • For more information on downstream impact, see Patch set release impact for other applications. For a detailed list of fixed issues, look for the following issues in the Fixed issues section: • Issue **37259277** in All users • Issues **38120683**, **38278228**, **38219969**, and **38239994** in Oracle Clinical One Analytics • Issues **37331039** and **36212384** in Facilities, settings, and user management • Issues **38267486**, **36465916**, **38209696**, and **36496392** in Forms, visits, and rules • Issue **37010117**, **38278228**, **38120683**, and **37566193** in Integrations • Issues **36343281** and **38272631** in Reports, archives, extracts, and notifications • Issues **36400347**, **38209696**, **36505556**,**37845829**,

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Release number	Release date	Notes
		38193545 in Site users and subject data
25.2.0.3	19-August-2025	For this release, we fixed issues related to the visit schedule. For more information, see issue **38260677** in Site users and subject data.
25.2.0.2	13-August-2025	For this release, we fixed issues related to visits and data collection. For more information, see the following issues: • Issues **37110046**, **38247383**, and **38235953** in Site users and subject data. • Issue **38259231** in Integrations. • Issue **38288851** in Reports, archives, extracts, and notifications.
25.2.0.1	31-July-2025	For this release, we fixed issues related to randomization, integrations, and more. For more information, see the following: • **38166723** in Facilities, settings, and user management • **38172469** in Integrations • **37914482** in Site users and subject data

What's new

- Data Collection
- Integrations
- Reporting, archives and analytics
- Randomization and Trial Supply Management
- Rules management
- User experience
- Data collection
- Data review
- Integrations
- Notifications
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management
- Study design

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- User experience
- User management
- Study design
- Data collection
- Randomization and trial supply management
- Integrations
- Reporting, archives, and analytics
- Notifications
- Other enhancements

Data collection

- Lock and unlock multiple subjects simultaneously
  Sponsor users can lock and unlock multiple subjects at the same time to safeguard data integrity and prevent unintended changes, ensuring studies stay on track.
- Upload and store any documents for your study
  Study designers can now include questions in forms that let other users upload relevant clinical documents during the study conduct period.
- Restore and view deleted forms
  Site users can restore deleted rows of a repeating form, or the repeating section of a two-section form, as well as instances of two-section forms, and lab forms. Sponsor users can also view deleted form records.

Lock and unlock multiple subjects simultaneously

Sponsor users can lock and unlock multiple subjects at the same time to safeguard data integrity and prevent unintended changes, ensuring studies stay on track.

This feature offers the following benefits:

- Enables sponsors to simultaneously lock multiple subjects - either all subjects or a subset of subjects within a site or across all sites - saving time and effort as key study milestones approach.
- Reduces manual effort by eliminating the need to lock subjects one at a time, allowing users to focus on other critical tasks.
- Facilitates faster data readiness for interim and final analyses by accelerating the subject lock process.
- Ensures subject data is finalized and no further changes are allowed, supporting both interim and final locks with greater ease.

Before working with this feature

No new permission or role is introduced along with this feature. However, as a user manager in your study, you must ensure that the appropriate sponsor users are assigned with the existing *Lock subject data entered at a site* permission.

Sponsor users who are not assigned this permission will not see the new and won't be able to switch between this view and the new .

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Details for sponsor users

If you're a sponsor user responsible for locking subjects in a study, here's what you need to know:

- On the Subjects page, you can now switch between two different views: the and the .
  - On the , you get to see all subjects at a site, as well as their visit schedule. You can continue filtering subjects and adding new subjects.
  - On the , you can now lock and unlock multiple subjects or multiple visits for the same subject.
- On the you can filter subjects by country, site, and status, as well as use the following new filters: **All Visits Complete**, **Queries**, **Verification**, **Signature**, and **Locked**. Moreover, you can sort subjects on their displayed columns.
- On the you can continue filtering subjects by country, site, status, review, and safety case status.
- On the , you can select multiple subjects then lock or unlock them in bulk. To do so, you can filter them appropriately or search for their subject numbers, select all of them, and then select **Lock** or **Unlock** from the **Manage** drop-down.
- While subjects or visits are being locked, you can still manage other subjects and their data.

Other user experience updates

Other new design changes are introduced with this release that may impact your workflows. Here's what else may be new for you in the User Interface (UI):

- You can now perform all query management activities on the new **Queries** page, located in the top menu bar. It opens the same page as the previous **Query List** button.
- On the , the **Add Subject** button is now located in the top-right corner of the page.
- The **Manage Subject** button is now called and remains located along the top of the Subjects page, on the .
- Upon selecting a subject, you no longer see the following options on the drop-down, since those actions are now available on the only: **Lock a Subject** or **Unlock a Subject**.
- On the Subjects page, using the , you can see the number of subjects at a specific site and continue managing subjects the way you used to. Your options to filter through subjects remain the same.
- On the , only visits that have been started, skipped, or that occurred before a started visit are shown. This may include visits marked as **Not Started**, except for those at the end of the visit schedule, when a Data Intake integration needs to send data into a later scheduled visit. Adverse events are still displayed in the same column.
- Filters set on the and the are not shared, but each view will remember its own filters when you return to it.

You can find additional information about this new feature in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Upload and store any documents for your study

Study designers can now include questions in forms that let other users upload relevant clinical documents during the study conduct period.

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Uploading and storing documents at the subject level is important for studies that require visual evidence, such as tracking the healing of a wound. By allowing you to upload documents, you can collect, analyze, and review more data, creating a complete picture of each subject. With this new feature, you can now preserve these documents that contain important details, typically harder to collect in structured formats, such as in a form.

Before you work with this feature

No new permission or role is introduced along with this feature. However, as a user manager in your study, you must ensure that the site staff and other sponsor users fulfill the following conditions:

- They're assigned with the following permissions, as applicable: *View Form Data for Subjects*, *Edit Form Data for Subjects*, *View Classified Subject Data Only*, and *Edit Classified Subject Data Only*. Note that users don't require all of these permissions, but rather the specific ones that align with their intended responsibilities. These permissions let them view forms and upload documents at sites that they're assigned to, including documents that are data classified, as relevant to their role. For more information, see Clinical Data Collection permissions.
- If documents can only be uploaded as classified data, then you should make sure users are assigned with the appropriate data classification permissions to view and manage classified documents. For more information, see Specify data classifications for a study role.

Details for study designers

As a study designer, here's what's new in your workflow, if you want to allow other users to upload documents to forms:

- On the Forms tab, within a form, when you select Add Question, you can now see the **File Upload** option.
- Upon selecting File Upload, you can fill-in this item's details just as you would for any other type of question. For example, you can specify a title for the File Upload question, specify a question hint, determine whether you want the item to be required hidden, or optional, and many more.
- You can also classify a File Upload question. Upon turning on the **Hidden** toggle, you can select a type of data classification to apply to the File Upload question.
- You can configure a File Upload question as read-only, but we don't recommend doing so. Configure a File Upload question as editable, since a read-only question does not allow any user to upload a document. If you need to apply any restrictions on the File Upload question, use data classifications to ensure that only certain users can upload documents.
- You can include a File Upload question in any kind of form, except for a Drug Reconciliation form. Also, you can include it in a question group.
- When it comes to predefined rules, the only rule you can configure for a File Upload question is the Auto-lock rule.
- You cannot configure a File Upload question as a coding question or specify Electronic Health Records (EHR) mappings for this type of question.

Details for site users and other sponsor users

As a site user, you may have to upload documents in your forms. As a sponsor user, you may be able to upload documents for classified questions, as well.

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- If your study allows it, you can upload documents in subject forms. Where a File Upload question is included, you see it represented by an **Upload** button and a distinctive instruction on what you can upload.
- If you cannot upload a file or don't have a file to upload, you can always mark a File Upload question with a data flag, as Not Done, Not Applicable, or Unknown.
- You can only upload a single file for each item in your form. For example, for an item labeled as "Upload supporting file of wound", you can only upload a single supporting file of the wound, not multiple.
- During the upload of the document, you can view the file's upload progress. You can cancel the upload or refresh your browser's page. If you cancel the upload of a file or you refresh your browser's page during upload, this failed upload attempt is not included in the application's audit trail. In other words, the application won't document this failed upload attempt anywhere in the User Interface (UI) or in reports.
- When your file upload fails for technical reasons, the specific failure reason is listed in the UI.
- You cannot modify subjects or forms while a file is uploaded.
- Once you successfully upload a file, you can preview it from the form and you can delete the file. When you successfully upload a file in the form, this is saved in the application's audit trail, and you can see details of the upload action on the Answer & Visit History sidebar.
- Upon deleting a file, you must specify a reason for this change. When you delete it, the file is not removed from the server's storage, it's just removed from the application. Any mention of a removed file is also cleared from the application. The only record of that file can be viewed on the audit trail in the Answer & Visit History, and any applicable reports.
- With the appropriate permission, you can sign, verify, freeze, lock, or raise a query against a File Upload question. If a new version of a document is re-uploaded, then the item or form associated with that document becomes unverified and unsigned.
- When a File Upload question is frozen or locked, you cannot upload or re-upload the file for that item.

Impact on custom JavaScript rules

If you're a rule designer, keep in mind that a File Upload question can be used as a query target and added as a rule variable, but it's not a valid target for calculation rules. The rule variable will store the question's identifier, which is populated when a document is uploaded; otherwise, it will be null.

Impact on reports and archives

The following reporting changes are introduced for this new feature:

> **Note**
>
> Want to learn more about the detailed impact and limitations on CRF Submit archives and reports? Check Oracle CRF Submit Archives requests include uploaded documents!

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Report	Type of change	Description
Annotated Case Report Form	New type of question included in the report	When a File Upload question is included in the study's design, a new row is included in the report with all of the design-related details of this question type.
Rules report	New type of question included in the report	When a custom JavaScript rule references a File Upload question, its question label is displayed on the **Target Question** column.
Subject Data Extract	New type of question included in the report	When a File Upload question is included in a study, the following columns display data related to the question's label: • **QUESTION LABEL**: displays the File Upload question name. • **QUESTIONLABEL_R**: displays the decoded raw value of the uploaded file's name. • **QUESTIONLABEL_F**: displays the formatted value of the uploaded file's name. • **QUESTIONLABEL_D**: displays the raw alphanumeric value of the uploaded file's name.
Subject Data report	New type of question included in the report	Whenever a File Upload question is included in a study, modified, or removed, its data is displayed on a new row for the following columns: Date & Time, Question Label, Type of change, and Value.
Subject Queries report	New row in report	When a query is raised against a File Upload question, data associated with this query is displayed across the applicable columns in this report. The name of the file is displayed on the **Value** column.
Study Design report	New type of question included in the report	When a File Upload question is included in the study's design, a new row is included in the report with all of the design-related details of this question type in the **Forms** section.
Study Design dataset	Modified data element description	When a File Upload question is included in a study's design, its label is displayed for the **ITEM_NAME** data element.

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Report	Type of change	Description
Subject Form Items dataset	Modified data element descriptions	When a File Upload question is included in a study, the following data elements display data related to the question's label: • **ITEM_NAME**: displays the File Upload question name • **ITEM_TYPE**: displays File Upload. • **ITEM_D**: displays the decoded raw value of the uploaded file name. • **ITEM_F**: displays the formatted value of the uploaded file's name. • **ITEM_R**: displays the raw alphanumeric value of the uploaded file's name.
ODM-XML extract	Modified field description	In the Clinical data extract, the uploaded file's name is displayed in the Value field.

Restore and view deleted forms

Site users can restore deleted rows of a repeating form, or the repeating section of a two-section form, as well as instances of two-section forms, and lab forms. Sponsor users can also view deleted form records.

This feature offers the following benefits:

- Ensures the transparency and auditability of data changes in repeating and two-section form records.
- Reduces the risk of data loss and errors by allowing users to view and verify deleted data that has undergone Source Data Verification (SDV) or signing.
- Enhances data integrity and compliance, increasing the visibility of deleted forms and their audit history to support data cleaning.

Before you work with this feature

To delete and restore forms as a site user, you only need to be assigned the existing permissions: *View Sites*, *View Form Data for Subjects*, and *Edit Data for Subjects*. No new permission is introduced for this enhancement.

As a sponsor user, you can view the deleted or restored forms if you're assigned the *View Sites* and *View Form Data for Subjects* permissions.

Details for sponsor users

Whether you're a CRA, a data manager, or any other type of sponsor users, here's what's new in your workflow:

- When a site user deletes a repeating form record, you can now see the new **Deleted Forms** link next to the repeating form's title. When they delete a two-section form instance, you can see the new **Deleted History** link next to the two-section form's title. Selecting either one of these links takes you to a new page where you can view all deleted repeating form rows or two-section form instances.

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- You can view more details about a deleted form record by expanding the Answer & Visit History sidebar while that form record is still deleted. After a repeating form row or a two-section form instance is restored, the Answer & Visit History sidebar displays a **Form Restored** action, along with the reason specified for restoring the form, the date of the action, and the user who performed it.
- You can only sign, verify, freeze, lock, or raise queries against restore deleted form records.

Details for site users

If you're a site user, here's what's new for you:

- Upon deleting a repeating form row, a **Deleted Forms** link appears next to the repeating form's title. Upon deleting a two-section form instance, a **Deleted History** link appears next to the form's title. Selecting either one of these links takes you to a new page where you can view all deleted repeating form rows or two-section form instances.
- Deleted repeating form rows are displayed in a consolidated table on the Deleted Forms page. In that table, you can select restore a single repeating form row by selecting the **Restore** button on the **Action** column or select multiple rows to restore by clicking **Restore All Selected**.
- To better determine which repeating form row to restore, you can also select the row number in the table. This opens the deleted repeating form in a new dialog. In there, you can look at the questions in more detail and browse the Answer & Visit History sidebar.
- Deleted two-section form instances are also displayed one under the other on the Deleted History page. Each instance is numbered - that way, you have a better way of identifying which instances you may want to restore. Similar to deleted repeating form rows, you can select the checkbox next to one two-section form instance to restore it or you can select multiple instances to restore them all at once.
- Upon choosing to restore a deleted repeating form row or a deleted two-section form instance, a new dialog is displayed. On this new dialog, you're being informed of what form rows or instances you're about to restore, that you may have to create new links between this restored form and other forms or questions in your study (if needed), and you have to specify a reason for this change.
- Upon restoring a form (whether a repeating row or a two-section instance), you can return to the associated visit to view the newly restored form.
- After a repeating form row or a two-section form instance is restored, the Answer & Visit History sidebar displays a **Form Restored** action, along with the reason specified for restoring the form, the date of the action, and the user who performed it.
- When it comes to a deleted two-section form instance, you can only restore the entire instance, not parts of the form. For example, you cannot restore just the introductory questions in the Questions Before the Table section, you have to restore all questions included in a deleted two-section form instance.
- You cannot modify deleted form records in anyway (whether it is to raise queries clear data). You can only view or restore them. You can only update form records after you restore them.
- When you delete and restore a lab form instance, lab normal ranges are calculated again as if the lab data is newly entered. Any updates to the normal range values are displayed on the Answer & Visit History sidebar. When you look at a deleted lab form instance, the normal ranges that were applied at the point of removal will be shown.

For more information, see the *Site User Guide* and the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade is complete.

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Impact on integrations

If your study is integrated with any of the following applications, here's what you may need to know:

- For any integrations with Oracle DMW, data on deleted form records continues to be displayed in the DELETED column. When a form record is restored, the flag changes from Y to N.
- When it comes to integrations with Oracle Central Coding, if a site user deletes a coded form row, the coding results remain, and the related data is sent to Oracle Central Coding, preserving the verbatim terms and context values. When a site user restored the deleted form record, Clinical One Cloud Service clears the coding target fields. After that, Oracle Central Coding follows the normal coding process to return the coding value, as usual.
- For integrations with Clinical One Digital Gateway and Oracle CRF Submit, restored data flows as usual.

Impact on reports

> **Note**
>
> When you restore a deleted form, its data is displayed in all applicable reports again, including the Subject Data Extract.

The following reporting changes are also introduced for this new enhancement:

Report or dataset	Type of change	Description
Subject Data report	Modified data description	Whenever a form is restored, the new **RESTORED** status is displayed on the **Type of Change** column. Moreover, data related to the restored form is displayed in all other applicable columns in the report.
Subject Forms dataset	Modified data element	Whenever a form is restored in Clinical One Cloud Service, the **FORM_RESTORED** status is displayed for the **FORM_STATUS** data element. data element.
Subject Form Items dataset	Modified data element	Whenever a form is restored in Clinical One Cloud Service, the **FORM_RESTORED** status is displayed for the **FORM_STATUS** data element.
Queries dataset	Modified data element	Whenever a form is restored in Clinical One Cloud Service, the **FORM_RESTORED** status is displayed for the **FORM_STATUS** data element.

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Report or dataset	Type of change	Description
All applicable CRF Submit archives and reports	Modified content	CRF Submit still shows deleted records in the table with DELETED next to the row number. In Form View, the header displays the following message: THIS REPEATING FORM HAS BEEN DELETED. When a form is restored, in the Audit History section, the status **Form Restored** is displayed, DELETED is removed from the row number, and the deleted header is removed from Form View.

Already working in a live study?

Once this feature is released, any repeating form rows or two-section form instances that were previously deleted will become available for you to review and restore.

A deleted repeating form that was verified or signed before the release of this feature can be viewed on the new Deleted Forms or Deleted History page. The deleted or restored form records are displayed as never having been verified or signed, and they will remain this way until you sign or verify them again.

Data review

- Manage manual query closure by role
  You can now manage queries based on user role and permissions with newly introduced permissions in Clinical One Cloud Service.

Manage manual query closure by role

You can now manage queries based on user role and permissions with newly introduced permissions in Clinical One Cloud Service.

Details for sponsor users

When it comes to managing query closure and related permissions, here's what's new for you as a sponsor user:

Permission	Description
Close All Queries	This permission is formerly known as the *Close Queries* permission. Users assigned this permission have the ability to close all queries they can view.
Close Auto Queries	Users assigned this permission can close automated queries they have permission to view.
Close Queries by Role	Users assigned this permission are able to close manual queries that were opened by users with the same assigned role when the query was opened.

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Permission	Description
Close Central Coding Queries	Sponsor users assigned this permission can close orphaned queries from Oracle Central Coding. ***Note**: This permission and workflow allows sponsor users to close these queries manually when necessary. It is recommended that sponsor users follow Oracle Central Coding workflows to manage queries in all other situations.*
Answer Assigned Queries	Only users assigned this permission are available for selection to answer an assigned query. ***Note**: Only users assigned the **Answer Assigned Queries** and **View All Queries** permissions are able to see the query. Previously, users who did not have the **Answer Assigned Queries** permission were able to be assigned to the query and view it.*

More details on these permissions can be found in the *Add Users Guide* after the Release Assessment Environment (RAE) upgrade completes.

Impact on reports

The **User Assignment** report and **User Assignment by Site** report now include details on when a user is assigned these new permissions if **Include Permissions** is selected at the time either report is generated.

For more information, see the *Reporting Guide*.

Integrations

- File-based integrations now support file name format changes
  Clinical One Digital Gateway now allows file-based integrations to utilize different file name formats more easily.
- Clinical One Cloud Service to Safety integration
  With the integration between Clinical One Cloud Service and Safety, users now benefit from a more efficient transfer of adverse event data. Not only does the integration improve patient safety by reducing reporting time, but it also reduces the possibility of manual intervention and improves the quality of data for safety cases.
- Screen, randomize, and dispense data can be integrated before visit completion
  Subject data for the screen, randomize, and dispense events can now be integrated with downstream systems before a visit is considered complete.
- The Multi-IWR integration has been simplified
  The way the IWR integration processes subject data sent by an IWR provider has been enhanced, resulting in the removal of unnecessary steps.
- The SAP Supply Management—Proof of Delivery integration supports alphanumeric characters in kit IDs
  The integration has been enhanced to allow kit IDs that contain alphanumeric characters to integrate with the SAP Supply Management system.

File-based integrations now support file name format changes

Clinical One Digital Gateway now allows file-based integrations to utilize different file name formats more easily.

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The ability to change the file name format used by Clinical One Digital Gateway for the SAP Supply Management (Stock Report, Shipment Notification, and Shipment Rejection) inbound integrations, as well as the MUL-User and MUL-Site Tenant integrations, has been made more flexible regarding what the Clinical One Digital Gateway integrations can consume.

> **Note**
>
> This feature was introduced to address an enhancement request (ID: **37810447**)

Clinical One Cloud Service to Safety integration

With the integration between Clinical One Cloud Service and Safety, users now benefit from a more efficient transfer of adverse event data. Not only does the integration improve patient safety by reducing reporting time, but it also reduces the possibility of manual intervention and improves the quality of data for safety cases.

With this new integration, users are no longer required to create new adverse event reports from scratch in Safety. Clinical One Cloud Service automatically creates and sends new safety cases to Safety along with the configured subject data.

Before you work with this feature

As a user manager, you should be aware of the new permissions introduced with this new feature. You should assign the new permissions to the designers, sponsor, and site users who work with safety cases.

Permission	Type	Details
Edit Safety Case Design	Designer	Enables study designers to configure safety case design properties, such as applying the Trigger Safety Case rule to a question or mapping questions to the E2B(R3) format.
Cancel a Safety Case	Site	Enables site users to dismiss or cancel a safety case.
Manage Safety Settings	Sponsor	Enables sponsor users to turn on the **Integrate with Safety System** toggle.
Modify a Safety Case	Site	Enables site users to edit safety cases after initial submission, which may include selecting or deselecting repeating forms, 2-section forms, and lab forms. Also enables site users to resend cases with a status of **Failed**.
Receive the Safety Case Creation Notification	Site, sponsor	Site users with this permission are notified of the creation of a new safety case for a subject.
Receive the Safety Case Updates Notification	Site, sponsor	Site users with this permission are notified whenever an existing safety case has been updated for a subject.
Receive the Safety Case Cancellation Notification	Site, sponsor	Site users with this permission are notified whenever an existing safety case has been cancelled for a subject.
Receive the Safety Case Acknowledgment Notification	Site, sponsor	Site users with this permission are notified whenever Safety has either accepted or rejected a case.

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Permission	Type	Details
Receive the Safety Case Could Not be Created Notification	Site, sponsor	Site users with this permission are notified whenever the system has attempted to create a safety case, but has failed, or whenever mandatory questions have not been completed for a case.

How it works

The new workflow begins at the study design phase, when study designers:

- specify when the system needs to automatically create and send subject data to Safety.
- indicate what data should be included in the transmission, where the subject data needs to be integrated in Safety.
- assess whether any missing data items should block the creation of this transmission.
- define when to send follow-up cases to Safety.

When a site user enters a subject adverse event, Clinical One Cloud Service determines, based on study design, if the adverse event should be sent to Safety. If so, Clinical One Cloud Service automatically creates a new case and associates data from other subject forms with the case. The system then sends the case to Safety.

The safety case is sent to Safety in near real-time via Clinical One Digital Gateway. According to the schedule configured for the integration, the system also sends follow-up cases to Safety.

Details for sponsor users

As a sponsor user, you can now enable the integration of adverse event data at the study level. You do this on the General tab in the study settings by turning the new **Integrate with Safety System** toggle on or off.

Once you have enabled the study-level setting, study designers can configure forms that trigger the creation of safety cases, as well as other forms that are sent to Safety along with the adverse event data.

As a sponsor user, you can also receive the notifications related to safety cases, provided that you have the appropriate permissions.

To begin integrating data to Safety, a Clinical One Digital Gateway integration must be configured. For more information, reach out to your Oracle point of contact.

You can find additional information in the *Sponsor and CRO User Guide*, as well as the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

Impact on library management

As a sponsor user working with library studies you should also be aware of the impact this new feature has on library management:

- The following safety configuration properties can be copied from a study to a library, as well as from a library to a study:
  - forms with the E2B(R3) data element mappings, as configured by study designers.
  - the Trigger Safety Case rule and the forms associated with adverse event data collection.
  - the configuration of questions as mandatory for the creation of a safety case.
  - the property of a question to trigger a follow-up case.

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- Safety cases cannot be created in libraries.

Details for study designers

As a study designer configuring a study that integrates with Safety, your responsibilities are focused on the following tasks as you design your forms:

- Create your adverse event form and specify which item initiates the safety case to be integrated with Safety. This is done by adding a Trigger Safety Case rule to one or more questions, which can only be checkbox, radio button, or drop-down type questions.

> **Warning**
>
> Triggering questions must only be designed on adverse event forms (repeating), in adverse event visits. Furthermore, we do not recommend applying triggering rules to multiple questions on different forms, as this could lead to duplicate cases.

- Indicate which forms should be included in the safety case by turning on the **Include in Safety Case Data** toggle, which can be found on the Details sidebar.
- Mark one or more questions as **Required for Case Creation** by enabling the toggle on the Advanced sidebar. Forms with this toggle enabled are mandatory for the transmission of the case to Safety. This means that adverse event data isn't sent to Safety unless site users answer these questions. You can mark forms as mandatory across multiple visits. Only questions whose data is considered obligatory in Safety can be marked as mandatory. When designing the forms which need to be integrated to Safety, you must also map any questions that are to be transmitted to Safety to the E2B(R3) standard, meaning that the input received by these questions must comply with the E2B(R3) format. To do so, select the appropriate E2B(R3) mapping for your question from the Advanced sidebar.

> **Caution**
>
> Unmapped questions are not integrated with Safety. Furthermore, for your case to be integrated to Safety, the following mappings must have the **Required for Case Creation** toggle switched on:
>
> – E.i.1.1a (Reaction / Event as Reported by the Primary Source in Native Language) or E.i.1.2 (Reaction / Event as Reported by the Primary Source for Translation)
>
> – G.k.1 (Characterization of Drug Role) and G.k.2.2 (Medicinal Product Name as Reported by the Primary Source)'
>
> – If using, E.i.2.1a (MedDRA Version for Reaction / Event) and E.i.2.1b (Reaction / Event (MedDRA code)).

- You can add E2B(R3)-specific codelists to questions once an E2B(R3) data element is mapped; this is not mandatory. Non-E2B(R3) codelists can be used too.
- Set up a follow-up safety case to be triggered whenever the data for a question is updated. To this end, enable the **Trigger a Follow-up Case** toggle on the Advanced sidebar.

You can find additional information in the *Study Designer User Guide* after the RAE upgrade.

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Details for site users

Your responsibilities include monitoring existing safety cases, filling in any gaps in adverse event data, and submitting and resubmitting cases.

You can start by filtering the list of subjects based on their safety case status:

- **Not submitted**: These are cases that have been created but have not yet been submitted to Clinical One Digital Gateway. Cases with this status may have mandatory questions that have not been completed. Follow-up cases may also have this status if the data pertaining to a question that triggered the follow-up has changed.
- **Submitted**: These are cases that have been submitted to Clinical One Digital Gateway.
- **Accepted**: This indicates that a case has been accepted by Safety.
- **Rejected**: This indicates that a case has been rejected by the recipient safety system. Cases with this status may or may not include a comment explaining the justification for the rejection.
- **Transfer failed**: This indicates that an internal error has occurred, and the case has not reached Clinical One Digital Gateway. If errors are encountered during the submission process, site users can address the error and resubmit the case.
- **Canceled**: These are cases that have been manually canceled by site users. If required, cases with this status can be re-opened and the form selections made for the initial case are preserved.
- **Dismissed**: When a site user manually dismisses cases with a status of **Not Submitted**, the system automatically converts them to this status. If necessary, site users can reopen them.

The Queries page reflects any safety case that requires your attention. As part of these automatically generated queries, you can see what has prevented the transmission of the case to Safety. For example, failure to complete a required item prevents the transmission of a case, which results in the creation of a query. You can easily navigate to the question from the query's Details panel. Once you have made the necessary changes, the query automatically closes.

As a site user, you can also make changes to the data included in a safety case after initial submission, provided you belong to a study role with the appropriate permissions. This includes adverse events, as well as the forms originally associated with the case, except for the triggering form.

> **Note**
>
> New data added for a subject is not automatically added to an existing case. A site user must manually add it.

You should also know that whenever the system triggers the creation of a new case that is to be sent to Oracle Safety One Argus, all data entered for that subject using E2B(R3) mapped forms will be included in the case.

You can find additional information in the *Site User Guide* after the RAE upgrade.

Impact on reports

The following reporting changes are introduced for this enhancement:

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Report	Type of change	Description
Study Design report	New section and new filter, as well as changes to an existing column	The following changes have been made to this report: • A new **Safety Reporting** section. • A new **Safety Reporting** filter, in the form of checkbox • The new safety-related properties of questions are reflected in the Advanced column: – E2B(R3) mapping – Required for Case Creation (Y/N) – Triggers a Follow-up Case (Y/N)
Annotated Case Report Forms	Changed content of existing column	The new safety-related properties of questions are reflected in a new Advanced column: • E2B(R3) mapping • Required for Case Creation (Y/N) • Trigger a Follow-up Case (Y/N)

Already working in a live study?

As a sponsor user, as soon as this release is available, you can reach out to your Oracle point of contact to configure the integration with Clinical One Digital Gateway. Once the integration is configured, you can enable the transmission of adverse event data on a study level for existing studies.

As a study designer, you should bear in mind the following:

- The Advanced Study Versioning (ASV) of a safety case triggering rule is supported.
- Changes to E2B(R3) mapping are supported with ASV changes.

> ⚠ **Caution**
>
> If mapping has changed, previously integrated cases will not be updated. This new mapping will only be reflected in new or updated cases.

Screen, randomize, and dispense data can be integrated before visit completion

Subject data for the screen, randomize, and dispense events can now be integrated with downstream systems before a visit is considered complete.

Before the release of Clinical One Cloud Service 25.2, the user actions to screen, randomize, and dispense a subject were only enabled after all required questions in the associated visit were answered; this is considered a complete visit. Upon selecting the action, subject data is integrated with downstream systems.

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Details for integration managers

Starting with Clinical One Cloud Service 25.2, studies can now be designed so that site users can screen, randomize, and dispense subjects without first needing to answer all of the required questions in the visit. This can result in data being integrated with downstream systems before a visit is considered complete.

To allow for this, study designers apply one of the following tags to form questions during the study design phase: Required for Screening, Required for Randomization, or Required for Dispensation. After a user answers all of the tagged questions, the action associated with the visit is enabled. This occurs even if all of the required questions have not been answered. For more information about the new study design feature, see Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM).

Once an event is triggered, the associated data is sent to any integrated downstream system; the integration no longer waits for the visit to be considered complete.

If your organization intends to implement this new feature for existing or future studies, make sure all questions that are to be integrated are tagged as required for the given event. This will ensure that the event (screening, randomization, or dispensation) is only allowed after all of the necessary information, being sent to a downstream system, has been collected. Doing this may limit integration failures caused by missing data or lead to the possibility of events being integrated out of logical order. For example, the randomization event could be integrated before the screening visit.

What integrations could this enhancement impact?

- Oracle's Siebel Clinical Trial Management System—Subject Visit (SV) Integration
  - Only subject status changes for screening and randomization can be sent to CTMS prior to visit completion. All other event data is integrated once a visit is considered complete.
- Outbound subject data integration
  - For studies with this design, integration template updates are required to ensure the tagged questions are integrated when the event is triggered and not when the visit is complete. For more information, reach out to your Oracle point of contact.
- Clinical One to Oracle InForm
  - For studies with this design, integration template updates are required to ensure the tagged questions are integrated when the event is triggered and not when the visit is complete. For more information, reach out to your Oracle point of contact.

You can find additional information about this feature in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

The Multi-IWR integration has been simplified

The way the IWR integration processes subject data sent by an IWR provider has been enhanced, resulting in the removal of unnecessary steps.

Details for integration managers

IWR providers use the Study Design report to obtain the visit, form, and question refnames, which they include in the payload request sent to Clinical One Cloud Service.

Prior to this enhancement, the IWR provider developed integration code to call an Clinical One Cloud Service API to retrieve the study design GUIDs for the questions that needed to be

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integrated, and an Oracle Services Consultant created the refname-to-GUID mappings in the integration configuration file.

Beginning with 25.2, the IWR provider no longer needs to develop integration code, and Oracle Services no longer needs to create mappings. Now, the IWR provider can simply include the refnames (from the Study Design report) in the payload sent to Clinical One Cloud Service via the API call.

The integration directly links to the Clinical One Cloud Service Design service and uses the refnames in the payload to find the questions where the data should be imported or updated; no extra integration code or mappings are required.

What do I need to know if I have an existing IWR integration?

There is no need to update existing IWR integrations. They will continue to function as originally configured.

You can find additional information about this feature in the guide of *REST API for Clinical One Platform* and the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

The SAP Supply Management—Proof of Delivery integration supports alphanumeric characters in kit IDs

The integration has been enhanced to allow kit IDs that contain alphanumeric characters to integrate with the SAP Supply Management system.

Previously, the inclusion of alphanumeric characters in kid IDs resulted in the file import failing.

Integration details: The Proof of Delivery integration sends confirmation details to the SAP Supply Management system after a site user confirms receipt of a shipment by changing the shipment status to Completed in Clinical One Cloud Service.

This feature was introduced to address an enhancement request (ID: **37815199**).

For more information, see SAP Supply Management Integration.

Notifications

- New notifications in Clinical One Cloud Service
  The following new notifications are now available for users assigned with the corresponding permissions.
- Customize your study's notifications
  Study managers and other sponsor users can customize notifications in their studies to provide valuable information to study users.

New notifications in Clinical One Cloud Service

The following new notifications are now available for users assigned with the corresponding permissions.

Kit Replacement Notification

This new notification informs users whenever a lost or damaged kit is replaced for a subject. It provides information about the site and study, the new kits replacing the old kits, as well as the user who performed the action and the date when it occurred.

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To receive this notification, users must be assigned to a study role that includes the *Receive the Kit Replacement Notification* permission. Consider that users receive notifications only for the sites that they're assigned to.

> **Note**
>
> This notification does not cover Unblinded Pharmacist kits. A different notification informs users of the replacement of this type of kits and a different unblinding permission is required for it.

Pharmacist Kit Replacement Notification

This new notification informs users whenever a lost or damaged Unblinded Pharmacist kit is replaced for a subject. It provides information about the site and study, the new kits replacing the old kits, as well as the user who performed the action and the date when it occurred.

To receive this notification, users must be assigned to a study role that includes the *Receive the Unblinded Pharmacist Kit Replacement Notification* permission. Consider that users receive notifications only for the sites that they're assigned to.

> **Caution**
>
> This notification contains unblinding information, so you must assign this permission with caution.

Undo Add Subject Notification

With this new notification, users can be updated every time site users undo the addition of a subject to a study, with the **Undo Add Subject** option.

> **Note**
>
> This option exists to support the removal of subjects added in error and is only available for subjects for whom data has not been saved. For more information, see Cancel a subject.

The Undo Add Subject Notification provides information about the site and study, as well as the user who performed the action and the date when it occurred. To receive this notification, users must be assigned to a study role that includes the *Receive the Undo Add Subject Notification* permission. Consider that users receive notifications only for the sites that they're assigned to.

Shipment Received Notification

With this new notification, users can receive updates whenever a shipment is marked as received at a site or depot. It provides information about the site and study, as well as the shipment's details, the user who received the shipment and the date when it occurred.

> **Note**
>
> This notification is not applicable for Pending Destruction Shipments received at a depot.

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To receive this notification, users must be assigned to study role that includes the *Receive the Shipment Received Notification* permission. Consider that users receive notifications only for the sites that they're assigned to.

Site Resupply Strategy Update Notification

With this new notification, you can be informed every time the resupply strategy is updated for a site. This includes any type of change, such as initial assignment, removal of the resupply strategy or update to a different resupply strategy. It provides information about the site and study, as well as the resupply strategy, the user who performed the update and the date when it occurred.

To receive this notification, users must be assigned to a study role that includes the *Receive the Site Resupply Update Notification* permission. Consider that users receive notifications only for the sites that they're assigned to.

You can find additional information about all these and other notifications in the *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade.

Customize your study's notifications

Study managers and other sponsor users can customize notifications in their studies to provide valuable information to study users.

With this enhancement you can now tailor notifications. For example, you can include guidance about how other study users can contact your organization's helpdesk. Furthermore, you can streamline communication by including any relevant information, which helps reduce follow-up questions and provide a better experience.

Before you work with this feature

To customize notifications, you only need to be assigned the existing *Edit Welcome Details in General Study Settings* permission. No new permission is introduced for this enhancement.

Details for study managers and other sponsor users

Here's what's new for you:

- In a study's settings, you can find the new **Notification** tab. Here, you can customize the text body of all notifications in a study.
- On the **Notifications** tab, you can see two fields: **Email Theme** and **Text Body**.
  - Under **Email Theme**, you can configure whether to hide or display the Oracle logo in your study's notifications with the **Hide Oracle Logo** toggle.
  - In the **Text Body** field, you can add your customized information. The text you include here is displayed across all notifications in your study.
- Depending on how each notification is formatted in the application, the customizable text you add may be displayed at the top of the notification or at the bottom.
- You are only allowed to include plain text. Links, images, or HTML code is not allowed.
- For the HTML notification that you typically receive over email, the footer text is now updated to state the following: *This message may contain privileged or confidential information. If you are not the intended recipient, do not view, copy, or distribute this message. Please destroy this message.*

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Already working in a live study?

You can customize notifications in existing studies at your organization. Any changes you make only impact future notifications.

You can find additional information in the *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- Randomization replacement
  Sponsor users can now replace subjects that have been withdrawn from a study with a new subject that is assigned to the same treatment arm.
- Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM)
  Sponsor users can now specify data points required for screening, randomization, and dispensation separately from those required for visit completion.

Randomization replacement

Sponsor users can now replace subjects that have been withdrawn from a study with a new subject that is assigned to the same treatment arm.

In certain scenarios, your study design statistician may want to replace a subject that has been withdrawn early in order to maintain the balance of treatment arms. Now, you can perform randomization replacement to replace withdrawn subjects with new subjects that are assigned the same treatment.

Before you work with this feature

User administrators and unblinded sponsor users assigned the new *Replace Randomization* permission can update a study's settings to allow randomization replacement.

More information on these permissions can be found in the *Add Users Guide* after the Release Assessment Environment (RAE) upgrade.

Details for sponsor users

As a sponsor user, here is what's new when it comes to your workflow:

- On the Study Settings tab, in the Visit Settings section, the **Allow Randomization Replacement** option is now available in the Randomization row.

  > **Note**
  >
  > This setting is set to Off by default.

  When you enable this setting, you're prompted with additional selections:

  – **Replacement Starting Prefix**: This option requires you to add a prefix for the randomization replacement. The prefix increases by an integer of 1 for each replacement.

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> **Note**
>
> A maximum number of 9 digits for the prefix is allowed.

  - **Set Max Replacements per Randomization Number**: This option allows you to specify how many times a randomization number can be replaced. You are then required to add a quantity in the **Max Replacements** field.

- Enabling the **Allow Randomization Replacement** setting does not count withdrawn and replaced subjects, including withdrawn subjects that are not replaced, towards the following study totals:
  - Study randomization limits
  - Site randomization limits
  - Study cohort limits
- Blinded users cannot undo withdrawal when the **Allow Randomization Replacement** setting is selected in order to avoid unblinding. Additionally, undo withdrawal information does not display in the Subject History for a blinded user.
- Once a subject's randomization has been replaced, the option to undo withdrawal is not available for the replaced subject.
- > **Note**
  >
  > Be aware that if a subject is marked for randomization replacement, then a new randomization list is uploaded, that randomization replacement is discarded, and the new randomization list does not contain the replaced randomization number created for that subject.
  >
  > Additionally, if a subject is randomized in a list, and a second list is generated with the subject marked for randomization replacement, the new randomization number is included in the original list, even though it is no longer active.
- On the Subjects tab, in the **Manage Subject** drop-down menu, the new **Replace Randomization Number** option is available when the **Allow Randomization Replacement** setting is enabled in the study settings. When **Replace Randomization Number** is selected for a subject, the subject's status updates to *Withdraw / Rand Replaced* in the Subjects list, and *Replacement Randomization* in the Subject History.

> **Note**
>
> Only users with the *Replace Randomization* permission can perform replacement and view a replaced randomization.

More information on randomization number replacement can be found in the *Sponsor and CRO User Guide* after the RAE upgrade.

Impact on reports

The following reporting changes are introduced for this feature when the **Allow Randomization Replacement** setting is selected:

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Report	Type of change	Description
Randomization List (Unblinded) report	Modified column data	The **Randomization Number** column displays the new randomization number after randomization replacement is updated in the Randomization List.
Study Design report	Modified column data	The **Setting** column indicates that the **Allow Randomization Replacement** setting is selected, along with details for: • Replacement Starting Prefix • Max Replacements (if **Set Max Replacements per Randomization Number** is selected)
Subject Enrollment report	Modified column data	The **Randomized Subjects** column does not count the number of replaced randomization subjects towards the total number of randomized subjects.
Study Settings report (Visit Settings tab)	Modified column data	The **Setting Option** column indicates that the **Allow Randomization Replacement** setting is selected.
Subject Events report	Modified column data	The **Event Type** indicates if a subject is marked for randomization replacement.

More details can be found in the *Reporting Guide* after the RAE upgrade.

Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM)

Sponsor users can now specify data points required for screening, randomization, and dispensation separately from those required for visit completion.

> **Note**
>
> Be aware that you can now only move forward to the next visit once you complete any RTSM marked as required *and* all required questions.

Details for study designers

As a study designer, when it comes to your workflow, here's what's new for you:

- When creating a form question, in the **Question Details** side panel, new options allow you to determine what type of visit action the question is required for:

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Required for	Description
Screening	A question marked as **Required for Screening** in the Screening Visit must be completed before a subject can be screened. ***Note**: This does not impact the ability to manually screen fail a subject.*
Randomization	A question marked as **Required for Randomization** in the Randomization Visit must be completed before a subject can be randomized. ***Note**: If the visit action also includes dispensation, assigned kits for the subject are dispensed at this time, as well.*
Dispensation	A question marked as **Required for Dispensation** in the Dispensation or Screening and Dispensation Visits must be completed before the subject can be dispensed to. ***Note**: If the visit action is a Randomization and Dispensation Visit, these marked questions are not considered, and only questions marked **Required for Randomization** are considered.*

- If no questions are selected as required for an RTSM action for the visit, then the corresponding options (Screen, Dispense, or Randomize) aren't included on the Subjects page in the **Manage Subjects** drop-down, and the user must complete all required questions on the Visits page.
- Questions required for dosing calculations, cohorts, and stratum factors must be marked as **Required for Visit Completion** in order for them to be available for selection in Study Design mode.
- This functionality does not apply to the Drug Reconciliation form, although the options are available for the form's questions.
- Repeating and two-section form questions cannot be marked as Required for RTSM events; only flat form questions are eligible for being marked with these new settings.
- Hidden and Data Classified questions can be marked as required for RTSM events, and they must be completed before the user can complete the event, even if they are not visible.

More information can be found in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

As a site user, your workflow is dependent on how your sponsor configures this function. Here's what you should be aware of:

- On the Subjects page, in the **Manage Subjects** drop-down, the Screen, Randomize, and Dispense options are only available when:
  - The selected subject has a visit with the related action in the **Next Visit** column, and
  - The sponsor has identified questions required for that action.

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> **Note**
>
> If a required RTSM action exists in a visit listed under the **Previous Visits** column and has not yet been completed, you must open that visit and review the action in the visit's focused view.
>
> After completing the questions in the focused view, you'll be able to complete the related RTSM event. However, you must still complete any questions designated as **Required for Visit Completion** before you can proceed to the next visit.

More information can be found in the *Site User Guide* after the RAE upgrade.

Impact on reports

The following reporting changes are also introduced for this new feature/ enhancement:

Report	Type of change	Description
The Annotated Case Report Forms	New data point	This report now displays details on questions and their required visit and RTSM action completion tags.
The Study Design report	New data point	This report now displays details on questions and their required visit and RTSM action completion tags.
The Subject Events report	New filter options	The following new filter options are introduced for the Event Type filter, to support reporting on data that is separate from visit completion: • Visit Screened • Visit Randomized • Visit Dispensed • Visit Randomized Dispensed

For more information, see the *Reporting Guide*.

Impact on integrations

For more information on the impact on integrations, see Screen, randomize, and dispense data can be integrated before visit completion.

Already working in a live study?

Once the Release Assessment Environment (RAE) upgrade has completed, and the updated study design has been moved to the appropriate container, these new functions will be applied to actions that have not yet been completed in your study; there is no impact to RTSM actions that were completed prior to the RAE upgrade.

Reporting, archives and analytics

- New datasets to track sign, verify, freeze, and lock actions
  You can now track Sign, Verify, Freeze, and Lock (SVFL) actions and their audit history with the three new datasets available in Oracle Clinical One Analytics.

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- New data element to track visit, form, and item level locks
  With the new data element added to multiple datasets in Oracle Clinical One Analytics, data managers can now create enhanced reports and include information about the current lock status for visits, forms, and questions.
- Enhancements to Oracle Clinical One Analytics datasets
  To help clinical supply managers gain a better understanding of investigational product dispensation, multiple (existing) datasets have been enriched with new data elements.
- Enhancements to Oracle DMW clinical data extracts
- Include a form preview in the Annotated Case Report Forms report
  You can now include a visual representation of study forms in the Annotated Case Report Forms standard report.
- New Study Settings report
  Study managers and other sponsor users can now run a report that captures all the study settings configured for your studies.
- Rules report is now available in XLSX format
  Starting with Clinical One Cloud Service 25.2, the Rules report is no longer available in CSV format. Instead, you have a new File Type option to generate the rules report in XLSX format.
- Subject Data Extract now includes forms with no data
  The Subject Data Extract now includes constructed datasets for all forms, even for forms with no subject data.
- Include subject event history in your Oracle CRF Submit Archive requests
  Sponsor and site users can now include details about subject events in Oracle CRF Submit Archives requests.
- Oracle CRF Submit Archives requests include uploaded documents
  Now, when you generate Oracle CRF Submit Archives requests, the request output includes documents that were uploaded to a question.

New datasets to track sign, verify, freeze, and lock actions

You can now track Sign, Verify, Freeze, and Lock (SVFL) actions and their audit history with the three new datasets available in Oracle Clinical One Analytics.

To track SVFL actions applied to an object (visit, form, or question), the following datasets are introduced as part of Clinical One Cloud Service 25.2.1:

- Subject Event SVFL dataset
- Subject Form SVFL dataset
- Subject Item SVFL dataset

These datasets provide current and historical data about SVFL actions applied to visits, forms, and form items, respectively.

Details for user administrators and global user managers

The new permission *Run Data Management Actions Datasets*, has been added in Clinical One Cloud Service to grant access to all three SVFL datasets. As a user administrator or global user manager, you can assign this permission to any sponsor user who requires the ability to work with these datasets in Oracle Clinical One Analytics.

This new permission is also now included in the following predefined template study roles:

- Clinical Research Associate (CRA)

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- Medical Monitor
- Data Manager
- View Only for Unblinded Support

Details for data managers, CRAs, and other sponsor users

> **Note**
>
> For repeating form instances, the Subject Form SVFL dataset now tracks instance-level statuses for all newly collected data, providing complete audit points going forward. Historical data is different: past repeating form instances don't include instance-level SVFL statuses, so you may see gaps when reviewing older records. Item-by-item actions are still tracked for the data itself, as well as at the visit level, but detailed status information at the form-instance level is only available for new data collected after this update.
>
> You can rely on full-instance level status and audit history for repeating forms from now on, but historical repeating form data will not retroactively include these details.

The SVFL datasets provide not only the current status, but also historical data about the SVFL actions applied to the given object over time. With these, data managers, auditors, and other sponsor users with appropriate permissions can now review when SVFL actions took place in a study and, more importantly, when any of them were undone and why. For example, if a form is currently unverified, you can track when it was originally verified and by whom, and also see what happened next that made it become unverified.

Additionally, with the SVFL datasets it is now possible to get detailed information about signatures at the same granular level (visit, form, or question). For instance, you can get details on the timestamp and specific user who signed the given object, metrics about how many times an investigator signs and unsigns objects within a casebook, or even retrieve the ALCOA audit details about how a signature changed.

Remember that to properly visualize data when working with any dataset, you must include at least one element from the folder listed as required. When working with the SVFL datasets, include data elements from the *Item (Required)*, *Form (Required)* or *Event (Required)* folder (respectively) on your custom reports, in addition to data elements from the *Actions* folder, and start analyzing your study's SVFL actions data at the visit, form or item levels.

Already working in a live study?

As soon as this release is available, you can be assigned with the new *Run Data Management Actions Datasets* permission and access these datasets. With them, you will be able to see all audits for the SVFL actions, including those that were applied to questions, forms, and visits before the dataset was introduced.

You can find additional information regarding the SVFL datasets and their data elements, in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

New data element to track visit, form, and item level locks

With the new data element added to multiple datasets in Oracle Clinical One Analytics, data managers can now create enhanced reports and include information about the current lock status for visits, forms, and questions.

A new data element called LOCKED is now available in the following datasets:

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- Blinded Subject Events dataset
- Unblinded Subject Events dataset
- Subject Forms dataset
- Subject Form Items dataset

Depending on the dataset being used, this data element reflects the status of an event or visit, a form, or a question.

> **Note**
>
> There is no LOCKED status for the entire subject that is tracked in Oracle Clinical One Analytics as part of this enhancement.

You can use this data element to track the current lock status of a given object (visit, form, or question). Regardless of the type of object you are analyzing, this data element can have the following lock status values:

Lock status	Description
<null>	No lock has ever been applied to this object.
LOCKED	All objects within the visit, form, or question have been locked.
UNLOCKED	The object has no locks applied after being locked at one point in the past. ***Note:*** *Event or visit locking applies to the entire visit, including the Visit Date. For a visit to be marked as LOCKED, the Visit Date and all associated objects must be locked. If the Visit Date is not locked, the visit cannot be locked.*

The data about the lock status will be loaded in Oracle Clinical One Analytics for the full audit history. This means that when past records of an item or form are retrieved, the lock status that the given item or form had at that time will be reflected for it.

> **Tip**
>
> If you want to work with the audit history of lock actions for a given visit, form, or question, check out the New datasets to track sign, verify, freeze, and lock actions, also introduced in this release.

You can find additional information regarding these datasets and the new LOCKED data element, in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to Oracle Clinical One Analytics datasets

To help clinical supply managers gain a better understanding of investigational product dispensation, multiple (existing) datasets have been enriched with new data elements.

Clinical supply managers and other Oracle Clinical One Analytics users can now generate reports and dashboards that include the following new elements:

- **ORDER_TYPE**: Provides detailed information about how a shipment was initiated in Clinical One Cloud Service.

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This data element is now available in the Blinded Kit dataset and the Unblinded Kits dataset.

- **FORCED_RAND**: Indicates if subjects underwent forced randomization. This helps track how many times forced randomization has been used over the course of the study, which can occur due to a lack of kits for at least one treatment arm in the study at the time of randomization.
  This data element is now available in the Unblinded Kits dataset and the Unblinded Subject Event dataset.

Impact on datasets

The following dataset changes are introduced for this enhancement:

Dataset	Type of change	Description
Blinded Kit dataset	New data element	• The **ORDER_TYPE** data element has been added to the Shipment folder. This data element can have the following values: *INITIAL*, *MANUAL*, and *RESUPPLY*.
Unblinded Kit dataset	New data element	• The **FORCED_RAND** data element has been added to the Randomization folder. This data element can have the following values: – *Y*: indicates that a subject underwent forced randomization. – *N*: indicates that a subject was randomized normally. – *NULL*: indicates that a subject has not yet been randomized. • The **ORDER_TYPE** data element has been added to the Shipment folder. This data element can have the following values: *INITIAL*, *MANUAL*, and *RESUPPLY*.
Unblinded Subject Event dataset	New data element	• The **FORCED_RAND** data element has been added to the Kits folder. This data element can have the following values: – *Y*: indicates that a subject underwent forced randomization. – *N*: indicates that a subject was randomized normally. – *NULL*: indicates that a subject has not yet been randomized.

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Already working in a live study?

For subjects that were randomized and the shipments that were triggered before the introduction of this feature, these new data elements are populated based on historical data.

You can find additional information about the new data elements in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to Oracle DMW clinical data extracts

STUDY column now updates based on Study Identifier

With this release, the **STUDY** column found in Oracle Life Sciences Data Management Workbench Clinical Data Extracts has now been remapped to draw data from the Study Identifier, in Clinical One Cloud Service. Previously, this column was populated based on the Study Version Title.

The Study Identifier is located on the **General** tab of the study settings for a Clinical One Cloud Service study. This change means that renaming to specific study versions, including Advanced Study Versioning (ASV) updates, no longer maps to the **STUDY** column.

> ⚠ **Caution**
>
> For studies integrated with Oracle DMW, the Study Identifier must no longer be updated after adding at least one study version to the Testing container. Modifying the Study Identifier after this stage prevents Clinical One Cloud Service from properly handling external inbound requests for the modified study.

Already working in a live study?

For studies already integrated with Oracle DMW, the **STUDY** column is updated to reflect this change.

This change is applied retroactively: on your next data load, the **STUDY** value for all clinical records will update. If you have questions about this update or need support, reach out to your Oracle point of contact.

> ⓘ **Note**
>
> Updates to the **STUDY** column do not impact primary keys maintained by Oracle DMW. However, this change to the **STUDY** column may impact your Transformations, Custom Listings, and Validation Checks in Oracle DMW, depending on your use of this application.

Include a form preview in the Annotated Case Report Forms report

You can now include a visual representation of study forms in the Annotated Case Report Forms standard report.

New filters and settings have been added to the Annotated Case Report Forms standard report that allow you to include a visual representation of study forms in the report. You can also include a section that provides a list of visits and the associated forms.

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Details for study designers

Including a visual representation of the forms in your study, along with a list of the forms per visit, can be useful for several reasons.

- You can distribute your study design to the individuals responsible for designing downstream integrated systems that are intended to consume data from an Clinical One Cloud Service study.
- You can circulate the report to facilitate the review and approval process to secure study design sign-off.

Details for report users

Users assigned with a study role that includes the *Run the Study Design Report* permission can use the new filters and settings below, located on the **Settings** sidebar, to generate the report.

Table 5-1 New report filters and settings

Filter/Setting	Details
Study Version	This is an existing filter that allows you to select a study version. Use this filter and the new filters and settings below, if applicable, to include specific forms in the report. ***Note**: The Visit and Form filters become active after you select a Study Version*.
Visit and Form filters (New filters)	If you want to include all forms from all visits for the selected study version, leave both the **Visit** and **Form** filters set to All (default). • If you want to include the forms from specific visits (for the selected study version), select the applicable visits in the **Visit** filter. **Note** Visits included in a branch are prefixed with the branch name in the Visit drop-down, making it easier to identify the correct visit if they share the same visit name with a visit in another branch. • If you want to include specific forms from the visits selected (for the selected study version), select them from the **Form** filter. ***Tip**: You can also leave the Visit filter blank and select specific forms from the Forms filter*. If you use both the Visit and Form filters, the report output only includes those forms that are associated with the selected visits. For example, a study's design includes the following visits and forms. • The Screening visit includes the Screening form. • The Baseline visit includes the RTSM and Vitals forms. • The Week-1 visit includes the Vitals form. If Week-1 is selected under the Visit filter and RTSM is selected under the Form filter, no forms are included in the report. If Baseline is selected under the Visit filter and the RTSM and Screening forms are selected under the Form filter, only the RTSM form is included in the report.

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Table 5-1 (Cont.) New report filters and settings

Filter/Setting	Details
Include in Report (New settings)	Use the following settings (enabled by default) to determine which sections to include in the report. ***Note**: Form Annotations, defined below, are included in the report output (by default) if you disable all three settings*. • **Forms by Visit**: Leave this setting enabled if you want to include the Forms by Visit section in the report, which lists each visit and its associated forms based on the study version selected. This section appears below the main report header and above the **Forms** section. ***Note**: The Visit and Form filters, if applied, have no impact on the content displayed in this section*. • **Form Preview**: Leave this setting enabled if you want to include a visual representation of the selected forms in the report. ***Note**: If enabled, you are only able to generate the report in HTML.* Each form preview is included in the **Forms** section immediately below the form name and above the form annotations, which includes the questions, reference IDs, answers, validations, and advanced setting details. • **Form Annotations**: Leave this setting enabled if you want to include the form annotations, which include the questions, reference IDs, answers, validations, and advanced setting details in the Forms section of the report.

Details about the Forms by Visit section

The report only includes this section if the Forms by Visit option is enabled under the **Include in Report** setting during report generation. When included, it provides a listing of all forms per visit, based on the study version selected.

- The Visit and Form filters have no impact on the content displayed in this section.
- Forms included in a visit multiple times are listed once, as the section provides a list of unique forms per visit.
- Forms that are part of a visit branch appear only once regardless of the number of cycles defined, as the table only includes the first instance of each cycle.
  For example, a study's design includes two visit branches: Branch 1 Male and Branch 2 Female, where Branch 1 Male consists of Day 1, Day 15, and Day 30 visits with a maximum of 5 cycles.

  In this scenario, the following details are included once in the **Forms By Visit** section, where each branch-visit combination and the associated forms are displayed under a separate header.

  Branch 1 Male - Day 1

  Each unique form for Day 1 is listed.

  Branch 1 Male - Day 15

  Each unique form for Day 15 is listed.

  Branch 1 Male - Day 30

  Each unique form for Day 30 is listed.

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Details about the Forms section

If the Form Preview setting under **Include in Report** is enabled, a visual representation of each form selected during report generation is included in this section.

- All form types are supported. Repeating and two-section forms are displayed as flat forms, but the header indicates the form type.
- Dynamic forms and questions are displayed.
- Hidden questions are displayed
- The **Select Lab** drop-down, which is present on lab forms and contains a list of existing labs, is included in the Form Preview, but the drop-down is empty.
- The report flattens Question Group type questions, positioning the question on the left and the answers on the right.

You can find additional information in the *Reporting Guide* (Annotated Case Report Forms) after the Release Assessment Environment (RAE) upgrade.

New Study Settings report

Study managers and other sponsor users can now run a report that captures all the study settings configured for your studies.

The new **Study Settings report** allows you to view all of a study's configured settings in one place. Use this report to regularly verify the consistency and integrity of the study settings, compare the beginning and end of a validation cycle, identify and resolve issues, and maintain a reliable record, which can be included in the study Trial Master File.

Before you work with this feature

To use this report, a user administrator must assign the new permission, *Run the Study Settings Report*.

This new permission was added to the existing **Study Manager** and **View Only for Unblinded Support Users** template study roles.

About the Study Settings report

As with any other report, you can locate the Study Settings report in the **Reports & Archives** screen within a study, on the **Reports** tab.

> **Note**
>
> This report cannot be scheduled and can only be generated in XLSX format.

You can use the **Settings** sidebar on the right to filter data in your report to do the following:

- Select a specific study mode (Production, Testing, and Training)
- Include an audit trail of changes made to study settings by entering a date range in the **From** and **To** settings. The audit trail shows the user who made the change, the operation, and when the change happened for one, specific, or all sections.

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> **Note**
>
> Enabling the audit trail provides an informative report output, displaying the last entered email address in the General Default Email Address row, instead of 'N/A'.

- Select one or more tabs that you want to include in the report.
- You can only include the tabs that you have access to. For example, you can include the **Study Settings** tab in the generated report, but only if you have the *Edit Study Settings* or *View Study Settings*permissions, either of which give you access to it.

The Study Settings report output is broken down into sections, each section corresponds to a different tab and displays on a separate XLSX sheet. The report can include details from the following tabs:

Tabs in the Study Settings report		
Sites	Enrollment Settings	Predictive Resupply
Site Settings	Screening and Randomization Limit Country	Do Not Dispense Settings
Site Address	Cohort Limits by Cohort	SDV Settings
Site Kit Shipping	Custom Enrollment Settings	SDV Strategies
Site Study Version Audit	Visit Settings	Signature Configurations
Site Resupply Audit	Randomization Regions	Archives Settings
Site SDV Audit	Resupply Schedule	Archives Notification Body
Labs	Blinded Group	Notifications
Lab Address	Locally Sourced Kits	--
Depots	Partial Kit Dispensation	--
Depot Resupply Audit	Dose Hold Settings	--
Study Settings	Minimum/Maximum Resupply	--

This report will be available for new and existing studies as soon as the upgrade completes.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Rules report is now available in XLSX format

Starting with Clinical One Cloud Service 25.2, the Rules report is no longer available in CSV format. Instead, you have a new File Type option to generate the rules report in XLSX format.

The Rules report now includes a new section for designer validation rules, in addition to the custom rules that were already part of it. With the inclusion of this new section, CSV is no longer compatible as an output format, given that with CSV files you cannot make a distinction between the two separate tables. However, the XLSX format is being introduced as a replacement for CSV, to support this enhancement. In an XLSX generated output, each section is included as a separate sheet.

If you need this report in a CSV format to work with its data, an XLSX file might still be useful to you. You can open the report generated in an XLSX format using a spreadsheet editor, and then save individual sheets as CSV files.

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> **Note**
>
> This action only saves the sheet that is active at the time, but you can repeat the process to save multiple sheets individually using a different file name for each.

For more information about the new section in the rules report for **Designer Validation rules**, see the *Impact on reports* section in Configure predefined validation rules to raise queries.

You can find additional information about all introduced changes to the Rules report in the *Reporting Guide*, after the Release Assessment Environment (RAE) upgrade.

Subject Data Extract now includes forms with no data

The Subject Data Extract now includes constructed datasets for all forms, even for forms with no subject data.

Previously, the Subject Data Extract did not include a dataset for forms that contained no data. Hence, depending on the output format, those forms were either not included in the extract or included but without a constructed column heading. A dataset with undefined columns would not show any data.

With this enhancement, the Subject Data Extract contains a constructed dataset for all forms, regardless of the existing records. Now, the datasets of forms with no data include fixed study information and all form items with the appropriate column names, as for the other datasets of forms where data is present. This ensures a stable and consistent data structure in the extracts, which allows SAS programmers to work with all forms datasets earlier, as soon as the form has been approved. Additionally, this makes it possible to work in advance with those forms that are not used very often in the study.

This feature was introduced to address an enhancement request (ID: **36160719**).

Include subject event history in your Oracle CRF Submit Archive requests

Sponsor and site users can now include details about subject events in Oracle CRF Submit Archives requests.

A new setting, **Include Subject Event Data**, is now available on the Advanced Settings page when you generate Submission, Archival (sponsor and site), and Custom Archives requests.

When enabled, the subject PDF contains the date and time of each event, as well as other subject event details. For a complete list of details, refer to the table below.

Details for sponsor and site users

This setting, in conjunction with the existing **Include RTSM Data** setting, determines what data is included in each Archives request.

- If **Include RTSM Data** is set to **Yes** and **Include Subject Event Data** is set to **No**,
  - The PDF includes a section labeled *Subject Randomization History*, which displays the randomization number and the date and time of randomization.
  - The PDF also includes a section labeled *Visit History*, which displays kit and dispensation details.
- If **Include RTSM Data** is set to **No** and **Include Subject Event Data** is set to **Yes**,
  - The PDF includes a section labeled *Subject Event History*, which displays each event (under the Action column) and the date and time of occurrence, as well as other

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subject event details (under the Details column). For a complete list of details, see the table below.

- If both are set to **Yes**,
  - The PDF includes a section labeled *Subject History*, which displays each event (under the Action column) and the date and time of occurrence, as well as other subject event details (under the Details column). For a complete list of details, see the table below.
  - The PDF also includes a section labeled *Visit History*, which displays kit and dispensation details.
- If both are set to **No** (system default), no sections appear in the output.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

What event details are included when the setting Include Subject Event Data is set to Yes?

The details below are listed in the order they appear in the PDF.

Table 5-2 Details included with each event

Event	Details included for each event
New Subject	• **Date**: Displays the date and time when the subject was added. • **User**: Displays the user who added the subject.
Screened	• **Date**: Displays the date and time when the subject was screened. • **User**: Displays the user who screened the subject.
Screen Failed	• **Reason**: Displays the **Reason for Screen Fail** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Screen Fail**. • **Date of screen failed**: Displays the **Date of Screen Fail** selected. If a date is not selected, the date and time the event occurred is displayed. • **Date**: Displays the date and time the user screen failed the subject, which could be different than the **Date of Screen Fail** selected. • **User**: Displays the user who screen failed the subject.
Screen Fail Update	• **Reason**: If a new reason is selected, that is displayed. If not, the original **Reason for Screen Fail** value selected when the subject was screen failed is displayed. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Screen Fail**. • **Date of update screen fail**: – If a new **Date of Screen Fail** is selected, that is displayed. The date selected when the subject originally screen failed is shown if no new selection is made. – If a date was not selected when the subject originally screen failed, then the date and time the Screen Fail event occurred is displayed. • **Reason for change**: Displays the **Reason for Change** selected. • **Reason for change comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date**: Displays the date and time the user edited the screen fail details. • **User**: Displays the user who edited the screen fail details.

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Table 5-2 (Cont.) Details included with each event

Event	Details included for each event
Reinstated (Undo Screen Fail)	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date**: Displays the date and time the screen fail was undone by the user. • **User**: Displays the user who completed the undo screen fail event.
Subject Enrolled	• **Date**: Displays the date and time the subject was enrolled. • **User**: Displays the user who enrolled the subject.
Randomized	• **Number**: Displays the randomization number assigned to the subject. • **Date**: Displays the date and time the subject was randomized.
Randomization number assigned to subject number	If you are working in a study that takes advantage of the ability to replace the subject number with the randomization number, the output includes the following. • **Date**: Displays the date and time the subject number was replaced with the randomization number. • **Screening Number**: Displays the original **Screening Number** assigned to the subject before it was replaced by the randomization number. • **User**: Displays the user who randomized the subject. For more information about this feature, see Replace a subject number with the randomization number.
Withdrawn	• **Reason**: Displays the **Reason for Withdrawal** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Withdrawal**. • **Date of withdrawal**: Displays the **Date of Withdrawal** selected. • **Date**: Displays the date and time the user withdrew the subject, which could be different than the **Date of Withdrawal** selected. • **User**: Displays the user who withdrew the subject.
Reinstated (Undo Withdrawal)	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date**: Displays the date and time withdrawal was undone by the user. • **User**: Displays the user who completed the undo withdrawal event.
Withdrawal Update	• **Reason**: If a new reason is selected, that is displayed. If not, the original **Reason for Withdrawal** value selected when the subject was withdrawn is displayed. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Withdrawal**. • **Date of update withdrawal**: Displays the new **Date of Withdrawal** selected. If a new date was not selected, the original date and time of withdrawal is displayed. • **Reason for change**: Displays the **Reason for Change** selected. • **Reason for change comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date**: Displays the date and time the user edited the withdrawal details. • **User**: Displays the user who edited the withdrawal details.
Study Completed	• **Date of study complete**: Displays the **Date of Completion** selected. • **Date**: Displays the date and time the user processed the study complete event, which could be different than the **Date of Completion** selected. • **User**: Displays the user who processed the study complete event.

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Table 5-2 (Cont.) Details included with each event

Event	Details included for each event
Reinstated (Undo Study Complete)	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date**: Displays the date and time study completion was undone by the user. • **User**: Displays the user who processed the undo study complete event.
Completion Update	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Date of update completion**: Displays the new **Date of Completion** selected. If a new date is not selected, the original study completion date and time is displayed. • **Date**: Displays the date and time the user edited the completion details. • **User**: Displays the user who edited the completion details.
Subject Number Changed	• **Reason**: Displays **Other** by default. • **Reason Comment**: Displays the **Reason for Change** text entered. • **Previous subject number**: Displays the subjects previous subject number. • **Date**: Displays the date and time the subject number was changed. • **User**: Displays the user who changed the subject number.
Subject-patient Link Created	• **Date**: Displays the date and time the user linked the subject for Electronic Health Record (EHR) data import. For more information, see EHR data import. • **User**: Displays the user who linked the subject for EHR data import.
Subject-patient Link Removed	• **Reason Comment**: Displays the text entered, indicating why the subject-patient link was removed. • **Date**: Displays the date and time the subject-patient link was removed. • **User**: Displays the user who removed the subject-patient link.
Code Break	• **Reason**: Displays **Code Break** by default. For more information, see Unblind a subject's treatment arm (code break). • **Reason Comment**: Displays the selection made for **Adverse Event** (Yes or No) when the code break event was completed. • **Date**: Displays the date and time the code break event was completed. • **User**: Displays the user who completed the code break event.
Visit Skipped	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Visit Name**: Displays the name of the skipped visit. • **Date**: Displays the date and time the visit was skipped. • **User**: Displays the user who skipped the visit.
Undo Visit Skipped	• **Reason**: Displays the **Reason for Change** selected. • **Reason Comment**: Displays the **Other Reason** text entered when **Other** is selected as the **Reason for Change**. • **Visit Name**: Displays the name of the visit that was previously skipped. • **Date**: Displays the date and time the visit was unskipped. • **User**: Displays the user that unskipped the visit.

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Oracle CRF Submit Archives requests include uploaded documents

Now, when you generate Oracle CRF Submit Archives requests, the request output includes documents that were uploaded to a question.

Clinical One Cloud Service 25.2 introduces the new **File Upload** question type, which enables study designers to include questions on forms that allow users to upload documents, such as images. For more information about this enhancement, see Upload and store any documents for your study.

Details for sponsors and site users

- For Custom requests:
  A new setting, **Include Uploaded Files**, is available on the Advanced Settings page. No new permissions are needed to use this setting.
  - When set to **Yes** (default), the uploaded documents are included in the Uploaded Files folder, which can be located in the site folder in the main zip file. Additionally, the subject PDFs contain the document title and a **View** link for questions related to the upload. Upon clicking, the system displays the relevant document.

    > **Note**
    >
    > The document title naming convention is *documentID_documentversion_filename.extension*.

  - When set to **No**, the documents are not included in the Uploaded Files folder, and a **View** link is not provided; only the document title is displayed on the questions related to the upload.
- For Submission, Archival (for sponsor users), and Archival (for site users) requests:
  The setting is visible on the Advanced Settings page; it is set to **Yes** by default and cannot be changed.
  - The uploaded documents are included in the Uploaded Files folder, which can be located in the site folder in the main zip file. Additionally, the subject PDFs contain the document title and a **View** link for questions related to the upload. Upon clicking, the system displays the relevant document.
- All archive requests include a set of blank forms for each study version. File Upload-type questions are marked with the **File Upload** label.

Limitations

If the title of an uploaded document includes multi-byte characters, such as Japanese and Simplified Chinese characters, Archive requests fail to generate.

How can I be certain I'm getting the most relevant documents?

The **As of Date** setting (available on the Settings side panel) determines which documents are included with the request.

- If you select **Now**, the View link is associated with the most recently uploaded document. Details about previous uploads and links to the associated documents can be found in the Audit Trail by CRF section of the PDF.
- If you select a specific date for **Select Date/Time**, the View link is associated with the document that was uploaded on or before the date selected. Details about previous

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uploads and links to the associated documents can be found in the Audit Trail by CRF section of the PDF.

> **Note**
>
> If you delete the last uploaded document, the question will no longer display the View link and document name. You can view the Audit Trail by CRF section of the PDF to see details for all uploaded documents. This section also includes a View link for each uploaded document.

Will the View links work if my request exceeds 200 MB?

If your request's total output surpasses 200 MB, Oracle CRF Submit divides the output into multiple zip folders to facilitate their download. If such an event occurs, the possibility exists that the subject PDF and the uploaded documents may end up in two different zip folders.

> **Tip**
>
> In order for the **View** links to work, you must extract all of the contents of the zipped folders to the same location. To achieve this, right-click each zipped folder, then select Extract All and follow the instructions in the extraction wizard.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- Optimize custom rules by defining relationships between repeating forms
  You can now define a relationship between two simple repeating forms (child and parent). This reduces the amount of rule threads that run when using aggregate functions, which are used to get data from other form instances, and improves the system performance.

Optimize custom rules by defining relationships between repeating forms

You can now define a relationship between two simple repeating forms (child and parent). This reduces the amount of rule threads that run when using aggregate functions, which are used to get data from other form instances, and improves the system performance.

When you create custom rules on a repeating form item, the new **Relation Mapping Definition** field is available in the Rule Editor. This field is displayed below the Variables section and allows you to select one of your previously defined variables as a relation item. This relation item acts as a link between the target repeating form, which is considered the child table, and a parent repeating form table.

With the Relation Mapping Definition, the rule no longer runs for every form instance in the target table after an update. This reduces the rule processing time in two key ways:

- If a user updates the rule variable item on the **parent form**, the rule execution logic loads data of the relation item and generates a list of instances in the child table that need to be evaluated and updated. As a result, only the corresponding instances of the child form are evaluated and updated.
- If a user updates the rule variable item on a **child form**, the rule runs only on the current instance.

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You can find additional information in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

Study design

- Configure predefined validation rules to raise queries
  You can now configure predefined validation rules, added in form design, to validate an answer, raise a query, or both.
- Future dates now raise queries when not allowed
  Study designers can configure whether future dates are allowed for Date/Time questions or not. Starting with Clinical One Cloud Service 25.2, future date validation is now applied through queries instead of error messages that must be resolved to continue.
- Modify custom code lists in approved study versions
  Study designers can now modify an existing custom code list even if used in approved study versions.

Configure predefined validation rules to raise queries

You can now configure predefined validation rules, added in form design, to validate an answer, raise a query, or both.

About this new feature

Study designers typically add predefined rules to the form design to validate an answer, to ensure a given criterion is met, or to trigger a specific action, such as to display a dynamic question or form or to send a notification. Other scenarios can be covered by using custom JavaScript rules, which are programmed and tested by rule designers.

This enhancement enables query functionality specifically for predefined validation rules that are added to the form design. With this, your team no longer needs to create custom rules to raise queries when validation criteria have not been met. This reduces the potential programming errors and time needed to apply this kind of rule. Additionally, the validation functionality is now optional, as well as the added query functionality. This means you can now create rules on forms that can act as:

- **Validation**, which throws errors and prevents site users from performing Randomization and Trial Supply Management (RTSM) actions until the errors are resolved.
- **Validation raised as a query**, which also prevents RTSM actions. However, in this case you can close the related queries to allow the impacted RTSM actions to proceed, without first being required to address the validation error.
- **Simple query**, which identifies the answers that do not meet the given criteria for data reviewers but without impacting RTSM actions. These raised queries will follow the normal query workflow.

The RTSM actions that can be impacted by validation rules are screening, randomization and dispensation. Whether a specific RTSM action is impacted or not depends on the question settings and whether it is required for those events. The ability to identify specific questions as required for specific RTSM actions is a new feature also introduced in this release. See Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM).

Details for study designers

If you are a study designer working with predefined validation rules, here is what's new for you:

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- When you add or update a validation rule in the form design, you now have two configuration toggles available: **Validation** and **Create a Query**.
- You must activate at least one toggle for a validation rule, or you can activate them both. Depending on the rule configuration the result can be different:

Configuration	Result
Validation	An answer that does not meet the rule criteria becomes invalid and may impact RTSM actions. Invalid answers include a red outline and an error message, which is defined by the study designer in the rule configuration.
Create a Query	Queries are raised for answers that fail to meet the rule criteria, but they are not invalid and do not impact RTSM actions. Queries only appear after data is saved and submitted. However, upon data entry, a red outline surrounds the answer, and an error message appears (as in validation) to inform the site user of the failed criteria and give them a chance to correct the answer before saving it, if applicable. If data is submitted and the query is raised, the failed validation indicators disappear.
Validation and **Create a Query**	An answer that fails to meet the rule criteria becomes invalid and a query is raised on it. RTSM actions may be impacted as well. If entered data fails to meet the validation criteria, a red outline and an error message appear upon data entry. A query is then raised, but only once data is submitted. Since the answer becomes invalid, the failed validation indicators remain.

- You can still add multiple validation rules to the same question, which get evaluated using a logical operator **AND** or **OR**. It is possible to combine rules configured differently (validation-only, query-only, or both) in a single question, but you cannot combine logical operators.

You can find more information about this functionality in the *Study Designer User Guide*, after the Release Assessment Environment (RAE) upgrade.

Details for site and other sponsor users

Whether you're a site user dealing with validation errors on collected data or a sponsor user reviewing data and managing queries, here's how your workflow might be impacted by this new feature:

- If any of these rules are triggered during data collection, the site user has the option to correct the entered data and resolve it. In the case of a raised query, the site user can also provide an answer to it, for example when it is not applicable to update the entered data. After that, if a sponsor user closes the query, the validation is resolved.
  Any user with permissions to close programmed and manual queries will also be able to close these types of queries.

  > **Note**
  >
  > If there is more than one query on a question, it is possible that some are validations and some are not.

- When multiple validation rules are added to a question, there is a difference in how these conditions are processed and how the error messages display:
  - For multiple rules following an **OR** condition, the validation rules are all evaluated until one validation is met or all have been evaluated and failed. Since an OR condition only

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fails when all validations fail, all associated error messages or queries will be displayed in that case. Then, if at least one error or query is resolved, the OR condition is met and all errors disappear and triggered queries are closed.

  - For multiple validations following an **AND** condition, the system evaluates all rules. If any condition is failed, the entire condition fails and an error message or query will appear for each and all failed validations. The question remains in a failed state until all errors or queries are resolved.

- If a query is closed manually, it will not be re-evaluated unless data is updated even if the rule is updated and changes are applied with Advanced Study Versioning (ASV). Predefined validation rules will always be re-evaluated when data is updated.
- As with any other query, these queries resulting from predefined validation rules are visible and can be managed from the queries side pane, within the visit, and from the Query List page for query management at the study level. These queries are also included in the Queries report, and they display everywhere with *Auto Calculation* as the issuing user.
- Future date validations for Date/Time questions are not exactly designer validation rules. However, these are now also triggered as queries. For more information see Future dates now raise queries when not allowed.

Impact on reports

The predefined validation rules are now included in the Rules report, but separate from custom rules. To support this, the Rules report is now available in an XLSX format, instead of a CSV format, which includes all the validation rules in a separate tab called **Designer Validation rules**. In the PDF and HTML formatted outputs, there is a new section with the same name for all these predefined validation rules added in form design. For more information see Rules report is now available in XLSX format.

Additional changes to other reports are also applied to support this enhancement. The following reporting changes are introduced:

Report	Type of change	Description
Study Design report	Modified column data	In the **Validation Rules** column for forms, for validation rules added in form design, the type (*Validation*, *Validation and Query* or *Query*) is appended to the front of the existing information. For example: *Validation and Query: Exactly 1*.
Annotated CRF report	Modified column data	In the **Validations** column, for validation rules added in form design, the type (*Validation*, *Validation and Query* or *Query*) is appended to the front of the existing information. For example: *Rule 1: Validation and Query: Exactly 1*.

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Report	Type of change	Description
Rules report	New section and columns	The predefined validation rules are included in this report, in a new **Designer Validation rules** section or tab (depending on the format). See the Rules report documentation for details about the columns added to this section.
Queries report	New column	A new **Type** column is added to indicate whether it has validation functionality (*Validation and Query*), is generated by custom rules (*Auto Query*), or is a manual query (*Manual*).

Already working in a live study?

When this new feature is released, existing validation rules will get configured with only the **Validation** toggle active, to preserve existing functionality. As soon as this release is available, you can create new validation rules that create queries or update any at any time to add query functionality to existing rules.

You can apply these or any updates to predefined validation rules using Advanced Study Versioning (ASV). Find more information about the impacts of using this new feature with ASV in About Advanced Study Versioning, after the RAE upgrade.

Future dates now raise queries when not allowed

Study designers can configure whether future dates are allowed for Date/Time questions or not. Starting with Clinical One Cloud Service 25.2, future date validation is now applied through queries instead of error messages that must be resolved to continue.

Previously, Date/Time questions that didn't allow future dates were considered invalid if a future date was entered. If not resolved, these invalid dates would prevent Randomization and Trial Supply Management (RTSM) actions, such as randomization, dispensation, or screening (in case the question is required for any of those events). With this enhancement, a query is now raised on the question instead of triggering errors.

Queries can be addressed by correcting the data, or they can be closed by sponsor users with the appropriate permissions, but they do not impact RTSM events at any time. This allows site users to continue with their processes without interruption.

Already working in a live study?

If there is a Future Date validation open in a study when this feature is introduced, it will remain a validation unless the data is updated. Queries will only be raised if data is updated and submitted for the question after this enhancement is introduced.

This type of future date validation and its change in behavior, do not interfere with other validations such as those configured with predefined designer rules or custom rules. For other enhancements related to validation rules, see Configure predefined validation rules to raise queries.

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Modify custom code lists in approved study versions

Study designers can now modify an existing custom code list even if used in approved study versions.

Details for study designers

When it comes to your workflow as a study designer, here's what's new for you:

- Users assigned the *Manage Study Code Lists* permission can access and modify a custom code list by adding new items, hiding items, changing the order of values, updating the code, and applying it to an existing question that previously had the code list applied to it (if assigned the *Design Forms* permission, as well), even if the study design has already been moved to Approved.

  > **Note**
  >
  > The Value and Label for any code list item assigned to a question in an approved study version *cannot* be modified.

- The newly applied code list must be the same, previously selected code list, that was originally associated to the question.
  - If you attempt to assign a code list to a question that is *not* the preexisting code list, the system displays the message alert:

    ```
    The following question is currently used in an approved study version. You can only modify and reload the existing custom code list for this question.
    ```

  - When the preexisting code list is applied to a question, the system displays the message:

    ```
    The following question is currently used in an approved study version. Any data previously collected will remain until updated by a system user.
    ```

- A different code list cannot be applied to an existing question once the study version has been moved to Approved.
- If you apply the new code list to a question that is used in a rule in the Design container, you must review the rules and ensure that they are not impacted.
- You are required to review and update your study's randomization design or dose calculations if hidden code values are used in stratification, dose calculations, or cohort management.

  > **Note**
  >
  > If you apply the updated code list to a question that is used as a branching question, none of the code list items can be hidden. Additionally, code values used in branching cannot be hidden.

More information on managing code lists can be found in the *Sponsor and CRO User Guide* and *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

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Impact on reports, extracts, archives, and datasets

Now, the **Study Design** report reflects any code list modifications within the form's attributes.

When it comes to Oracle CRF Submit, be aware that when a label is changed and the Advanced Study Version is applied, discrepancies may occur between the user interface (UI) and the generated study version PDF.

You can find more information in the *Reporting Guide* after the RAE upgrade.

User experience

- A fresh new Redwood look
  We've refreshed the User Interface (UI) to align with Oracle's Redwood design system - bringing a cleaner, more modern look that's consistent with other Oracle products.
- Applying an advanced study version recalculates forms and visit statuses
  Applying an advanced study version change now recalculates forms and visit statuses automatically.

A fresh new Redwood look

We've refreshed the User Interface (UI) to align with Oracle's Redwood design system - bringing a cleaner, more modern look that's consistent with other Oracle products.

While the look & feel has changed, your existing workflows and navigation paths remain the same, so there's nothing new to learn.

This update is purely cosmetic, with the exception of two newly added features: locking multiple subjects at the same time and updating multiple study users at the same time. Everything else works just as it did before - now with a more sleek, modern, and polished User Interface (UI).

> **Tip**
>
> Want to learn more about the two new features with Redwood navigation improvements? Check out:
>
> - Lock and unlock multiple subjects simultaneously
> - Update multiple study users simultaneously

Applying an advanced study version recalculates forms and visit statuses

Applying an advanced study version change now recalculates forms and visit statuses automatically.

The act of implementing a study change using Advanced Study Versioning (ASV) triggers an asynchronous job to recalculate form and visit statuses for all subjects impacted by the change being applied. This removes the need for users to open a visit to force the system to recalculate the form and visit statuses.

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What happens if I open a visit or attempt an RTSM action before the job finishes?

- If you manually open a visit when the asynchronous job is still in progress, the system updates the visit status (if applicable) after checking whether all required questions are complete or not. Updated visit statuses are reflected on the visit tile.

  > **Note**
  >
  > Opening a visit does not update form statuses on the forms pane. This update is visible only after the job completes.

  Also, any new or updated validation checks are reflected on the questions as a red outline, but these do not reflect on the visit status until the job is complete. Furthermore, any queries raised (by a validation rule) are visible only when the job completes. For more information, see Configure predefined validation rules to raise queries.

  Once the asynchronous job completes, validation failures appear on the visit tile.

- If a user attempts to complete a Randomization and Trial Supply Management (RTSM) action while the job is still running, the system recalculates the validations to confirm that the RTSM action is allowed. If not, the system will, as expected, block the action. Until the job completes, the visit status and Oracle Clinical One Analytics do not reflect the permitted action.

Does the new asynchronous job recalculate form and visit status for a locked subject?

No, a user must unlock and open the visit where the ASV change was applied in order for the visit and form statuses to be recalculated; the act of unlocking a subject does not trigger a recalculation. This is current system functionality.

User management

- Update multiple study users simultaneously
  User administrators assigned with the *Study Creator* or *Global User Manager* global roles can now update multiple study users simultaneously on the enhanced **Users** tab. Review the details below to familiarize yourself with this enhancement and other updates made to the Users tab.

Update multiple study users simultaneously

User administrators assigned with the *Study Creator* or *Global User Manager* global roles can now update multiple study users simultaneously on the enhanced **Users** tab. Review the details below to familiarize yourself with this enhancement and other updates made to the Users tab.

Details for user administrators

Here's a list of new features, available on the **Users** tab, that simplify study user management.

- The user table now includes additional user details, these being the user’s name, study role, user type (sponsor, site, or design), and status (active or inactive).

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> **Note**
>
> The system uses the start and end dates (in UTC), defined under the Effective Dates section in a user's account, to determine their status.

- A new mode selector is available, allowing you to quickly view all users assigned to a specific mode. You also use the mode selector when applying updates to multiple users assigned to a mode.
- In addition to the ability to search for users, new filtering capabilities have been added, making it easy to locate a group of users. Some use cases include:
  - Updating the study role, assigned to a group of users, to a different one.
  - Assigning sites to a group of users.

    > **Note**
    >
    > You cannot unassign sites when applying bulk user updates.

  - Setting the effective dates (start and end dates) for a group of users. This includes the ability to not define end dates.
    For example, you can easily set an end date for all users that are assigned to a retired or soon-to-be-retired site, ensuring access is removed in a timely manner.
  - Send training records to a group of users.

    > **Note**
    >
    > The ability to view and send training records is only available if the global setting **Product User Training**, located on the **Users** tab, is enabled. For more information about the setting, see Turn off the training requirement for an organization.

- A new **More Actions** drop-down is available, which allows you to download and upload the user templates for creating and updating users. There are also options available to send training records to a group of users based on their training completion status.
- A new **Actions** drop-down is available at the far right of each row allowing you to view a snapshot of a user across all modes, view and send training records, edit user details, and delete a user.

Details about filtering

You can enter part of a user's first name, last name, email address, or username in the **Search field** to quickly pull up a user.

You can filter the user table by Depot (if your study includes them), Role, Site, Type (sponsor, site, or design), and User Status (active or inactive). The filters are located directly under the Search field, and there are multiple ways to use them.

- Click in the **Search** field to be presented with the list of filters. The filter selected is added to the Search field, and you are presented with a drop-down containing a list of options for that filter. Select the filter again to update your choices.

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- Alternatively, you can manually select a filter to move it to the Search field, where you are presented with a drop-down containing a list of options for that filter. Select the filter again to update your choices.

You can stack filters. For example, you can use the Site filter to locate all users associated with site 101, then use the Role filter to view only CRA users at the site.

The filters you apply remain intact even if you change tabs, return to the Home screen, or refresh the page. The filters only reset when you change modes.

Details about how to apply updates to multiple study users

Start by selecting the mode in which the changes are to be made.

Use the filters to locate the users you want to update. Using filters is optional but helpful to quickly locate them.

After applying your filters, you can select individual users by checking the box next to each name. Alternatively, to select all users, check the box to the left of the **Manage** drop-down.

After you have selected the users, choose one of the options from the **Manage** drop-down:

- Roles
- Effective Dates
- Sites
- Send Training Records

A window opens based on the selection made. Follow the prompts to apply the updates.

> **Note**
>
> A window does not open after selecting Send Training Records, but you do receive a message indicating they were successfully sent to the selected users.

A success message appears once the updates are complete.

Additional changes on the Users tab

Review the table below to familiarize yourself with other changes that were applied to the **Users** tab.

Action	Details
Assign a user	Prior to this enhancement, you selected **Create/Update Users** at the top left of the **Users** tab. You then selected **Assign a user** followed by completing the Details & Roles and Sites & Depots pages. Now, you select **Add User** at the top right of the **Users** tab. Once selected, the system presents you with a single page used to collect all of the user's details. ***Note**: You do not need to select a mode when adding a user*. The newly added user appears on the user table for those modes where a study role was selected. For example, if you selected a study role under Production and Testing, the user is added to those modes. To add the user to other modes, select a mode where the user was initially added, then edit the user to select a study role for the mode you want to add them to.

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Action	Details
Create or update multiple users at once using templates	Prior to this enhancement, • You downloaded the Create Users and Update Users templates from the **Download Template** drop-down, located in the top left of the **Users** tab. • After updating the templates, you selected **Create/Update Users** (on the **Users** tab). • You were then presented with an option to upload Clinical One SSO users or upload Federated SSO users. • Finally, you would map the roles before uploading the users. Going forward, • You download the Create Users and Update Existing Users templates from the **More Actions** drop-down (under Download Templates) located at the top right of the **Users** tab. • After updating the template, select Clinical One Users or Federated/ IDCS Users (under Upload Templates) from the same **More Actions** drop-down on the **Users** tab. • Finally, map the roles before uploading the users. ***Note**: No other changes were made to this process or the MS Excel templates.*
Update a single user	Prior to this enhancement, you would select a user on the **Users** tab, followed by the Edit option under the **Manage Users** drop-down located at the top left of the **Users** tab. Now, you select the user you want to update from the users table on the **Users** tab, and then expand the **Actions** drop-down located at the far right of each row, selecting Details (then Edit) or Edit to make the necessary updates.

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Action	Details
Send training records	Prior to this enhancement, you selected one or more users from the table and then selected Send Training Record from the **Manage Users** drop-down at the top left of the **Users** tab. There was also a link available above the right sidebar, when the User Training section was expanded, that allowed you to send training record details to the selected user. Now, there are multiple ways to send training records to users. ***Note**: The ability to view and send training records is only available if the global setting **Product User Training**, located on the **Users** tab, is enabled. For more information about the setting, see Turn off the training requirement for an organization*. • To send training records to a **single user**, go to the **Users** tab and select the user, then select Send Training Records from the **Manage** drop-down. Alternatively, you can select the **Actions** drop-down at the far right of the row, where you have multiple options. – Select the Training option to see a list of the user's training courses and the status of each. A Send Training Records link is also available here. – You can also select Send Training Records under **Actions** to skip the training details page. • To send training records to **multiple users**, go to the **Users** tab, select the users, and then select Send Training Records from the **Manage** drop-down. Alternatively, you can select one of the following options, which are available under Send Training Records on the **More Actions** drop-down. – All Users – Completed Users (select this option to send training details to any user who has completed all trainings). – Incomplete Users (select this option to send training details to any user who has at least one incomplete training).
Delete a user	Prior to this enhancement, you selected the Remove option from the **Manage Users** drop-down on the **Users** tab or you selected above the right sidebar to remove a user. Once you locate the user you want to delete, select Delete from the **Actions** drop-down located at the far right of the row, then click **Delete** when prompted.

You can find additional information in the *Add Users Guide* after the Release Assessment Environment (RAE) upgrade.

Fixed issues

- All users
- Oracle Clinical One Analytics
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Reports, archives, extracts, and notifications
- Site users and subject data

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- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

Clinical One Cloud Service automatically scrolls to the top of page when a date/time question is modified for a visit

Now, the visit page remains on the same form where data was modified. Previously, when data was updated for a date/time question that contained a custom query rule, the application would automatically scroll to the top of the visit page after the saving and validating process.

(Issue **37259277**)

Oracle Clinical One Analytics

Data Hub APIs for several datasets retrieve data with delays

Data Hub APIs now respond within the expected time frames for all Oracle Clinical One Analytics datasets, including the Study Codelist dataset and the Subject Form Items dataset. Previously, users may have encountered delays - sometimes over 15 minutes - or API failures when retrieving data. This fix improves how study data is handled during API calls, resulting in faster response times across multiple endpoints. Users can now reliably run APIs without unexpected timeouts or performance issues.

(Issue **38489911**)

Data Hub APIs for the Subject dataset may time out

Data Hub APIs now return results quickly when accessing the Subject dataset or other data sets, such as the Subject Form Items or Subject Forms datasets.. Previously, users may have experienced timeouts when retrieving code list data due to slow back end processing. This was caused by back end queries taking a longer time to complete. With this fix, data retrieval through APIs works as expected for code lists and other data types.

(Issue **38515304**)

Testing mode didn't surface Advanced Study Versioning (ASV) changes in Oracle DMW and Oracle Clinical One Analytics

Now, when a study version that includes ASV changes is moved to Testing mode, any subject data collected for forms and questions introduced or modified through the ASV process is correctly sent to Oracle DMW and Oracle Clinical One Analytics. Previously, data entered in Testing mode for Active study versions that used these ASV items wasn't transferred, resulting in incomplete runtime data for Testing mode in Oracle DMW and Oracle Clinical One Analytics.

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> **Note**
>
> This fix applies only to data captured after the fix is deployed. Existing Testing mode data from before the fix remains unavailable in Oracle DMW and Oracle Clinical One Analytics.

(Issue **38359126**)

Incremental data load takes too long to process

An optimized algorithm now more efficiently identifies and processes only the relevant changes, significantly reducing the incremental load execution time by up to 40%. Previously, the incremental load process may have exceeded 30 minutes under certain scenarios observed in Production, as all candidate records were considered for a data update. With this enhancement, the system is more responsive and puts less unnecessary load on the database, while maintaining data accuracy.

(Issue **38055482**)

ODM API doesn't return demographic fields when authorized

The unblinded ODM extract now consistently includes subject demographic fields - date of birth, gender, race, and ethnicity - when the API caller's study roles has the required data classifications and permissions. Previously, these read-only items were omitted from the JSON response even for authorized users, because the extract logic skipped hidden or read-only demographics and applied outdated access checks for users. This caused incomplete data in reconciliation and safety database uploads. The fix updates the API's permissions framework to use the new access control view introduced in the Oracle Clinical One Analytics architecture, ensuring demographics and other restricted items are properly returned. Similar improvements were applied across related datasets for consistent item access: Subject Forms dataset, Subject Form Items dataset, Subject Item SVFL dataset, and the Queries dataset.

(Issue **38469837**)

Missing verified records after data update

Now, SDV actions on standard repeating forms (Sign, Verify, Freeze, Lock) are stored with the correct INNER_REPEAT number, so Oracle Clinical One Analytics displays them against the right items. Previously, when completing form-level verification on a standard repeating form, the INNER_REPEAT number could be saved incorrectly for these tracking records. As a result, Oracle Clinical One Analytics displayed actions on the wrong repeat, even though the core Clinical One Cloud Service showed statuses correctly and the study data tables had the correct repeat links.

(Issue **37999017**)

Oracle Clinical One Analytics API pagination issues

Oracle Clinical One Analytics APIs now return consistent, complete results regardless of limit values, ensuring API pagination is stable across data sets and studies. Previously, applying limits returned varied or mismatched result sets, hindering data reliability and complicating data analysis. The applied fix standardizes the pagination logic and ordering, so users receive predictable API results that can be aggregated safely.

(Issue **38331231**)

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The Subject Forms dataset doesn't show full audit history

The Subject Forms dataset now shows both current records and the full audit history of form updates, rather than only displaying the current status. Previously, users couldn't view all past status changes - records that were version ended were omitted from the dataset, which made it difficult to track historical form status changes. After this fix, users can see a comprehensive audit of all form updates, including historical data related to form status, improving transparency and traceability.

(Issue **38274625**)

Visit status updates prevent duplicate visit IDs and lock errors

Visit status updates now create only one record per visit, even after long-running queries or database disconnections. Previously, partial commits or connection failures caused duplicate visit instance IDs in the DC_VISITS_INFO table in Oracle DMW, leading to inconsistent data and lock errors. This fix ensures each update or data insert runs only when appropriate, aligning the visit schedule and status APIs with actual database content. Users will now see accurate visit status without duplication or data conflicts.

(Issue **38120683**)

Advanced Study Versioning (ASV) changes now correctly applied to approved study versions

ASV changes are now applied only to approved study versions when a study is moved from Testing to Approved. Previously, ASV updates intended for Testing mode could unintentionally affect both test and approved study versions, leading to metadata differences between older and newer Oracle DMW metadata points. This fix ensures that ASV changes affect only the intended study versions, preventing unintended data changes and improving consistency across studies in Testing and Production modes. Users will now see accurate metadata for Production studies.

(Issue **38278228**)

Oracle DMW form values display incorrect data

Numeric values in ITEM_F fields are now displayed correctly. Previously, the system captured data from an incorrect source, resulting in numeric item types to display inaccurately.

(Issue **38239994**)

ITEM_F columns display incorrectly for measurement item types in Oracle DMW

Now, the ITEM_F columns in Oracle DMW are visible and display the correct values for measurement item types from the current schema, ensuring values are populated accurately. Previously, if a measurement item was set as text in the previous architecture, some data extraction errors would occur. This fix ensures that each item's value is sourced using up-to-date information, preventing type mismatches and improving data reliability.

(Issue **38219969**)

ITEM_F data element displays inaccurate data

ITEM_F data elements in Oracle Clinical One Analytics now correctly display both date and time, and future dates are no longer shown as past dates. Previously, after a system architecture change, ITEM_F data elements dropped the time component and incorrectly displayed future dates as dates in the past. This happened because the system truncated timestamps, removing the time and misinterpreting some dates. The issue was resolved by

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adjusting the logic to preserve the full date and time values, using a more accurate conversion method.

(Issue **38144855**)

Facilities, settings, and user management

User administrators cannot remove all roles and site assignments

User administrators can now remove all study roles and site assignments from a study user. Previously, after assigning a role or site to a user, there was no option to fully remove the role or site assignment - user administrators couldn't save the changes without assigning at least one role or site to the study user. The applied fix restores this flexibility, allowing roles and site assignments to be cleared and saved for existing users, as expected. (Issue **38430197**)

Depot-to-depot shipments don't accept larger quantities

Manual depot-to-depot shipments now allow quantities from 1 to 9,999, with messaging and limits consistently displayed across the UI and kit types. Previously, quantity input for kit types was capped at 99 due to inconsistent validation introduce with a previous feature, blocking certain shipments. This fix balances the system's validation with the intended capacity, ensuring users can create large shipments without conflicting tool tips or constraints, while still respecting lot-based availability when applicable.

(Issue **38336630**)

Query List now loads faster for forms with many ASV items

The Query List page now opens significantly faster, even for studies with forms containing many questions with ASV changes and data classifications. Previously, users experienced long and inconsistent loading times, impacting workflow and usability. With this fix, the improved logic reduces delays and improves response times - dropping load time from over two minutes to about 17 seconds - resulting in a smoother experience when accessing the Query List in studies with complex forms.

(Issue **37331039**)

Blinded depot user can update the status of kits without being assigned the required permissions

Now, when a blinded depot user is assigned at least one site and given the *Create Manual Shipments* permission, they receive a system message - `Your roles do not allow you to manage supplies.` - when accessing the Site Inventory page. Previously, when blinded depot users were assigned to at least one site and the *Create Manual Shipments* permission, they had the ability to view and manage kits in the site inventory.

(Issue **36212384**)

A randomization list isn't linked to a new study version

A re-randomization list is now automatically associated with a new study version, as expected. Previously, when moving a study to Testing, you may have encountered a "Randomization List is not available" error due to a cache issue in the application. The system failed to link the re-randomization list because cached data was unintentionally overwritten during previous randomization steps. This caused a mismatch when comparing randomization designs across study versions.

(Issue **38166723**)

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Users assigned the *Receive the Unblinded Kit Misallocation Notification* and the *Receive the Unblinded Dose Hold Notification* permissions can view all shipments for all sites

Now, users assigned both the *Receive the Unblinded Kit Misallocation Notification* permission and the *Receive the Unblinded Dose Hold Notification* permission can only view the shipments for the sites they're assigned to under the Shipments tab.

(Issue **36955042**)

Users tab takes an excessive amount of time to load

The Users tab in a study's settings now takes an adequate amount of time to load. Previously, studies with many users could experience slow loading times when accessing the Users tab. This issue was caused by the large training history logs that each user had included in the system.

(Issue **37306363**)

Replace a subject number with randomization number is still allowed after a subject has been registered in a study

Now, once a subject is registered in a study, the Replace Subject Number with Randomization Number setting on the Study Settings page is not accessible, as expected.

(Issue **37786596**)

Add Shipment to Inventory option is not available when assigned the multiple permissions

Now, site users are able to see the **Add Shipment to Inventory** option when managing their site inventory. Previously, the **Add Shipment to Inventory** option was not appearing for site users assigned the *Receive the Unblinded Dose Hold Notification* and *Receive the Unblinded Kit Misallocation Notification* permissions, as these are incorrect permissions for their role.

(Issue **36395452**)

Forms, visits, and rules

Clearing hidden dynamically-displayed questions doesn't work

When a site user clears a parent dynamic question, any linked hidden, or read-only questions with data classifications now clear without errors - even if the user doesn't have access to them. Previously, this action failed when triggered by a runtime custom rule, because the Clear Item API endpoint passed a null data classification, instead of the `ALL` parameter. This prevented hidden questions from being fetched and validated. As a result, the system displayed an error and left the child question values uncleared. The fix ensures rule-based clearing actions include all data classifications so that hidden questions are properly validated and cleared.

(Issue **37700629**)

Non-repeating lab tables don't return cleared rows

APIs that support rule execution now return cleared rows for non-repeating lab table sections, ensuring that custom JavaScript rules using `getValues()` align form instances correctly. Previously, when data in a non-repeating lab table row was cleared, that row was omitted from the API response, causing misaligned or missing values in rules. Repeating lab forms already

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returned cleared rows correctly, but non-repeating ones didn't because the API logic treated them as non-repeating objects and excluded cleared items. The fix introduces a shared logic path used by repeating lab forms, ensuring cleared rows are consistently returned for all lab table sections, including non-repeating ones.

(Issue **38371717**)

System user interface (UI) displays incorrect branch when adding, updating, or deleting branch data

Now, the correct branch is consistently displayed in the UI when adding, updating, or deleting branch data, ensuring that all changes are applied in the correct location. Previously, when a user would click on, update, add, or delete branch data, the UI would often display the incorrect branch, requiring users to manually correct their updates and confirm they were made in the intended place.

(Issue **38437568**)

Rule execution errors occur when coding terms

Oracle Central Coding context items are now correctly transferred from Clinical One Cloud Service to Oracle Central Coding. Previously, if both the route and indication context items were populated into the coding target questions by JavaScript calculation rules, it was possible that one or both of the values would not be successfully transferred to Oracle Central Coding.

This is also related to issue **37669804** in Site users and subject data.

(Issue **37895326**)

Form status does not update properly for forms containing rule-populated items

Now, flat and repeating form statuses update properly for those containing design or custom rules. Previously, when rules populated select form items, the form status would not update correctly. Additionally, when multiple forms were saved at simultaneously, their statuses would not update correctly.

(Issue **38209696**)

Adding new rules and updating existing data takes an inadequate time to process in Production mode

When adding a new rule or updating saved data, the application now processes these changes in an adequate amount of time. Previously, changes made to existing data took over 30 seconds to be saved, while adding a new rule took more than a minute for the application to finish processing.

(Issue **38267486**)

Duplicate queries no longer block closing automated queries

Users can now successfully close automated queries using custom JavaScript rules, even when duplicate or deleted entries exist. Previously, attempts to close such queries failed with an error if the application encountered duplicate records - including deleted ones - which prevented it from finding the correct open query. This fix updates how queries are identified for closure, ensuring that only active, relevant queries are targeted. As a result, users no longer experience errors when closing queries in these situations.

(Issue **36465916**)

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The getValues() helper function does not return accurate results when data flags are present (former known issue)

Using the getValues() helper function returns accurate results when questions include data flags. Previously, using the getValues() helper function to check for NULL (missing data) on date/time questions on a repeating form did not return accurate results if questions included a data flag such as Not Done, Not Applicable, or Unknown.

(Issue **36496392**)

Date and time items display inaccurately in forms

Date and time form items display correctly. Previously, date and time components appeared inaccurately for certain columns.

(Issue **38144855**)

Unable to complete the randomization visit for a subject

You can now complete randomization visits without unexpected errors, allowing the visit status to update properly. Previously, when the configuration service was down, the system couldn't complete the visit status update, leaving visit stuck in a status of In Progress and preventing progression to the next visit.

(Issue **37102836**)

Saving the Visit Start Date field might take longer when numerous visits exist in a study (former Known Issue)

When you save the Visit Start Date in a study that includes a large number of visits, the time it takes the system to save the data has improved to a more acceptable time frame.

(Issue **32342403**)

Rule validation text is not displayed for read-only questions

Now, validation error text displays for read-only items. Previously, when a validation rule failed for a read-only question, a red border indicated validation failure, but the associated validation description text, for example, *You have not selected the required option*, did not display.

(Issue **34785185**)

Cannot screen subjects due to a mix of mandatory and optional questions

A screening form now works as expected, allowing users to screen subjects without answering all questions. Previously, the system incorrectly prevented the screening if a non-mandatory question had dynamic dependent questions, requiring users to answer those items even if the initial question was left blank.

This fixed issue is part of a new feature. For more information, see Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM).

(Issue **37077702**)

Dynamic question item continues to appear intermittently after changing the initial answer value

Now, when you change an initial answer for a dynamic question that is configured to trigger additional questions, the new question is cleared and hidden. Previously, when an answer

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value was changed for an item containing a Show Question rule that elicited additional questions, the new questions would intermittently display and disappear.

(Issue **36626039**)

Unable to enter data into dynamic visits in cycles

Now, users are able to enter data into dynamically triggered visits in cycles. Previously, when Day 1 Dispensation for a cycle was initiated, the Day 1 visit in any cycle would not display, and the visit would be moved to the next cycle. This prevented users from accessing the visit entirely.

(Issue **37375355**)

Integrations

Verbatim terms don't populate appropriately

Verbatim terms are now successfully transferred to Oracle Central Coding after entry and being picked up for the GET job. Previously, some verbatim were never transferred to Oracle Central Coding, causing the coding process to miss updates unless users re-entered data as a workaround. This update ensures the expected data flow between data entry in the Clinical One Cloud Service and coding in Oracle Central Coding, ensuring all changes are captured and processed.

(Issue **38284857**)

Oracle DMW data load fails because of unblinded kit records

The data load process now correctly interprets the Version_Start parameter during view processing, preventing older audit records from remaining open, and generating duplicate records in the Unblinded Kits dataset. Previously, the data logic missed the Version_Start conditions, leaving some historical rows without proper version end markers, which created duplicates during data load and caused downstream failures.

(Issue **38315906**)

Oracle DMW data load doesn't use consistent extract table names

Oracle DMW data loads now succeed by referencing consistent table and column names across all schemas. Previously, mismatches between active and test schema table names caused data loads to fail. With this fix, names are now calculated from the test schema and stored in unified dictionary tables. All extract tables now reference these dictionaries, ensuring identical table and column names, and preventing mismatches regardless of the schema used, which improves reliability and consistency for data loading processes.

(Issue **38330398**)

Coding records don't update correctly or have duplicates

Coding requests now update with the correct context data in Clinical One Cloud Service and Oracle Central Coding without generating duplicate or invalid records. Previously, when updates or queries were processed at the same time as the coded terms, Clinical One Cloud Service created new coding IDs and marked old ones as "removed". This caused Oracle Central Coding to display multiple coding requests for the same record, leading to confusion and loss of audit history of coded terms. The fix ensures updates to the coded terms reuse the same ID, preventing "orphaned" entries.

(Issue **37566193**)

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Incorrect values display in Oracle DMW for Advanced Study Version (ASV) changes

Now, ASV changes are correctly applies only to the latest active study version when moving from Test to Active mode, ensuring the correct values are displayed. Previously, when moving a study from Test to Active mode, ASV changes were incorrectly applied to older versions, resulting in data discrepancies and incorrect values displaying in the active study version.

(Issue **38278228**)

Multiple visit ID instances appear in Data Capture Service

Now, the system ensures visits records are processed and updated correctly. Previously, the system retrieved incorrect study version data, resulting in multiple IDs generated for the same visit and visit status inconsistencies.

(Issue **38120683**)

Verbatim and context item statuses are marked incorrectly

Both verbatim and context items are now validated together successfully when coding returns are processed. Previously, when verbatim or context items were updated after form submission, and before coding returns completed, the items were marked with an incorrect status.

(Issue **37010117**)

Large CSV files now reliably sent to SFTP for each country

The VCT integration now successfully sends large CSV files to the SFTP location for every country, as expected. Previously, files over 20MB could not be sent due to a system limit, causing output deliveries to stop unexpectedly and disrupting shipment operations. This fix increases the supported file size, ensuring that even large files are consistently transferred. As a result, operations and downstream integrations continue smoothly without missed output or manual intervention.

(Issue **38259231**)

Emails now sent to correct depot address despite extra spaces

Emails triggered by the Almac integration are now correctly sent to the intended depot address, even if the Depot ID from the Clinical One Cloud Service includes extra spaces. Previously, if a depot's name had a trailing space, the integration couldn't match it with the ID in the code list. As a result, emails were sent to a default address instead of the depot's address. The fix ensures that depot IDs are now "trimmed" before matching, allowing proper email routing.

(Issue **38172469**)

SAP Shipment Rejection integration cannot process XML files

XML files are now successfully processed even if their namespace differs from the expected format. Previously, files with a valid structure but mismatched XML namespaces caused de-serialization errors during integration - such as “unexpected element” errors - leading to failed processing. The fix ensures that the XML namespace is ignored during de-serialization, allowing integrations to continue working as long as the file structure remains unchanged.

(Issue **37815624**)

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Withdrawal dates and the reason for withdrawal do not integrate with CTMS

Now, when a subject is withdrawn from a study, the date and reason for withdrawal, entered by the user performing the withdrawal visit in Clinical One Cloud Service, integrates successfully with CTMS.

(Issue **37878378**)

CTMS Site integration fails when the country name contains a comma

A site associated with a country that contains commas in their name is now successfully integrated into Clinical One Cloud Service. For example, if a site is associated with "Tanzania, United Republic of", the integration job no longer fails with a site status code of 400, stating that no country was found.

(Issue **37426697**)

Integrated forms that include instructional text create system error

Now, instructional text is hidden for integrated forms. Previously, forms integrated to Oracle InForm that included instructional text would receive a system error.

(Issue **37750681**)

Reports, archives, extracts, and notifications

User Assignment report doesn't reflect permission changes

When a User Assignment report contains historical data, it now displays permission updates and changes for users assigned to specific sites or depots, not just for users associated with all sites or all depots in a study. Previously, some updates were missing because site IDs in the reports didn't match stored values when a user was associated with individual sites. Modifications to the role would not match the Site filter (on the **Users** tab) for the selected site, causing a mismatch when looking for the history of changes to assignments. The fix standardizes site ID comparison and includes permission-only updates in the report, ensuring all relevant user changes within the selected time frame appear accurate. (Issues **38285107** and **38511005**)

Study design-related reports fail due to form rules

The Study Design and Annotated Case reports run successfully even when forms include **Must be** validation rules or null code list values. Previously, reports failed to handle null values returned by reporting queries, causing errors in the report generation process, unless form data was excluded from the reports. This fix includes robust handling of null data and consistent validation across form sections, allowing study team members to include all desired report sections and generate reports successfully.

(Issue **38245796**)

The Subject Data Extract now includes all expected fields

Users with the required data classifications permissions now consistently receive complete Subject Data Extract reports, including hidden fields. Previously, running this extract multiple times or after logging in sometimes caused certain headers and columns to be missing. This occurred because the system inaccurately assessed the user's assigned data classifications, which meant that some fields the user had permission to view were not included in the report.

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The fix ensures the report data is always complete and unaffected by other users' actions or previous runs.

(Issue **38372054**)

Oracle CRF Submit archives' Subject Event History show NULL values

Now, the Subject Event History in Oracle CRF Submit archive requests no longer displays a value of NULL for events. Previously, when a request containing multiple selected subjects, and subject events were performed by different users, the Subject Event History showed a value of NULL for majority of events.

(Issue **38272631**)

Study Design report shows incorrect dates for kits added to treatment arms

Now, the Study Design report reflects the specific date of when a kit type was added to a treatment arm. Previously, the report showed the latest modified date, instead of the date the kit types were added.

(Issue **36343281**)

Undo skip visit now records correctly as a single entry

Now, only one entry appears in your CRF Submit archives, in the Event History section, after an **Undo Skip Visit** action is performed. Previously, performing this action displayed three duplicate entries with missing details, which could confuse users reviewing a subject's event history. This fix ensures that each undo skip visit action is shown just once, providing accurate and clear tracking of visit status changes. The improvement eliminates unnecessary duplicate records and streamlines the event history for better user understanding.

(Issue **38288851**)

The Study Design report is not generated as expected

The Study Design report now appears under the **Download Reports** sidebar, as expected, when run in Testing mode. Previously, the report failed to generate due to missing data in some columns returned by the system, caused by a recent change to the reporting SQL. The issue occurred because the number of data points did not match the number of expected columns. The underlying code and SQL query were corrected to ensure consistent column and data alignment.

(Issue **37842526**)

Site users and subject data

Vendor codes aren't validated for flat forms in scheduled visits

The upsert API now returns a clear error message when a vendor code is submitted for a flat form in scheduled visits (except for unscheduled visits and cycled branch visits): "Vendor code is not applicable to non-repeating forms. Vendor code can only be used for repeating forms". Previously, the system accepted vendor codes for flat forms in scheduled visits, which caused data inconsistencies when corrections were made. This enhancement ensures vendor codes are only allowed in repeating forms or valid flat forms in scheduled visits, improving data integrity and user feedback during data entry.

(Issue **37507918**)

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Repeating form status is inaccurate when adding or removing instances

Now, adding or removing a repeating form instance doesn't change the status of other instances in the database. Previously, creating or deleting a repeating form could unexpectedly mark earlier form instances as incomplete or completed, causing confusion and potential data issues in reports. With this fix, only the correct instance's status is updated, ensuring all repeating form statuses remain accurate and reliable.

(Issue **38198276**)

Duplicate code list options appearing in forms

Choice questions (check boxes and radio buttons) show each choice only once, as specified in the associated code list. Additionally, users can change answers without errors, and dynamic questions appear correctly, if associated with any choices in the radio button question. Previously, some code list values differentiated only by trailing spaces, caused duplicate options and blocked answer changes. This issue also prevented dynamic elements (questions, forms, sections, form associations) from being displayed. For example, a question displayed two "Yes" options, and selecting either of them produced errors and hid a dynamic child question. We adjusted the process used to identify Advanced Study Versioning changes to the study to ensure only new, removed, or modified code list labels are updated, while leaving unchanged labels as is.

(Issue **38255228**)

Forms incorrectly pre-filled with data

Now, lab forms with automated query custom rules only display data for the current visit, preventing confusion. Previously, data entered in a lab form associated with Visit A, for example, could incorrectly appear in the same lab form for Visit B, even though no data had been entered during Visit B yet and no data was actually saved in the database. The issue is fixed by adding a check for the current visit ID, making sure only the right data displays.

(Issue **38316955**)

Errors occur when saving data for Route of Administration and Indication terms

Now, when both Route of Administration and Indication are used as context items in Oracle Central Coding, and both are populated by rules, they will be transferred, as expected. to Oracle Central Coding with the verbatim term. Previously, after the rules populated the values on the form, an error could occur during the transfer process to Oracle Central Coding that would result in the context items not being transferred as expected.

(Issue **37669804**)

Visits are grouped incorrectly after study version and branch updates

The visit order now follows the schedule of the study version in which the most recent visits were completed. Previously, if multiple branch visits were completed by subjects in different study versions, and the visit branch schedule changes (for example, a visit or branch visit is removed, added, or re-ordered), visits could be incorrectly grouped at the end of the subject's visit schedule.

(Issue **36400347**)

Form status isn't updated correctly when questions are populated by custom rules

Site users now see the form status marked as **Complete** after questions populated by calculation rules are answered, allowing actions such as dispensation to proceed as expected.

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Previously, completed non-repeating, one-section (flat) forms incorrectly displayed as **In Progress** when some fields were filled by custom JavaScript rules, preventing certain actions and impacting downstream integrations. The change ensures that form and visit statuses are updated appropriately when one or more questions within the visit are populated by a JavaScript calculation rule.

(Issue **38209696**)

Status of lab form with hidden or optional questions doesn't update after data entry

Lab forms with only hidden or optional questions in the flat section now show a Complete status after all required questions are answered and data is saved. Previously, even when users completed all required questions, the lab form status remained Incomplete, causing confusion. This fix ensures that completing all required questions updates the lab form's status, aligning the visible status with the backend logic, and allowing clearer tracking of visit progress and completion.

(Issue **36505556**)

System doesn't consider the latest study version for a locked and skipped visit

The system now correctly displays and locks forms from the current study version, even when a visit was skipped in an older version. Previously, when a visit was skipped in an older study version, and then locked in a new study version, forms in the new study version displayed incorrectly. Additionally, new forms associated with the new study version appeared as Not Answered in the old study version.

(Issue **38193545**)

Unable to enter data in a subject visit due to duplicate form level signed records being created

Now, site users can enter data in a subject visit, and depending on whether the data is signed or unsigned afterwards, only one form level record, either signed or unsigned, is generated. Previously, site users were not able to enter data in a subject visit due to duplicate form level records, both signed and unsigned, being created, resulting in system errors.

This issue occurred when data was previously entered into a form through the execution of custom JavaScript rules.

(Issue **37845829**)

Scheduled visits now display only after completing current visit

Scheduled visits are now displayed in a subject's schedule only after the current required visit is fully completed. Previously, if a user started an unscheduled visit after branch visits had begun, simply answering any question in it could incorrectly display the next scheduled visit in the subject schedule - even when the current visit was not completed. For example, entering a date in an unscheduled visit could cause Visit 5 to appear before Visit 4 was done. The fix excludes unscheduled visits from the scheduling logic to ensure accurate sequencing.

In Release 26.0.1, we suppressed visits that were displayed incorrectly due to this big; if a subject later reaches one of these visits as part of the normal schedule, the visit will automatically reappear in the user interface (UI).

(Issue **38260677**)

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Unable to complete choice questions that contain more than 10 options

Now, the system saves selected answers for choice questions that contain more than 10 options. Previously, if you selected an option in position 10 or greater for a choice question, the system would present a misleading error message and prompt you to refresh the page. In turn, this blocked you from saving the form. This fix restores consistent data handling, ensuring forms with many choices work as expected.

(Issue **38235953**)

Visit status remains as In Progress when all questions are populated by rules

Now, when all form questions in a visit are populated using custom JavaScript calculation rules, the correct visit status is displayed as Completed. Previously, the visit's status remained In Progress even after all fields were populated by the calculation rules. In order to update the visit's status to Completed, site users had to manually re-enter the visit date as a workaround. With the fix, when all required fields in a visit's forms are populated by JavaScript rules, the visit status now correctly updates to Completed, with no need for further user input.

(Issue **38247383**)

Extra visits are added in a subject's visit schedule

Now, if a site user navigates to another subject, using the subject selection drop-down in the upper-right corner of the Visit page - while data is saving for the current subject - there is no longer a risk that unexpected visits will be added to the new subject's visit schedule. Previously, navigating between subjects while subject data was saving for the original subject could result in visits that exist for the original subject, being incorrectly added to the second subject's visit schedule.

In Release 26.0.1, we suppressed visits that were displayed incorrectly due to this big; if a subject later reaches one of these visits as part of the normal schedule, the visit will automatically reappear in the user interface (UI).

(Issue **37110046**)

Lab normal updates not saved if rule execution fails

Lab normal values are now correctly saved and reflected in lab forms, even when the process of running a rule fails. Previously, if lab forms had custom JavaScript rules referencing lab normal ranges, any update to lab normals (such as adding or updating missing low or high values), or adding/updating referenced data (eg. gender, date of birth) failed silently due to a backend rule error. This prevented updates from appearing in subjects' forms. To fix the issue, the process of running custom JavaScript rules is separated from the process of saving data, allowing lab normals to be stored even if rules don't execute successfully.

(Issue **37914482**)

Previous visit becomes the current visit in the schedule when cleared and its status moves to *New*

Now, when a previous visit's data is cleared and its status updates to *New*, the current visit remains the current cycle's visit. Previously, even when there were other visits in the schedules, a previous visit would become the current cycle's visit when its data was cleared and the status updated to *New*.

(Issue **37375385**)

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Dispensation Information dialog displays screening number

Now, after randomization is complete and drug dispensation is initiated, the Information dialog displays the randomization number. Previously, the Information dialog showed the screening number instead of the randomization number after randomization completed and drug dispensation was initiated.

(Issue **37768406**)

System allows additional data entry before data fully refreshes

Now, after you enter data in a form containing date/time questions and click outside the form to allow saving and validating, the system disallows any additional data entry. Previously, after a user would enter data for a form that included date/time questions, the system would continue to allow additional data to be entered before the data could refresh through the saving and validating process. This resulted in a system generated error.

(Issue **37258410**)

Fixed issues in 25.2.1.5

- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

Facilities, settings, and user management

It appears to View-only users that it is possible to edit SDV settings when it is not

Now, users can edit Source Data Verification (SDV) settings only in modes where they have edit permissions. Settings are grayed out in modes where edits cannot be made.

Previously, view-only users could make changes and select **Apply Changes** in modes where they did not have edit permissions; no changes were saved, and no message indicated this, creating confusion for the user.

(Issue **37816125**)

User administrators encounter a frozen screen when attempting to add sites to users

Now, user administrators can successfully assign sites to users even when they do not have depots associated with their accounts.

Previously, the user interface froze when user administrators without depots associated with their accounts attempted to add sites to users.

(Issue **38198217**)

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Forms, visits, and rules

Error encountered when a user tried to clear a selected lab when no data was previously saved

Now, when a user selects **Clear Lab Selection** from the **Lab** drop-down and no data has been captured for that lab, the system clears the previously selected lab without error.

Previously, the system displayed the following error: “An issue occurred in the system. Try performing this action again.” The lab value was not cleared.

(Issue **38198138**)

Details for the Visit Date are not displayed for users assigned to a non-data entry study role

Now, the Answer & Visit History sidebar displays the Visit Date details for users assigned to a non–data entry study role when the visit date has an associated (active) rule.

Previously, the visit date was skipped, and the system displayed the answer and visit history for the first question on the first form.

(Issue **38504328**)

View-only users can select from the Select Lab dropdown on a lab form

Now, users assigned to a view-only study role can no longer select from the **Select Lab** value dropdown. The dropdown is now disabled and displays the previously selected lab.

Previously, the dropdown appeared editable, but the change was blocked at submission, which caused confusion.

(Issue **37246186**)

Source Data Verification (SDV) checkboxes do not appear for lab form and two-section repeating form rows

Now, data verification checkboxes appear, where applicable, for each row in lab forms and two-section repeating forms.

Previously, due to the Redwood upgrade, the checkboxes were rendered but were obscured by the repeating form's rows. As a result, users had to validate data at the question level, adding unnecessary effort.

(Issue **38540346**)

Route of Administration and Indication are missing in Oracle Central Coding for restored rows

Now, restoring a previously deleted repeating form row also restores the Route of Administration and Indication values to the applicable system tables, making them available again in Oracle Central Coding.

> **Note**
>
> The Concomitant Medications form typically includes Route of Administration and Indication, which are used during medical coding.

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Previously, the data for these fields was not fully restored, resulting in missing values in both the applicable system tables and Oracle Central Coding.

(Issue **38553728**)

Users prevented from entering data in a Logs visit after a site's study version was updated

Now, site users no longer encounter errors when entering data in a Logs visit after the site's study version changes.

Previously, this occurred if a repeating form was deleted and the visit contained no data when the new study version was applied to the site. This was due to a conflict between the study version stamped on the Logs visit and the one assigned to the site.

(Issue **38528093**)

Fully verified visits containing lab forms are incorrectly shown as unverified (former Known Issue)

Now, the green check mark appears, indicating that all data for a visit, including those with lab forms, has been verified.

Previously, if a user verified some data, exited, and later reentered the visit to complete verification, the green check mark did not display. This made it appear that verification remained incomplete.

(Issue **36122564**)

The Create Visit Schedule (POST) API creates Adverse Event (AE) events when instance number is not null

Now, validation added to the Create Visit Schedule (POST) API enforces that eventInstanceNum is null when creating Adverse Events.

If a request attempts to create an adverse event visit with a non-null instance number, the API returns an error. This prevents integration failures by allowing event creation only when eventInstanceNum is null.

(Issue **38552905**)

Integrations

The Oracle Central Coding GET job results in UNDERLYING_SERVICE_DOWN errors

Now, if a user updates a verbatim term or an associated context value between successive GET job runs, Oracle Central Coding no longer encounters UNDERLYING_SERVICE_DOWN errors. This exception was not previously handled in the code.

> **Note**
>
> The Get jobs purpose is to retrieve uncoded or edited (after coding) verbatim terms and return them to Oracle Central Coding to be coded.

(Issue **38461830**)

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The CTMS Subject Visit (SV) integration fails when the label for a code list option includes a dollar ($) symbol

Now, the Oracle Siebel CTMS Subject Visit (SV) integration successfully imports data into CTMS when a code-list option label includes the dollar sign ($).

(Issue **38353201**)

Randomization and kits

Read-only users can no longer see the site options on the Shipments tab under Supplies

Now, users assigned to a read-only study role that includes the *View Shipments to Sites* and *View Site Inventory* permissions can once again see the options in the Site drop-down list. This list appears on the Shipments tab under Supplies within a study.

The ability to view these options was inadvertently removed during the last Clinical One Cloud Service upgrade.

(Issue **38478524**)

Reports, archives, extracts, and notifications

The Subject Data report shows N/A for Form Title and Question labels when a visit was skipped in a previous study version and locked in a new one

Now, only those forms included in the visit at the time it was skipped appear in the report. Forms added in a new study version and assigned to a site after the visit was skipped are included in the report if the visit is unskipped.

Previously, forms that were added to the visit after it was skipped were incorrectly included in both the visit and report output.

(Issue **38193558**)

Site users and subject data

Screen Fail is available under Manage Subjects in the Screening visit for Enrolled subjects

Now, when you open the screening visit for a subject in the enrolled state, the Screen Fail option is no longer displayed under **Manage Subjects**.

Previously, using the screen fail option in the screening visit for an enrolled subject resulted in an error because the system treats the transition from enrolled to screen failed as invalid.

(Issue **36230101**)

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Release impact on other applications

This document describes the known impact and limitations that new features and enhancements introduced in Clinical One Cloud Service 25.2 may have on downstream applications.

Oracle Clinical One Analytics also known as Data Hub

Some new features and enhancements in this release impact datasets in Oracle Clinical One Analytics as follows:

- No new runtime datasets will be introduced with the new adverse event data collection functionality. For more information, see Clinical One Cloud Service to Safety integration.
- New runtime datasets for the new Clinical One Cloud Service to Oracle Argus Safety integration will be introduced as part of a future release. For more information, see Clinical One Cloud Service to Safety integration.

Clinical One Digital Gateway configured integrations

Some new features and enhancements in this release impact Clinical One Digital Gateway integrations as follows:

- The restoration of deleted repeating forms is not currently supported by integrations that send data to Clinical One Cloud Service, such as the Multi IWR or Data Intake integrations. For the CTMS integration, data generated by deleting or restoring a form will not be integrated, unless a visit completion or data update event is triggered by these actions. For more information, see Restore and view deleted forms.
- With this release, sponsor users can allow site users to screen, randomize, and dispense kits with minimal data collection. The Clinical One Cloud Service to iMednet EDC integration does not support this feature as part of this release. Instead, Clinical One Digital Gateway integrates screening, randomization, and dispensation data on completion of visits, not as these events occur. For more information, see Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM).
- The new subject related document upload functionality is not supported for Clinical One Digital Gateway integrations. For more information, see Upload and store any documents for your study.

Oracle Life Sciences Data Management Workbench integrations

Some new features and enhancements in this release impact Oracle DMW integrations as follows:

- The new subject related document upload functionality will be added in an upcoming release. For more information, see Upload and store any documents for your study.
- With this release, sponsor users can allow site users to screen, randomize, and dispense kits with minimal data collection. Study design dataset changes will not flow through to Oracle Life Sciences Data Management Workbench and the following columns will be introduced as part of an upcoming release:
  - REQ_SCREENING
  - REQ_RANDOMIZE
  - REQ_DISPENSE

  For more information, see Improved data entry workflows for Data Collection and Randomization and Trial Supply Management (RTSM).

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- Patch set release impact for other applications
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Patch set release impact for other applications

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Oracle Life Sciences Data Management Workbench

- As part of this release, a new dataset has been introduced to support changes in the Sign, Verify, Freeze, and Lock (SVFL) statuses for objects (visits, forms, or questions). The enhancements to clinical views or the additional operational tables in support of this new dataset will be added as part of an upcoming release. For more information, see New datasets to track sign, verify, freeze, and lock actions.
- The newly implemented lock status will be introduced as part of a future release. For more information, see New data element to track visit, form, and item level locks.
- The new data elements related to order type and forced randomization will be added as part of a future release. For more information, see Enhancements to Oracle Clinical One Analytics datasets.
- Clinical data extracts now support loading data for the **STUDY** column from the Study Identifier, found in the **General** tab of the Study Settings of a Clinical One Cloud Service study. Previously, STUDY information would be loaded from the Study Version Name related to that study's clinical data. For more information, see Enhancements to Oracle DMW clinical data extracts.

ODM Extract

- Sign, Verify, Freeze, and Lock (SVFL) audit transactions are not included in the ODM extract as part of this release. For more information about this new feature, see New datasets to track sign, verify, freeze, and lock actions.
- The newly implemented lock status is not currently reflected in the ODM Extract. For more information, see New data element to track visit, form, and item level locks.

Rest API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.2.

Permissions

- The *ec-designer-study-svc* permission has been added to access some APIs of the Designer category.

Services updates

The following service has been added:

- Designer Study

The following services are updated:

- Data Capture
- Data Hub
- Data Integration

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- Designer
- Designer EDC
- Notifications
- Query
- Randomization and Supplies
- Rule Designer
- Sites and Depots
- Users, Permissions and Roles

Designer Study

> **Note**
>
> Designer Study endpoints are listed under the Designer category.

Change	Endpoint
New	• POST /v3.0/studies/{sourceStudyId}/copy • GET /v4.0/studies/{studyId}/statuses/latest

Data Capture

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/safetycase/{id} • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/nextVisitAction • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/visitstatus • POST /v12.0/studies/{studyId}/{mode}/dataelements • GET /v13.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • POST /v15.0/studies/{studyId}/{mode}/visitstatus/subjects • GET /v2.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/form/dataelements • PUT /v4.0/studies/{studyId}/{mode}/dataelements/clear/{scope} • POST /v4.0/studies/{studyId}/{mode}/dataelements/multirepeatingform • GET /v4.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata • DELETE /v4.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements • GET /v8.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items • POST /v8.0/studies/{studyId}/{mode}/subjects/visitschedule

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Change	Endpoint
Deprecated	• POST /v10.0/studies/{studyId}/{mode}/dataelements • GET /v10.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v10.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • GET /v11.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v11.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v11.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v12.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v13.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v2.0/studies/{studyId}/{mode}/dataelements/multirepeatingform • DELETE /v2.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements • POST /v3.0/studies/{studyId}/{mode}/subjects/randomizeordispense • POST /v3.0/studies/{studyId}/{mode}/subjects/visitschedule • PUT /v3.0/studies/{studyId}/{mode}/subjects/{subjectId} • POST /v4.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v4.0/studies/{studyId}/{mode}/subjects/{subjectId} • GET /v5.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items • POST /v5.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v6.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items • POST /v6.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v8.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • POST /v8.0/studies/{studyId}/{mode}/visitstatus/subjects
Deleted	• POST /v6.0/studies/{studyId}/{mode}/dataelements

Data Hub

Change	Endpoint
New	• GET /v10.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v10.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v7.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v8.0/studies/{studyId}/{mode}/odm/metadata

Data Integration

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/dataElements/subjects/{subjectId}/documentDetails

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Designer

Change	Endpoint
New	• POST /v10.0/studies/{studyId}/studyDesign • GET /v12.0/studies/{studyId}/versions/{version}/forms/randomizationfactors • POST /v2.0/studies/{studyId}/forms/{formId}/choiceoptions • GET /v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/cohorts • GET /v3.0/studies/{studyId}/approved/choiceoptions • GET /v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/strata • POST /v6.0/studies/{studyId}/allForms • POST /v4.0/studies • PUT /v5.0/studies/{studyId} • GET /v7.0/studies/{studyId}/statuses/{version} • GET /v7.0/studies/{studyId}/statuses • POST /v9.0/studies/{studyId}/design

Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/e2bmapping/all • GET /v1.0/studies/{studyId}/versions/{version}/formssummary • POST /v19.0/studies/{studyId}/versions/{version}/forms • GET /v19.0/studies/{studyId}/versions/{version}/forms • GET /v19.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v19.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v19.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v19.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v19.0/studies/{studyId}/versions/{version}/forms/{formId} • GET /v19.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms • GET /v2.0/studies/{studyId}/{mode}/forms/formitems • GET /v2.0/studies/{studyId}/{mode}/forms/latest • POST /v4.0/studies/{studyId}/lockObjectDetails

Notifications

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/report/{reportName}

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Query

Change	Endpoint
New	• GET /v11.0/studies/{studyId}/{mode}/openQueryDetails • GET /v11.0/studies/{studyId}/{mode}/queryDetails • POST /v2.0/studies/{studyId}/{mode}/querymgmt/openQueryList • POST /v2.0/studies/{studyId}/{mode}/querymgmt/queryList

Randomization and Supplies

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/reports/supplysettingsaudit • POST /v2.0/studies/{studyId}/{mode}/reports/cohortenrollments • POST /v2.0/studies/{studyId}/{mode}/reports/cohortenrollments/history

Rule Designer

> **Note**
>
> Rule Designer endpoints are listed under the Rules category.

Change	Endpoint
New	• POST /v2.0/rule/studies/{studyId}/{mode}/ruleIds/operands

Sites and Depots

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/site/{mode}/{sdfId}

Users, Permissions and Roles

Change	Endpoint
New	• GET /v1.0/authstudies/{studyId}/siteDepot/users

- Rest API patch updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.2.1.

Rest API patch updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.2.1.

Services updates

The following services are updated:

- Data Actions
- Data Capture

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- Data Hub
- Data Integration
- Sites and Depots
- Users, Permissions and Roles

Data Actions

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/subjects/bulkaction

Data Capture

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/subjects/forResupply • PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/replaceSubject • POST /v16.0/studies/{studyId}/{mode}/visitstatus/subjects • PUT /v2.0/studies/{studyId}/{mode}/codingstatus/codedItems • GET /v6.0/studies/{studyId}/{mode}/subjects • GET /v7.0/studies/{studyId}/{mode}/subjects/{subjectId} • GET /v9.0/studies/{studyId}/{mode}/subjects/sitestudyversion • POST /v9.0/studies/{studyId}/{mode}/subjects/visitschedule
Deprecated	• POST /v4.0/studies/{studyId}/{mode}/subjects
Deleted	• POST /v1.0/studies/{studyId}/{mode}/asynch/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/reports/{reportName} • POST /v1/studies/{studyId}/{mode}/report/{reportName} • POST /v2.0/studies/{studyId}/{mode}/report/{reportName} • POST /v3.0/studies/{studyId}/{mode}/report/{reportName} • POST /v4.0/studies/{studyId}/{mode}/report/{reportName}

Data Hub

Change	Endpoint
New	• POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms/actions • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/items/actions • POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/visits/actions • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v11.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v12.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits

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Data Integration

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/subjects/forResupply • GET /v4.0/studies/{studyId}/{mode}/subjects/history/all

Sites and Depots

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/sdfs/lov/{pathAttr}
Deprecated	• GET /v1/studies/{studyId}/{mode}/sdfs/lov/{pathAttr}

Users, Permissions and Roles

Change	Endpoint
New	• POST /v1.0/authstudies/{studyId}/userdetails • GET /v1.0/authstudies/{studyId}/users/{userId}/userrights • PUT /v1.0/authusers/studies/{studyId}/users/effectivedates • PUT /v1.0/authusers/studies/{studyId}/users/roles • PUT /v1.0/authusers/studies/{studyId}/users/sites

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6

Clinical One Cloud Service and Clinical One Digital Gateway 25.1

- Patch log
  This page briefly describes the history of fixed issues and new functionality applied on top of the 25.1 release.
- What's new
- Fixed issues
- Release impact on other applications
  This document describes the known impact and limitations that new features and enhancements introduced in Clinical One Cloud Service 25.1. may have on downstream applications.
- Rest API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.1.

Patch log

This page briefly describes the history of fixed issues and new functionality applied on top of the 25.1 release.

Table 6-1 Patch log

Release Number	Release Date	Notes
25.1.1.4	26-June-2025	For this release, we fixed issues related to forms and extracts. For more information, see the following: • **38071927** in Reports, archives, extracts, and notifications • **38068146** in Forms, visits, and rules

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Table 6-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 25.1.1.3	28-May-2025	For this release, we fixed several issues related to Oracle Clinical One Analytics. For more information, see the following issues in Oracle Clinical One Analytics: • Issue **37925063** • Issue **37924980** • Issue **37925071** • Issue **37924902** We also included two key notes related to the Oracle Clinical One Analytics functionality. For more information, see the revision history of the *Analytics User Guide*.
Release 25.1.1.2	06-May-2025	For this release, we applied required security updates. Also, we fixed several issues related to Oracle Clinical One Analytics datasets, permissions, notifications, and form text fields. For more information, see the following: • For issue **37756629**, see Oracle Clinical One Analytics. • For issues **37664506**, **37644881**, and **37669116**, see Reports, archives, extracts, and notifications. • For issue **35763244**, see Site users and subject data. • For issue **37813937**, see Randomization and kits.
Release 25.1.1.1	11-April-2025	For this release, we fixed an issue related to visit branches. See issue **37777103** in Forms, visits, and rules.

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Table 6-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 25.1.1	18-March-2025	For this release, we introduced new features and enhancements in the What's new section. For more details, see: • Import Electronic Health Record (EHR) data • Update tabular forms included in live studies • Manage subject event related data and visits better • Trace queries for a target question • Include or exclude screen failed subjects from Source Data Verification • Support for undoing subject events • Enhanced kits pooling for the quantum shipment model • Enhancements to the Projected Supply (Unblinded) report • Review Source Data Verification (SDV) status across subjects and sites in Oracle Clinical One Analytics • Improved performance in Oracle Clinical One Analytics with new data elements to track data reliability For a detailed list of fixed issues, look for the following issues in the Fixed issues section: • Issue **37491783** in All users • Issue **36976923** in Oracle Clinical One Analytics • Issues **33131649**, **36846469**, **34663292**, **36908511**, **37222257**, **36874703**, **35358331**, **37615271**, and **37583470** in Forms, visits, and rules • Issues **37582436**, **37263806**, **36884046**, **37009038** in Integrations. • Issues **36797483**, **37386222** in Randomization and kits • Issues **37330486**, **37538595** in Reports, archives, extracts, and notifications • Issues **36836388**, **37044789**, **37649070**, **37570275**, **37330940** in Site users and subject data

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Table 6-1 (Cont.) Patch log

Release Number	Release Date	Notes
		For more information on REST API updates and downstream impact, see the following: • Patch set impact on other applications • Rest API patch updates
Release 25.1.0.2	03-March-2025	For this release, we fixed one issue related to code lists. For more information, see issue **37541991** in Code lists.
Release 25.1.0.1	25-February-2025	For this release, we fixed several issues related to integrations and ODM-XML extracts. For more information, see the following: • Issues **37607525** and **37619360** Integrations • Issue **37522360** in Reports, archives, extracts, and notifications

What's new

- Data collection
- Data review
- Integrations
- Randomization and trial supply management
- Reporting, archives, and analytics
- User experience
- User management

Data collection

- Import Electronic Health Record (EHR) data
  Site users can now import EHR data into Clinical One Cloud Service studies leveraging the Oracle Clinical Connector (OCC).
- Update tabular forms included in live studies
  Study designers can now perform Advanced Study Versioning (ASV) changes to tabular forms that include label items. This includes lab forms, repeating forms with label items, and the repeating section (Questions in the Table) with label items, included in a two-section form.
- Manage subject event related data and visits better
  Sponsor and site users can view the Screen Failure, Study Completion, and Withdrawal visits until all data is removed or the related statuses are reverted, allowing site staff to access undone visits during this time. Site users can also edit a subject's study completion or withdrawal date, as well as the reason specified for a subject's withdrawal.

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Import Electronic Health Record (EHR) data

Site users can now import EHR data into Clinical One Cloud Service studies leveraging the Oracle Clinical Connector (OCC).

Previously, clinical trial coordinators and researchers spent valuable time manually reentering subject data from an EHR system into an Electronic Data Capture (EDC) system like Clinical One Cloud Service. This manual process, which involved duplicate data entry, increased the chance of data discrepancies, creating additional work, and increased costs.

When enabled for a study, OCC allows site users to easily import EHR data directly into Clinical One Cloud Service forms for new and existing subjects, improving efficiency and data quality.

OCC connects to various EHR systems to extract and normalize patient data, creating a single record for each subject.

After enabling a study, mapping the questions, associating a site with a connector, and linking subjects, a site user can open a visit and select **Import EHR Data**. Once selected, OCC establishes a connection with Oracle technology Health Data Intelligence (HDI) to obtain the EHR data for questions mapped during study design. The system presents the data to the user for selection before automatically importing it.

Before you work with this feature

Global user managers and site user administrators should be aware of three new permissions, as well as one existing permission that has some additional capabilities.

Permission	Type	Details
View EHR Connectors (New)	Global	This global role allows sponsor users to view the Oracle-created connectors on the **EHR Connectors** tab under Global Settings.
Create and Manage Sites (Existing)	Sponsor	In addition to the ability to create and manage sites, this permission now enables sponsor users to select a connector from the **EHR Connections** setting for participating sites. You can do this on the **Sites & Labs** tab under Study Settings.
Link and Unlink Subject with EHR Patient (New)	Site	Allows site users to link a subject number to the subject's Medical Record Number (MRN), making it possible to import their Electronic Health Record (EHR) data.
Manually Update EHR Imported Data (New)	Site	Allows site users to update, delete, and clear Electronic Health Record (EHR) data after import.

How it works

Contact your Oracle point of contact for more information if you wish to integrate your study with OCC. In the meantime, here's a brief overview of the process:

1. A sponsor decides they want to enable OCC for a study and reaches out to their Oracle point of contact.
2. Oracle onboards participating sites in HDI and creates the necessary connectors in OCC.
3. The Clinical One Cloud Service site administrator maps each site to their connector.

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4. During the study design period, the study designer maps the relevant questions to the appropriate EHR data dictionary element.
5. Site users link subjects (new and existing) to their Medical Record Number (MRN).
6. For linked subjects, a new button called **Import EHR Data** is available. When selected, the system presents the subjects' EHR data. The user chooses which data to import, and upon selecting **Submit**, the system automatically populates the questions.

> **Note**
>
> The same validation checks apply to imported data as they do to manually entered data.

Details for sponsor users

You can easily view a list of Oracle-created OCC connectors and establish the necessary connections between participating sites and their respective connectors. These simple steps enable new features for site users, allowing them to quickly view and import a subject's EHR data, eliminating the need for duplicate data entry.

- The **General** tab under Study Settings displays a new label, **Oracle Clinical Connector Enabled**. This is the first indication that the feature has been enabled for the study.
- You can view a list of available connectors on the new **EHR Connectors** tab, under Global Settings.
- You can map your sites to their OCC connector using the new **EHR Connection** dropdown, located on the **Sites & Labs** tab.

You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for study designers

A few extra steps in the design phase can result in more efficiently designed studies and downstream benefits for site users and subjects. Easily map form questions to elements in an Oracle-managed data dictionary and use new pre-seeded code lists to ensure successful data import and minimize data cleaning.

- You can find a new setting named **EHR Mapping** under the Advanced sidebar when adding or editing form questions. This setting allows you to map form questions to EHR data dictionary elements. Below is a partial list of the EHR data dictionary categories and elements. A complete list will be available in the *Study Designer User Guide*, under the title Data dictionary question type mapping reference guide, after the Release Assessment Environment (RAE) upgrade.
  - **Demographics**: Birth Date, Birth Sex, Ethnicity, and Race.
  - **Labs**: Lab Test Name, Lab Result, and Lab Result Units.
  - **Vitals**: Body Height, Body Weight, BMI, Body Temperature and the associated units and dates of collection.
  - **Medications**: Medication Name, Medication Dose, and Medication Dose Units.
  - **Medical History**: Medical History Diagnosis, Medical History Start Date, and Medical History Status.
  - **Procedures**: Procedure Name and Procedure Start Date.

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- You can access new EHR code lists (available in English only) by selecting **Code List** during the question creation and mapping process. These custom code lists are mapped to the EHR data dictionary and include lists for race, sex, ethnicity, and units, to name a few.
- During major releases, Clinical One Cloud Service adopts updated versions of the data dictionary and associated code lists. This ensures that your EHR-enabled study uses the latest EHR data dictionary.
- The EHR mapping feature is available for your library studies, so you don't have to recreate the mappings each time.

You can find additional information in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

With just a few clicks, you can link a subject to their Medical Record Number (MRN), then import their EHR data, removing the need for redundant data entry. You can even re-import data repeatedly, guaranteeing the most accurate data for your subjects.

> **Note**
>
> You do not need to link all subjects in a study. You determine which subjects to link.

- For OCC-enabled studies, you must provide the subjects' MRN when linking new or existing subjects.
  - For new subjects, the process begins by linking their Clinical One Cloud Service subject number to their MRN. This is referred to as Subject-Patient linking and has been seamlessly added to the add subject process.
  - For existing subjects, select the new **Link EHR Patient** option in the **Manage Subjects** drop-down. Additionally, you can remove a Subject-Patient link by using the new **Remove EHR Link** option, also available in the **Manage Subjects** drop-down.
- The **Import EHR Data** button becomes available on the Subject Visit screen after you link a subject. When you select it, the system presents you with the subject's EHR data. You can then select the specific data you want to import.

  > **Note**
  >
  > The data classification rules, defined in Clinical One Cloud Service, determine the EHR data presented. If a question is not visible in the study, then the EHR data associated with it is not available for selection and import.

- Users assigned to a study role that includes the *Update EHR Data* permission have the ability to edit data after import if necessary.

You can find additional information in the *Site User Guide* after the Release Assessment Environment (RAE) upgrade.

Impact to reports, extracts, and datasets

To support this enhancement, we introduced the following reporting changes:

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Report	Type of change	Description
Annotated Case Report Forms	Modified data element description	The **Advanced** column includes **EHR Mapping** and displays the data dictionary mapping values for the parent and child (if applicable). For example, EHRMapping:Birth Sex or EHR Mapping:Labs-Lab Test Name.
Sites and Depots	Modified data element description	The **Attribute** column, in the Site Additional Information section, includes **EHREnabled** and displays the EHR Connector (Health System) name under the **Data** column.
Study Design	Modified data element description	The **Properties** column, in the Forms section, includes **EHR Mapping** and displays the data dictionary mapping values for the parent and child (if applicable). For example, EHR Mapping:Birth Sex or EHR Mapping:Labs-Lab Test Name.

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Report	Type of change	Description
Subject Data	Modified data element description	• **User Name** displays the logged-in user who imported the data. • **Date & Time** indicates when the data was saved. • **Type of Change** indicates if the data was created (initial import) or modified (subsequent imports). • **Value** provides the imported EHR data value. • **Reason for Change Comment** includes the following: – **Data Originator**: Indicates the connector name plus the HDI Record ID. – **Date of Collection**: Displayed as YYYY-MM-DD (if collected). – **OCC Mapped Codes**: Provides the codes from the source EHR system, which are associated with the EHR mapping value selected during form design and the associated imported data value. – **Source Date and Converted Date**: Included if the source date was converted to match the date format defined for the question in the study. For example, the source date YYYY-MM-DD is converted to DD-MMM-YYYY. – **Source Units and Converted Units**: Included if the source unit was converted to match the unit defined for the question in the study. For example, the source unit inch is converted to cm. – **Source Value and Converted Value**: Included if the source precision was converted to match the precision defined for the question in the study. For example, the source value 4.00 is converted to 4.0.
Subject Events	Modified data element description	The **Event Type** column includes **Subject-patient Link Created** and **Subject-patient Link Removed**.

To support this enhancement, we introduced the following Oracle Clinical One Analytics changes:

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Dataset	Type of change	Description
Blinded Subject Event	Modified data element description	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.
Queries	Modified data element description	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR. • The **Audit Folder** section includes **EHR_IMPORTED** indicating if a question was populated via an EHR data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.
Study Design	Modified data element description	• The **Study Folder** section includes **OCC_ENABLED** and displays Yes or No, indicating if a study is enabled for EHR data import. No is displayed if your study is not currently enabled; this includes those studies that previously were. • The **Item Folder** section includes **EHR_MAPPING** and displays the OCC data dictionary mapping value for a question mapped for EHR data import.
Subject	Modified data element description	• The **Subject (Required) folder** section includes **EHR_LINK_STATUS** and displays Yes or No, indicating if a subject is currently linked for EHR data import.
Subject Forms	Modified data element description	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.

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Dataset	Type of change	Description
Subject Form Items	Modified data element description	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR. • The **Audit Folder** section includes **EHR_IMPORTED**, indicating if a question was populated via an EHR data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.
Unblinded Subject Event	Modified data element description	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.

You can find additional information in the *Reporting Guide* and the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Already working in a live study?

If enabled, the EHR features defined above are backward compatible for use with existing studies.

Update tabular forms included in live studies

Study designers can now perform Advanced Study Versioning (ASV) changes to tabular forms that include label items. This includes lab forms, repeating forms with label items, and the repeating section (Questions in the Table) with label items, included in a two-section form.

With the ability to update tabular forms with label items, you'll save time and reduce transcription errors by avoiding the need to recreate forms and re-enter previously collected data, ensuring a smoother and more efficient user experience.

Before you work with this feature

No new permission is introduced with this enhancement. To make ASV updates to a tabular form that contains label items, you only need to be assigned the existing *View Design* and *Design Forms* permissions.

Details for study designers

Here's what's new in your workflow:

- The **Apply Changes to Study Version** drop-down now becomes available for you to use in a tabular form that contains label items (including lab forms, repeating forms with label items, and the repeating section, with label items, of a two-section form). The drop-down is only available for non-label questions.
- You can perform question-level ASV changes to any question type included in a tabular form, except for the label items included in that form. For example, you can update the Lab

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Result question in a lab form (since it's specified as a text question), but you cannot update the Lab Test item since that is a label item.

- You can continue performing regular Study Versioning (SV) changes to a tabular form if you need to include a label item in an existing form.
- You can perform ASV changes to non-label questions in any form included in both existing and new studies.
- When you apply ASV to a question in a repeating form with label items or a two-section form with or without label items (including lab forms), keep in mind that the ASV flag is applied to all non-label questions on the form. For example, if you apply an ASV change to the Lab Result text question, all other questions in the lab form display the study version you selected for the Lab Result text question in the **Apply Changes to Study Version** drop-down, except for the label item.

Impact on reports

The following reporting changes are introduced for this enhancement:

Report	Type of change	Description
Study Design report	Modified column description	In the **Properties** column, non-label questions in tabular forms also display details of any ASV changes performed by a study designer. For example, you may see: **Apply Change to Study Version: 1.0.0.5 P01-123-A3**.
Annotated CRF report	Modified column description	In the **Advanced** column, non-label questions in tabular forms also display details of any ASV changes performed by a study designer. For example, you may see: **Apply Change to Study Version: 1.0.0.4 P01-123-A3**.
Subject Form Items dataset and the Study Design dataset	Modified data element descriptions	Data for any new or modified questions in a tabular form (updated through ASV) is displayed in the Item folders for both the Study Design datatset and the Subject Form Items dataset.

You can find additional information in the *Study Designer User Guide* and *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Manage subject event related data and visits better

Sponsor and site users can view the Screen Failure, Study Completion, and Withdrawal visits until all data is removed or the related statuses are reverted, allowing site staff to access undone visits during this time. Site users can also edit a subject's study completion or withdrawal date, as well as the reason specified for a subject's withdrawal.

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> **Note**
>
> With the release of this enhancement, issue **31272901** is now fixed, as well. Previously, this was reported as a Known Issue in our documentation. When a site user decided to undo a subject's withdrawal, their associated Withdrawal visit remained displayed, and the subject remained signed when the visit data should have become unsigned. Additionally, the system counted the Withdrawal visit as a signed visit. Now, when a site user undoes a subject's withdrawal event, upon clearing the data for their Withdrawal visit, the subject and visits status align since the visit is removed from the User Interface (UI).

Before you work with this feature

As a user administrator, there are some new permissions that you need to be aware of. These are now included by default in the CRA, Data Manager, and Site User global study role templates. The following new permissions are introduced:

New permission	Description
Receive the Subject Undo Completion Notification	You can assign this new permission to a sponsor or site user that needs to be notified when a subject's Completion visit is undone.
Receive the Subject Undo Withdrawal Notification	You can assign this new permission to a sponsor or site user that needs to be notified when a subject's Withdrawal visit is undone.
Receive the Subject Undo Screen Failure Notification	You can assign this new permission to a sponsor or site user that needs to be notified when a subject's Screen Fail visit is undone.

For more information on these new permissions, see Notifications permissions in the *Add Users Guide* after the Release Assessment Environment (RAE) upgrade.

Details for sponsor users

Whether you're a study designer, a clinical supply manager, or a site administrator, here's what you need to know about this enhancement:

- If your study has a predictive resupply strategy set up, the algorithm determines the appropriate amount of kits to be sent out to sites based on the subjects' current state (whether Screened, Enrolled, Randomized, Active, etc.).
- With the appropriate permissions, you or any other user can now receive any of the three new notifications: **Subject Undo Completion**, **Subject Undo Withdrawal**, and **Subject Undo Screen Failure**.

If you're interested in learning more about the changes in site users' workflow, check the **Details for site users** section below.

Details for site users

Here's what's new in your workflow for managing subjects, their data, and their status in the context of screen failure, study completion, and withdrawal:

> **Note**
>
> Editing details for a subject's screen failure event (such as the date and reason for the screen failure) is existing functionality.

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- Upon choosing to undo a subject's event (whether it's manually undoing a subject's screen failure, study completion, or withdrawal), a specific dialog is displayed. The Undo dialog requests you to specify a reason for this change and it also notifies you that undoing this subject's event preserves all data from the associated visit. The visit remains visible and accessible until you clear all data, including hidden data.
- Once you undo a subject's, screen failure, completion of the study, or their withdrawal, if there's an associated Screen Failure, Study Completion, or Withdrawal visit, that visit is displayed on the **Previous Visits** column. This also applies to a subject that you successfully re-screen.
  Once all data is cleared from the visit and all associated queries are closed, the visit is no longer displayed on the **Previous Visits** column. The visit will only remain visible if there is data present in the associated visit.
- When a subject's screen failure, study completion, or withdrawal event is undone, the status of that subject is updated again to **New**, **Screen Failed**, **Active**, **Screened**, or **Enrolled**, depending on the situation.
- You can also edit a subject's study completion and withdrawal details, such as the date of the event (for both Study Completion and Withdrawal), or the reason for that subject's event (only available for Screen Failure and Withdrawal). When you select a subject who's already withdrawn or completed, the **Manage Subjects** drop-down displays two new options: **Edit Withdrawal** and **Edit Completion**, respectively.
- If a subject's Screen Failure, Study Completion, or Withdrawal visit contains locked or frozen data, you cannot undo a subject's event. When you attempt to undo a subject whose Screen Failure, Study Completion, or Withdrawal visit contains these types of data, an Error dialog is displayed informing you of this issue.
  If a subject's overall status is *Locked*, the option to undo any of their events isn't displayed on the **Manage Subjects** drop-down at all.
- Before you undo a subject's event, if there are any open or answered queries included in forms for the associated visit (Screen Failure, Study Completion, Withdrawal visit), you should reach out to a sponsor user to ensure that all open or answered queries are manually or automatically closed.

Impact on integrations

For more information on the impact on integrations, see Support for undoing subject events.

Impact on custom JavaScript rules

If you're a rule designer, publisher, or tester, here's what you need to know about this enhancement:

- Whether it's specified or edited by a site user, or defaulted by the application, the dates of a subject's withdrawal, completion, and screen failure (as well as the date of the undoing) are returned to the Subject Object attributes for the respective dates. The subject object used in custom rules throughout your study reflects the updated data.
- If clearing a question triggers a calculation rule to populate a target field in a visit that is being cleared, that visit will not be hidden until the calculation is cleared by the rule.

For more information

Impact on reports

For more information on the modified reports, see the corresponding reporting topics in the *Reporting Guide* and the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

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Consider the following notes for how data is reported in certain reports for this enhancement:

- In the *Subject dataset*, only the reason specified for a subject's screen failure or withdrawal events is displayed. In Clinical One Cloud Service, you are not required to specify a reason for the subject's study completion, therefore there is no reason to display for this event for the REASON data element.
- For the *Subject dataset*, the *Subject Events report*, and the *Subject Data for CTMS report*, while you can see the reason for change that is specified anytime an update occurs for a subject's screen failure, study completion, or withdrawal event, you cannot view any updates to the event's specific reason. For example, if a subject's **Reason for Screen Fail** is updated in Clinical One Cloud Service, this update is not specified in these reports. This capability will be introduced in a new future release. For more information on release impact to other applications, see Patch set impact on other applications.

Report	Type of change	Description
Subject Events report	Modified column description and new filter	The following changes can be found in this report: • New options are available for the **Event Type** filter: Screen Fail Update, Completion Update, Withdrawal Update. • When a site user edits a subject's date for their withdrawal, screen failure, or study completion, the **Event Type** column displays this as a separate event (Completion Update, Withdrawal Update, or Screen Fail Update). • The **Visit/ Event Date** column, displays the updated date of a subject's withdrawal, screen failure, or study completion event when edited by a site user.

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Report	Type of change	Description
ODM-XML extract	New field	The following Clinical One extension fields are included at the subject level: • **co: WithdrawalDate**: This field will only be visible for subject status transactions with a status of Withdrawn, when the date entered does not match the current system date (the user-entered date). It doesn't display for other subject status transactions. • **co: CompletionDate**: This field will only be visible for subject status transactions with a status of Complete, when the date entered does not match the current system date (the user-entered date). It doesn't display for other subject status transactions. • Additionally, when a site user edits a subject's withdrawal and completion dates, these new dates are reflected in the **Clinical data extract**, including the updated date and reason for change.
Subject dataset	Modified data element descriptions	• When a subject's withdrawal, screen failure, or study completion details are updated, the following data points are now included in the EVENT_TYPE data element: – Screen_Fail_Update – WithdrawalUpdate – CompletionUpdate • The reason specified for the overall update to a subject's event details is included in the REASON data element. • The date associated with a subject's Screen Failure, Study Completion, and Withdrawal event (along with undoing these events) is displayed in the STATE_DATE data element. The Withdrawal date is also displayed for the STATE_DATE when a subject's withdrawal occurs due to code break.

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Already working in a live study?

If you're already working in a live study, consider the following notes that apply once this new feature is released:

- If a Withdrawal, Screen Fail, or Study Completion visit was previously hidden, while having any data, open, answered, or candidate queries associated with it, the visit will resurface in your study after the upgrade is complete, and it can only be hidden if you clear its data.
- Any statuses related to Source Data Verification, data freezing, or signing are not impacted by any resurfacing Screen Failure, Study Completion, or Withdrawal visits.
- Queries are hidden if the associated visit (Screen Failure, Study Completion, or Withdrawal visit) is in a state of *New* when this feature first becomes available in your study. To view the queries, go to the **Queries** sidebar or access the **Query Management** page.
- If a locked subject's Screen Fail, Study Completion, or Withdrawal hidden visit resurfaces after this upgrade, a sponsor user must first unlock the subject before they or another site user can clear that visit's data and hide it again. The resurfaced visit's status is not displayed as *Locked*.

For more detailed information on this enhancement, see the following user guides after the Release Assessment Environment (RAE) upgrade:

- *Site User Guide*
- *Sponsor and CRO User Guide*
- *Notifications and Permissions Guide*

Data review

- Trace queries for a target question
  You now have the ability to better trace and review your queries in the **Answer & Visit History** sidebar by following numeric ordering tags added to each query.
- Include or exclude screen failed subjects from Source Data Verification
  Sponsor users can now have more control over a study's Source Data Verification (SDV) definition and decide whether to include or exclude screen failed subjects from the pool of subjects that require data verification.

Trace queries for a target question

You now have the ability to better trace and review your queries in the **Answer & Visit History** sidebar by following numeric ordering tags added to each query.

Details for sponsor users

When it comes to your workflow, here's what's new for you when working with queries:

- When you view the **Answer & Visit History** sidebar for a question that has at least one query, a numeric ordering tag is associated to each update for a query.

> **Note**
>
> These ordering tags are only visible in the **Answer & Visit History** for the query's target question.

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- Ordering tags are assigned in ascending order based on when the query was created.

  For example, the first query created would be assigned as *Query 1*; the second query created would be assigned as *Query 2*, and so on.

  > **Note**
  >
  > When queries are opened at the time same, the numeric ordering tags are assigned chronologically and dynamically based on the time the queries are opened. For example, a Query A and Query B are opened at the same time. The first time the **Answer & Visit History** is opened, Query A is tagged as *Query 1*, and Query B is *Query 2*. When the **Answer & Visit History** is opened the next day, Query A displays as *Query 2*, and Query B as *Query 1*.

- The numeric tag assigned to a candidate query remains with it through its life cycle. For example, if a candidate query raised is labeled as Query 2, when that query's status is updated to Open, its label remains Query 2.
- The numeric ordering tags display only in the Clinical One Cloud Service user interface (UI) and are not available in any downstream system.
- Queries that you do not have permissions to view, such as candidate or assigned queries, are not considered in the numeric ordering. Therefore, the numbering may vary between users based on query related permissions.
- A similar functionality currently exists in Oracle CRF Submit. Because the numeric ordering tags are generated dynamically in both systems, the numbers may vary slightly between Clinical One Cloud Service and Oracle CRF Submit for queries created at the same time.

For more information about queries and related workflows, see Create and manage queries in the *Sponsor and CRO User Guide*.

Include or exclude screen failed subjects from Source Data Verification

Sponsor users can now have more control over a study's Source Data Verification (SDV) definition and decide whether to include or exclude screen failed subjects from the pool of subjects that require data verification.

> **Note**
>
> This new enhancement doesn't impact your study's integrations, JavaScript custom rules, standard reports in Clinical One Cloud Service, data extracts or archives. While it doesn't introduce any workflow changes in Oracle Clinical One Analytics, consider that this setting may impact SDV requirements for a question and subject, and that this data will be refreshed in Oracle Clinical One Analytics datasets to reflect the latest updates.

Before you work with this feature

No new permission is introduced with this enhancement. To include or exclude screen failed subjects from your SDV strategy, you only need to be assigned the existing permission *Create and Manage SDV Strategies*.

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Details for study managers or other sponsor users

If you're a study manager or other sponsor user who's in charge of managing SDV in a study, with the **Include Screen Failure** setting you can now control whether to include or exclude screen failed subjects.

This setting is available for studies that use any type of SDV, full or targeted. However, it is particularly useful for targeted SDV studies. This is because targeted SDV studies require data verification only for a randomly selected subset of subjects, and there is typically just a small amount of data collected for screen failed subjects. If a screen failed subject is selected, they take the place of an enrolled subject who could have otherwise been chosen for the SDV pool. With this setting, you can ensure that only enrolled subjects are selected for data verification, as they generally provide more data that might provide more relevant insights for your study's analysis.

When you define study level SDV settings, on the **Source Data Verification** tab, the **Include Screen Failures** setting can now be set to either **Yes** or **No**.

- When the **Include Screen Failures** setting is set to **Yes**, the SDV subject pool considers subjects for data verification as soon as they have been added to the site.
  Given that screen failed subjects are eligible for SDV, the total count of subjects considers screen failed subjects. This total count of subjects is used to calculate the percentage of remaining subjects to be selected (targeted SDV only).
- When the **Include Screen Failures** setting is set to **No**, the SDV subject pool doesn't consider subjects for data verification until their status is **Enrolled** or **Randomized**. When considering the initial subjects selection, subjects are evaluated in the order that they are added to a site and a subject is not skipped for data verification unless it gets a status of **Screen Failed**. Even if a subject added later is enrolled first.
  Given that screen failed subjects are not eligible for SDV, newly added subjects, screen failed subjects, and subjects whose screening is in progress are excluded from the total count of subjects, which is used to calculate the percentage of remaining subjects to be selected. These subjects can only be later included in the total count if they become eligible for SDV, and this may happen if they get later successfully screened or become completed.

> **Note**
>
> For targeted SDV, questions that are marked as **SDV for All Subjects** still require verification for screen failed subjects, even if excluded from SDV. Questions marked as **Critical Variables** and other questions with no SDV configuration do not require verification for excluded subjects.

Details for Clinical Research Associates (CRAs)

While nothing has changed in your application's workflow, know that you may be able to verify data of subjects whose status is **Screen Failed** in the application. This all depends on whether your study's SDV settings allows that or not.

Already working in a live study?

If you are already working in a live study, updating this setting may impact the subject selection for SDV:

- If you update the **Include Screen Failures** setting from **Yes** to **No** after adding subjects in a specific study mode (Testing or Production), any screen failed subjects previously

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selected for the **Initial Subjects** or **Remaining Subjects** pools get excluded and no longer require data verification.
A new subject is to be selected only if the site's current strategy requires replacement. For example, if you had selected three initial subjects and one of them was a screen failure and gets deselected, a new subject will be selected to meet the initial subjects count. But, if you also changed the strategy to two initial subjects, no new subject would be selected since two initial subjects would remain.

- When you update the **Include Screen Failures** setting from **Yes** to **No**, and excluded screen failed subjects no longer require SDV, any data that was previously verified remains verified. Any subsequent data changes will not impact the SDV status of the subject.
- If you update the **Include Screen Failures** setting from **No** to **Yes**, no changes occur for existing screen failed subjects, although they become eligible for SDV moving forward, based on your existing SDV strategy's algorithm.
- If a screen failed subject gets withdrawn or completed, it is no longer considered as screen failed but as either withdrawn or completed. Completed subjects are eligible for selection of the SDV subject pool, but withdrawn subjects are not.

> **Note**
>
> These scenarios are only possible if the **Screen Failed Subjects** setting in the study settings is set to **Allow Withdrawal** or **Allow Completion** respectively.

- If you change the **Include Screen Failures** setting from **Yes** to **No** or viceversa, any SDV-related information existing in Oracle Clinical One Analytics datasets is updated to reflect the changes to the SDV selection status (SDV_SELECTED_STATUS) for an item and subject.

For more information about SDV, SDV strategies and subject selection see Understand Source Data Verification and related topics in the *Sponsor and CRO User Guide*. You can also find additional information about this new functionality, after the Release Assessment Environment (RAE) upgrade.

Integrations

- Support for undoing subject events
  The undoing of a subject's Withdrawal and Study Completion visits is now supported for specific Clinical One Digital Gateway integrations with Clinical One Cloud Service studies.

Support for undoing subject events

The undoing of a subject's Withdrawal and Study Completion visits is now supported for specific Clinical One Digital Gateway integrations with Clinical One Cloud Service studies.

Details for integration managers

Moreover, user-edited dates and details for a subject's Withdrawal and Study Completion can be integrated. The integration logic for sending data related to Screen Failure, Study Completion, or Withdrawal events is not changing as part of this feature.

For more information about this new enhancement, see Manage subject event related data and visits better.

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The following integrations now support the transmission of data related to a subject's Withdrawal, Screen Failure, and Study Completion visits. This includes data related to undone events or edited dates for the Withdrawal and Study Completion events:

- The integration between Clinical One Cloud Service and Oracle InForm
- The integration with Medidata Rave
- The integration between Clinical One Cloud Service and Oracle's Siebel Clinical Trial Management System (CTMS).

Reach out to your Oracle point of contact if you would like to update the integration's configuration to support the integration of data related to a subject's Withdrawal, Screen Failure, and Study Completion events. If you don't update the integration configuration file, the data doesn't integrate.

You can find additional information in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- Add a sequence number to a randomization list
  Sponsor users can now upload or generate a randomization list with a sequence number.
- Assign kits from a lot to a manual shipment
  Clinical supply managers can now enter a specific quantity from a lot containing serialized and non-serialized kits to include when creating a manual shipment.
- Blind subject randomization numbers
  Sponsor users can now hide randomization numbers in their studies to prevent unblinding.
- Enhanced kits pooling for the quantum shipment model
  If your study uses the quantum shipment model, clinical supply managers can now benefit from several enhancements to the existing workflow.
- Randomize subjects only when all required kits are present at the site
  Sponsor users can now condition randomization to occur only when enough kit types at the site and enough quantities of dispensation kits are available.

Add a sequence number to a randomization list

Sponsor users can now upload or generate a randomization list with a sequence number.

The sequence number option will assign the randomization numbers by sequence number, allowing for sounder blind study protection. Instead of assigning randomization numbers down the list (1001, 1042, 1203), now with the sequence number option the system will assign the randomization number according to the sequence number column (4, 50, 993), resulting in the randomization numbers being less predictable.

You can use the sequence number option when a study is being run for a very small set of subjects. It can add an additional layer of blinding, especially if you think a subject might be at risk of being unblinded.

> **Note**
>
> The process applies to re-randomization and forced randomization.

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There is no change in permissions to make use of this new feature. Users with the existing permission to *Manage Randomization Lists* can add and use sequence numbers for randomization.

Details for sponsor users

As a statistician, a clinical supply manager, or a sponsor user who manages randomization, here's what's new in your workflow:

- When you generate a randomization list, or upload a randomization list, a new field for the sequence number is available:
  - If you upload a randomization list, a new option in **Mapped to** drop-down is available, giving you the option to map a column from the imported file to the sequence number. If you don't want to use this field, leave it empty.
  - When generating a randomization list, a new field called **Starting Sequence Number** is introduced on the **List Settings** view of the Generate Randomization List dialog. Use this field to set the sequence number you want the randomization list to start with. For example, you can start with number 90 or with number 1000.
- When managing randomization lists, on the Manage Randomization Lists window, you can view the new **Sorted by Sequence Number** grayed-out title under the list name. This allows you to identify if randomization was done by sequence number.
- When viewing the randomization list of an active study, on the **Randomizations** tab in the **Supplies** screen, a new column is available for the **Sequence Number**. If the sequence number option is not used, the column for it is not included in this table.

Impact on reports

Once this feature is available, you can find a new column for **Sequence Number** in the **Randomization Report (Unblinded)** report.

You can find additional information in the *Sponsor and CRO User Guide* and the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Assign kits from a lot to a manual shipment

Clinical supply managers can now enter a specific quantity from a lot containing serialized and non-serialized kits to include when creating a manual shipment.

In some cases, your study may benefit from creating a manual shipment. For example, if your study experiences a high volume of subjects enrolling faster than anticipated, a manual shipment can be created to quickly send additional supplies to meet the demand. The ability to create a manual shipment allows flexibility in distributing supplies as needed.

Details for clinical supply managers

Clinical supply managers assigned the existing *Create Shipments to Depots* permission can add a specified quantity of kits from a particular lot to a shipment.

In the Supplies window, under the **Shipments** tab, you now have the option to include a count of kits and lot number when you click **Create Shipment**. This selection is optional for serialized and non-serialized inventory, but is *mandatory* for a lot selection of pooled kits.

Once the Release Assessment Environment (RAE) upgrade for this release completes, clinical supply managers can begin creating manual shipments with specified quantities of kits from assigned lots for serialized and non-serialized kits.

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More information and step-by-step instructions can be found in the *Sponsor and CRO User Guide* after the RAE upgrade.

Blind subject randomization numbers

Sponsor users can now hide randomization numbers in their studies to prevent unblinding.

In some cases, your study may call for blinding randomization numbers. For example, randomization numbers in large global studies can be potentially unblinding when blinded sponsor users have access to multiple countries' site data. By suppressing randomization numbers in your study, you prevent possible unblinding situations.

Details for sponsor users

As a sponsor user, here's what you should be aware of in your workflow:

- Users assigned the existing *Manage Subject Number Configurations* permission can prevent randomization numbers from appearing in the system's user interface (UI) for their studies.
- On the **Study Settings** tab, the new **Blind Randomization Number** setting allows you to hide subject randomization numbers throughout the system's UI for your study when set to **Yes**. Instead, *Blind Randomization Number* is displayed throughout the UI in places where a subject randomization number would typically appear.

> **Note**
>
> Setting the **Blind Randomization Number** option to **Yes**, disables the **Replace Subject Number with Randomization Number** option.
> Conversely, both the **Replace Subject Number with Randomization Number** and **Blind Randomization Number** settings can be set to **No**, and *both* are set to **No** by default.

  - When the **Blind Randomization Number** setting is configured to **Yes**, the **Subject Randomization notification** displays the randomization number as *Blinded*.
  - When a subject completes the randomization or dispensation visit, in the Randomization and Dispensation dialog, the randomization number shows as *Blinded*.
  - Randomization numbers appear as *Blinded* in non-subject data forms for blinded users.
  - When the **Blind Randomization Number** setting is set to **Yes**, randomization numbers are displayed as *Blinded* for blinded users in the **Subject History** side panel.
  - The **Blind Randomization Number** setting configuration is taken into account at the time a report is run. If a user changes this setting from **Yes** to **No** after generating the report, the report is not impacted and the randomization number is shown in the report.

Impact on reports, extracts, archives, and datasets

The following reporting changes are introduced for this new feature when the **Blind Randomization Number** setting is configured to **Yes**:

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> **Note**
>
> You can configure your study to use blinded randomization numbers, but they won't yet be available in the expected Blinded Kits and Blinded Subject Event datasets. They will be appropriately displayed in the blinded datasets once the new Analytics architecture is implemented for your organization's studies. More details on this feature and its release will be available soon. For more information on the Analytics re-architecture, see Improved performance in Oracle Clinical One Analytics with new data elements to track data reliability.

Report, extract, archive, dataset	Type of change	Description
Kit Dispensation report	Modified column data	The **Subject's Randomization Number** column displays as *Blinded*.
Randomization List (Blinded) report	Modified column data	The **Randomization Number** column displays as *Blinded*. ***Note**: Be aware that if you're assigned one or more permissions with ORSUnblinded rights the randomization number details display in the **Randomization Number** column as opposed to **Blinded**.*
Subject Events report	Modified column data	The **Randomization Number** column displays as *Blinded*.
Oracle CRF Submit archives	Modified PDF output data	Randomization number instances display as *Blinded*.
Blinded Kits dataset	Modified data element description	When a randomization number is blinded, the **RAND_NUMBER** data element displays 0.
Blinded Subject Event dataset	Modified data element description	When a randomization number is blinded, the **RAND_NUMBER** data element displays 0.

Enhanced kits pooling for the quantum shipment model

If your study uses the quantum shipment model, clinical supply managers can now benefit from several enhancements to the existing workflow.

Enhancing the workflow for pooled kits and the quantum shipment model aims to improve the management of material IDs, lots, and shipments. This ensures a more efficient and accurate process, reducing the potential of errors for sponsor users running multiple studies for the same drug compound across multiple vendors.

Additionally, implementing key User Interface (UI) enhancements can benefit any clinical supply manager working with manual shipments, regardless of whether their studies deploy the quantum shipment model or not.

Before you work with this feature

No new permission is introduced with this enhancement. To create and manage pooled kits, you require the following existing global roles and permissions:

- *Create and Edit Library Kits for Pooled Supplies*

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- *Approve Library Kits for Pooled Supplies*
- *Delete Library Kit*
- *Create Manual Shipments (Unblinded)*

For more information on these global roles and permissions, see Roles for global users and Inventory Management permissions in the *Add Users Guide*.

Details for clinical supply managers

If you're a clinical supply manager or another type of sponsor user who works in a study that uses the quantum shipment model, here's what's new for you:

- When you ship pooled kits through a supply integration, the new Material ID field and the Lot Number value are associated to kits. These values are integrated into the stock report that runs daily and updates the quantities in lots created in your study.
- Each material ID can be associated with multiple countries and multiple kit types, but each unique material ID can only be assigned to one kit type. Each material ID can contain multiple lots, and each lot is assigned to only one material ID. This allows for more precise tracking and management of lots.
- When generating shipments through a resupply strategy (whether it's the first shipment, a manual shipment requested by site, or the resupply shipment created automatically), the system now selects the lowest batch expiry date (first to expire to last to expire) and the lowest material ID (lowest to highest). Moreover, the system ensures that each material ID corresponds to one country and one kit type.
- Resupply shipments are now generated from lots that have a full count of kits. If no lots can ship the full count of kits requested, the resupply shipment cannot be honored and sent to the sites.
- The system now reconciles the count of kits after each shipment request (manual and resupply), ensuring that the inventory is accurately updated.

If you're a clinical supply manager who works in a study that uses a different shipment model, the following enhancements may be of interest to you, as well:

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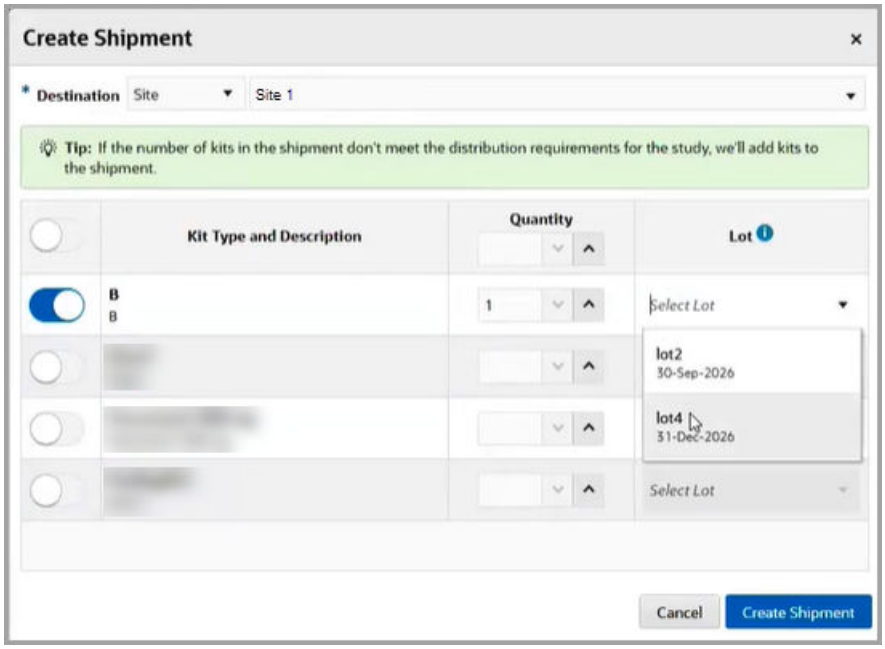
Figure 6-1 How a clinical supply manager sees the new lot details



- When you choose to create a manual shipment, on the Create Shipment dialog, the **Select Lot** drop-down now displays lots specific to every available kit type for serialized, non-serialized, and pooled kits.
- For pooled kits specifically, the **Select Lot** drop-down only displays lots that correspond to the kit type for the country shipping to.
- On the **Select Lot** drop-down, you can also see the expiry date for each lot. That way, when you select the lot for a manual shipment, you can make sure the lot won't be expiring before the kits need to be dispensed to the site.
- If the kits included in a shipment pertain to a blinded lot, then the blinded lot expiry date is displayed.

Impact on reports

The new Material ID field is already displayed in the Unblinded Kits dataset in Oracle Clinical One Analytics.

Impact on integrations

If your study uses a SAP integration to ship pooled kits, know that your integration configuration files need to be updated to return the Material ID field during the integration of pooled kit data. For more information, reach out to your Oracle point of contact.

More details on these new enhancements can be found in the following publications after the Release Assessment Environment (RAE) upgrade is complete:

- *Depot User Guide*
- *Sponsor and CRO User Guide*

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Randomize subjects only when all required kits are present at the site

Sponsor users can now condition randomization to occur only when enough kit types at the site and enough quantities of dispensation kits are available.

If you choose to confirm kits' availability at randomization with the **Randomize Only when All Kits are Available at Site** setting, from the **Study Settings** tab, you can select the specific kit types required in the inventory to be able to randomize a subject. With this enhancement, this functionality now verifies that there are kits at the site for the randomization, but will also take into account that the quantities of kits at the site meet the requirement for randomization.

While there is no visible change in the **Study Settings** tab, the behavior of the existing **Randomize Only when All Kits are Available at Site** setting has now changed to reflect the above.

You can find more information about this and other supply settings in the *Sponsor and CRO User Guide*.

Reporting, archives, and analytics

- Enhancements to Oracle CRF Submit archives and reports
- Enhancements to the Projected Supply (Unblinded) report
  In the Projected Supply (Unblinded) report, clinical supply managers can now identify which kits are locally sourced and avoid sending manual shipments to a site that is not sourced locally.
- Improved performance in Oracle Clinical One Analytics with new data elements to track data reliability
  The Oracle Clinical One Analytics performance is now significantly improved to handle all your study data demands. Additionally, a new dataset has been introduced to verify data consistency with Clinical One Cloud Service.
- Review Source Data Verification (SDV) status across subjects and sites in Oracle Clinical One Analytics
  You can now generate reports in Oracle Clinical One Analytics to measure and review SDV progress for subjects and sites in a study.

Enhancements to Oracle CRF Submit archives and reports

Site IDs are now included when generating archives based on Select Sites

The options displayed under the **Select Sites** setting (under **Included in Report**), in the Settings panel, now include the site ID, ensuring you select the correct sites for your Submission PDF, Archival PDF, and Custom PDF archives.

The new site ID value is also reflected in the Site Confirmation report, in a new column.

Better control over data exported in Custom PDFs for transferred subjects

Sponsor users now have better control over the data exported in Custom PDF requests, with the option to include only data from a transferred subject's current site.

To access the new setting (**Transferred Subjects in Current Site Only**), click the **Advanced** link at the bottom of the **Settings** side panel when you generate a Custom PDF request.

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You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to the Projected Supply (Unblinded) report

In the Projected Supply (Unblinded) report, clinical supply managers can now identify which kits are locally sourced and avoid sending manual shipments to a site that is not sourced locally.

Details for clinical supply managers

When generating the Projected Supply (Unblinded) report, the **Project Locally Sourced Sites** filter is now available, allowing you to view additional details on locally sourced kits.

> **Note**
>
> The **Project Locally Sourced Kits** filter is set to **Yes** by default. When set to **No**, a value of zero (0) populates the **Projected Kit Count** and **Projected Need** fields for locally sourced sites.

Report	Type of change	Description
Site tab	New columns	• A new column, **Kit ID**, has been added and displays a kit's ID. • A new column, **Locally Sourced**, has been added and indicates whether or not the kit is locally sourced.
Country tab	New column	A new column, **Kit ID**, has been added and displays a kit's ID.
Depot tab	New column	A new column, **Kit ID**, has been added and displays a kit's ID.
Site and **Depot** tabs	Modified column data	When the **Project Locally Sourced Sites** filter is set to **Yes**, the **Projected Kit Count** and **Projected Need** columns display a projected quantity for locally sourced sites.

More information can be found in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade completes.

Improved performance in Oracle Clinical One Analytics with new data elements to track data reliability

The Oracle Clinical One Analytics performance is now significantly improved to handle all your study data demands. Additionally, a new dataset has been introduced to verify data consistency with Clinical One Cloud Service.

The main improvement for this release is to make data processing incremental at a study level with automated data reprocessing. With this, we have build a data processing model scalable for all customers and their specific needs, whether they're operating a smaller or more complex study. By using a more efficient data replication model, data is now refreshed more frequently in your Oracle Clinical One Analytics datasets than before.

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New dataset in Oracle Clinical One Analytics

To provide you with evidence that data is refreshed appropriately, you can now use a new data set called **DH Metrics** to ensure that you're looking at the latest version of your study's data in Oracle Clinical One Analytics.

- The DH Metrics dataset is available to you in Oracle Clinical One Analytics and you don't require any new permissions to access it. If you already have any permission to view and work with datasets in the application, you will be able to see this new dataset, as well.
- You can use this new dataset when configuring dashboards to ensure you are visualizing your study's data in an efficient manner and gain more confidence in the accuracy of the data.
- The DH Metrics dataset contains the following folders: **Study** and **Metrics**. While the Study folder contains the standard data elements related to the study's details, the **Metrics** folder features new data elements that you can use to be certain of your data's consistency with Clinical One Cloud Service. The most important metrics that you can use to test that you're looking at the latest study data are the following:
  - **HEARTBEAT_CONSOLIDATION_TS** indicates the date and time of the latest study data refresh that occurred.
  - **IS_DATA_CONSISTENT** indicates either a label of **Yes** or **No**. The Yes label validates that your Oracle Clinical One Analytics data is currently consistent with Clinical One Cloud Service, according to when the latest study data refresh occurred (HEARTBEAT_CONSOLIDATION_TS).
- Other data elements listed in this folder can be used together with the **HEARTBEAT_CONSOLIDATION_TS** and **IS_DATA_CONSISTENT** data elements to further confirm that your study's data is properly reflected in the Analytics application. For example, you can use a data element such as **C1_INVENTORIES_MAX_VER_START** to view the latest version of the table with study's inventory data that was last pulled from Clinical One Cloud Service and **DH_INVENTORIES_MAX_VER_START** to see that same inventory-related data from what was last refreshed into Oracle Clinical One Analytics.

> **Note**
>
> All data elements in the Metrics folder that begin with ***C1*** are related to the data tables in Clinical One Cloud Service. All data elements in the Metrics folder that begin with ***DH*** correspond to the data tables in Oracle Clinical One Analytics.

You can view all definitions of these new data elements, as well as a detailed description of the new DH Metrics dataset in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade is complete.

Other enhancements

For more information on these enhancements and the re-architecture, reach out to your Oracle point of contact.

Currently, you may observe other functionality enhancements as a result of the new data processing model. For example, see the following:

- When there are blinded randomization numbers in your study, the Blinded Kits Dataset dataset and the Blinded Subject Events Data Set dataset display a *Blinded* label for the **RAND_NUMBER** data element, instead of 0. This is a change required for the previous release of blinded randomization numbers and will become available in your Assesment

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Environment (AE) and your Production environment once the new Analytics architecture is implemented. For more information on the new blinded randomization numbers feature, see Blind subject randomization numbers.

- In the Subject Forms Dataset, a form's status is now calculated at runtime. After this upgrade, as a form's status is calculated for the first time, the audit records that are created for the form status change indicate a CREATED operation_type with the current timestamp, rather than a historical one.
  Moving forward, every time a form's status changes the audit record will indicate a MODIFIED operation_type and the timestamp will accurately reflect the time when the form status changed.
- In the Subject Forms dataset, records of completely cleared forms are now persisted and properly displayed, allowing you to track all forms that ever existed for a subject. The records of cleared forms display with a status of New or Optional.
  When some but not all data is cleared in a completed form, its status is displayed as follows:
  - The first time the form's status is calculated, after this upgrade, its status is displayed as IN_PROGRESS.
  - Moving forward, every time that data in a completed form is cleared, its status is updated as INCOMPLETE, which is the expected behavior.
- Also in the Subject Forms dataset, for the audit records of a form status change, the user name is now displayed as "System", as the system calculates the form status at runtime. If a user enters the last items on a form, that updates a form's status from *In Progress* to *Complete*, their username and timestamp are still stored for the item modification in the *Subject Form Items dataset*, but for the form status change record in the *Subject Forms dataset*, the user name of the user performing the action is displayed as "System".
- Projected visit dates, in the Blinded Subject Events dataset and the Unblinded Subject Event dataset, are now displayed appropriately for all records. Previously, data related to the projected visit dates was only populated for current records and not for audit records. Also, these fields now display the date value only and not the time value.
- Also in the Blinded Subject Events dataset and the Unblinded Subject Event dataset, the following fields are now properly populated for missing visit records, while previously they were only populated for started visits:
  - VERSION_START
  - VERSION_END
  - OPERATION_TYPE
  - USER_ID
  - USER_WID
  - USER_NAME
  - OBJECT_VERSION_NUMBER
  - SOFTWARE_VERSION_NUMBER
  - REASON
  - COMMENTS
- The unblind date in Unblinded Subject Event dataset is now a timestamp, instead of a simple date field. This displays a proper timestamp value, for example `2025-01-02 15:08:20.000000000`.

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- In the Blinded Subject Events dataset, you can now see the records of dynamic visits that were added or removed for a subject. These records display the EVENT_TYPE as **Visit_Show** or **Visit_Hide**, respectively.
- In the Study Design Dataset, the ALLOW_ADDITIONAL_ROWS data element now displays only **Yes** and **No** values. For the cases in which this value was previously populated as **Null**, this now displays as **No**.

Review Source Data Verification (SDV) status across subjects and sites in Oracle Clinical One Analytics

You can now generate reports in Oracle Clinical One Analytics to measure and review SDV progress for subjects and sites in a study.

A new data element called SDV_SELECTED_STATUS is introduced in the Subject Form Items dataset. With this, you can now retrieve item-level information about verification requirements, which reflect the SDV configuration applied to a given question. This includes the study SDV settings, the SDV strategy assigned to a given site, and SDV settings defined at the item level in form design.

The SDV_SELECTED_STATUS data element is populated with four possible values. These values indicate if, after all applicable SDV settings combined, the question requires verification or not for the subject.

These values include:

- **OBLIGATORY**: indicates the given question is considered required for SDV and must be verified.
- **OPTIONAL**: indicates the given question is not considered for SDV for that particular subject. Verification is optional but not required.
- **OPTIONAL_CRITICAL**: indicates the given question is set as a critical variable but not considered for SDV for that particular subject. Verification is optional but not required.
- **IRRELEVANT**: indicates the given question is not configured for SDV and it is not expected to be verified.

This new data can be used in combination with the previously available data element about item verification (the VERIFIED data element) to track SDV progress. You can use these to identify which items require verification, and out of those which have already been verified or are still pending verification. Some metrics you can obtain from this analysis include:

- How many form items that require verification are there pending to be verified for a subject?
- How many form items that require verification are there pending to be verified for a site ?
- Retrieve a list of all individual form items that require verification for a subject, visit, site, or study.
- Calculate the completion percentage of overall SDV and targeted (obligatory) SDV, either for the entire study, by subject or by site.

For more information about SDV see Understand Source Data Verification and related topics in the *Sponsor and CRO User Guide*. You can also find additional information about this new data element in the *Analytics User Guide*, after the Release Assessment Environment (RAE) upgrade.

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User experience

- Removed alerts for mismatch between visit date and screening date
  Site users no longer receive automatic alerts when the screening visit date and the actual screening event date do not match.

Removed alerts for mismatch between visit date and screening date

Site users no longer receive automatic alerts when the screening visit date and the actual screening event date do not match.

Previously, as per product design, site users were alerted whenever a subject was screened on a date different than the date entered for the screening visit. This is not relevant for some studies and sometimes leads to confusion for site users. For example, when a site user specified a screening visit's date, but then proceeded to actually screen the subject the next day.

Starting with this release, this automatic alert is no longer displayed for this particular use case. In case your study requires this type of alert, you can set up a custom rule to either send notifications or raise queries when this screening visit date mismatch occurs. While the previous visit date mismatch alert was only visible for the user performing the screening action, custom rules have the additional benefit that they can reach multiple users. Rules that send notifications allow multiple email addresses and, in the case of queries, they are visible for all users with the appropriate permissions or roles.

If you decide on using custom rules to alert site users of the mismatch between a screening visit's date and the actual screening date, you may want to review The Subject object documentation. The Subject Object was introduced in Clinical One Cloud Service 24.1 to access data not collected in forms, such as the screening date.

> **Note**
>
> Remember that rules run at the time data is submitted. So, for these cases, it is recommended that the rule you configure targets or references data entered in a visit occurring after the screening visit.

You can find additional information on the Subject Object and how to create different types of custom rules in the *Rules Developer Guide*.

User management

- Update existing study users in bulk with an auto-populated template
  A new download option is available for the user upload template, which generates the normal template file but including an auto-populated list of current study users in Production mode. This option makes it easier to update existing study users in bulk.

Update existing study users in bulk with an auto-populated template

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Besides creating users, user administrators can also edit Clinical One Cloud Service study users in bulk using the user upload template. Now, from the **Users** tab, you have two different download options to cover different use cases: to **Create Users** and to **Update Users**.

- The template generated to **Create Users** is the same blank template that has been available until now in Clinical One Cloud Service.
- The template generated to **Update Users** includes an auto-populated list of existing users and their current details from Production mode.

This auto-populated list, in the template generated to Update Users, makes it even easier to apply bulk updates to existing users, since you no longer need to manually enter all their data in the template. All you have to do is locate the attribute for the users you wish to update and make the change.

In both cases the template is processed the same way after upload and there is no change in the way it is validated. In fact, you can use both of them to either create or update users. For instance, if you include updated details for an existing user in the template used for creating users, your updates are successfully applied. Similarly, you can include rows with details for new users to create them, in the template used for updating users. The purpose of having two different templates is just so you can decide which works best for your needs.

You can find additional information about the user upload template in the *Add Users Guide*. Details about this enhancement are included after the Release Assessment Environment (RAE) upgrade.

Fixed issues

- All users
- Code lists
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

Users encounter poor system performance during and after log in

Users no longer encounter intermittent system performance issues when logging in, selecting a study, and taking other actions in the system. We have addressed the high CPU memory usage that caused the issues.

(Issue **37491783**)

The response time for saving a form is above the Service Level Agreement (SLA)

The response time for saving a standard form is now within the Service Level Agreement (SLA) metric of five (5) seconds.

Issue (**32604915**)

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Code lists

Updated code list isn't applied to an approved form

We've updated the system to allow replacing an existing code list with a modified version for approved forms, ensuring that the changes are applied correctly. Previously, study designers were unable to select an updated code list with new options, at the bottom of the code list, for an approved form question in the Draft study version. This resulted in no action being taken when selecting **Use Selected List** for a question.

(Issue **37541991**)

Facilities, settings, and user management

The Users tab is inaccessible under Study Settings

You can now access the **Users** tab under Study Settings, even when users with no permissions are associated with a Clinical One Cloud Service study. Previously, when a user associated with a study lacked permissions, one of the Clinical One Cloud Service services would throw an error, rendering the **Users** tab inaccessible.

(Issue **36684764**)

A POST API endpoint allows for the updating of lab test results without a property ID

The dataelement POST API now incorporates the necessary validations to prevent data from saving when a property ID is absent and to ensure that the correct validation errors occur. Previously, there were no validation errors, and the data saved successfully.

This issue impacted the following DCS endpoints:

- /ec-dc-svc/rest/v8.0/studies/{{studyId}}/{{mode}}/dataelements
- /ec-dc-svc/rest/v11.0/studies/{studyId}/{mode}/dataelements

(Issue **36542136**)

Forms, visits, and rules

Form status updates and projected visits are not processing for all subjects

Now, the FORM_STATUS event processes successfully for all subjects after processing the first 100 subjects and moving them from IN_PROGRESS to SUCCESS. Previously, when a FORM_STATUS event was created for more than 100 subjects, only a portion of subjects would be processed.

For example, when a FORM_STATUS event for 250 subjects was created, the system would only process the first 100 subjects.

(Issue **38068146**)

A visit branch is not triggered as expected

Now, the expected visit branches are displayed when the appropriate data is collected for the triggering question, as configured in study design, for the **Form Item Settings** field. Previously, when data was updated in a cycling branch visit to exit the branch, the specified branch was not shown as expected. This issue was caused by the system prioritizing the visit order and branch order in the study's design over the specified form item triggers.

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(Issue **37777103**)

Withdrawal visit is displayed for a complete subject (former Known Issue)

After you withdraw a subject from a study, undo the withdrawal, and then set the subject's status to *Complete* from the **Manage Subjects** menu, the Withdrawal visit no longer appears in the Next Visits column.

(Issue **33131649**)

Dynamic visits display incorrectly

Now, a dynamic visit that is triggered from an optional visit, after a subsequent visit has been started, displays as expected when the triggered visit is not complete.

(Issue **36846469**)

Visit status remains In Progress after a subject's status is updated to Complete

Unscheduled visits update to the correct status after a subject has finished their Completion visit and their status has been updated to *Completed*. Previously, when a subject was marked as *Complete*, the unscheduled visits remained in a state of *In Progress*.

For additional information, see Manage subject event related data and visits better.

(Issue **34663292**)

Subjects become unverified after a withdrawal visit is undone

After Undo Withdrawal is performed for a Withdrawal visit and the visit is hidden from the visit train, a subject's status remains verified.

For additional information, see Manage subject event related data and visits better.

(Issue **36908511**)

Withdrawal visits with cleared data that are not visible in the User Interface (UI) are signed by the system

Now, only the respective visits for screen failed subjects are signed successfully. Previously, withdrawal visits containing cleared data were signed by the system, even if they were not visible in the UI.

For additional information, see Manage subject event related data and visits better.

(Issue **37222257**)

Users encounter an error when attempting to close a query from the Queries side panel for Withdrawn and Completed subjects

After processing the undo withdrawal and study completion actions for a subject, you can now successfully close the queries you opened and answered during subject withdrawal. Previously, you would encounter an error when trying to close the query.

The problem also arose when a user initiated a study completion visit, which included data and a query, and then withdrew the subject.

In both cases, the DC POST API did not return visit withdrawal or completion details, resulting in the inability to close the query.

(Issue **36874703**)

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Visit branching is not based on the last registered visit (former Known Issue)

Returning to a previous visit and updating the answer to a branching question no longer results in the incorrect branch being triggered for a subject.

(Issue **35358331**)

Forms with more than two hundred (200) questions can encounter issues

Now, forms with more than two hundred (200) questions no longer encounter issues with Oracle Clinical One Analytics datasets and downstream applications like Data Management Workbench (DMW).

(Issue **37615271**)

Rule does not execute properly for repeating form items

Now, when a query is created for an initial repeating form item, then a second repeating form item using an identical Assessment Timepoint value is created, the initial query is closed as a result of the rule execution. Previously, the executed rule did not close the target query and an additional query was created.

(Issue **37583470**)

Integrations

Subjects fail to transfer correctly in Oracle's Siebel Clinical Trial Management System (CTMS)

Subject integration jobs no longer fail in Clinical One Digital Gateway, resulting in the creation of the subject in CTMS and correctly transferring the subject from site to site. The subject's visit status also remains as *Completed* after integration, and the completion status is sent to CTMS.

(Issue **37582436**)

A duplicate site primary address is created for the CTMS site integration

Now, when the CTMS Site Integration runs, a duplicate site primary address is not created. Previously, this issue occurred due to a missing validation step.

(Issue **37263806**)

Integration error occurs repeating forms with incomplete data

Now, integration jobs run successfully when a repeating form includes blank questions that are verified or signed, and when the system has applied a data flag, for example, *Not Done*.

(Issue **36884046**)

Integration upsert fails, resulting in an error when a question is verified or includes a data flag

Now, upsert, which is a database operation that updates existing rows or inserts new rows based on a unique identifier, is successful even when a data flag is set or the question is verified.

(Issue **37009038**)

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Data Intake integration cannot load data for choice-based question

If your study uses a Data Intake integration to load data into forms in the Clinical One Cloud Service, know that data is now successfully integrated and no related jobs are failing. Previously, upon attempting to integrate form data for choice-based questions, in particular, jobs would fail with an error indicating a malformed string representation of JSON.

(Issue **37607525**)

Shipments are stuck when sent through the Almac integration

Shipments sent through the integration with Almac Global Depot Network are now successfully reported in your system. Site staff can also receive and register the shipments, as expected. Previously, shipments were stuck with a status of *Pending* or *Confirmed* while sites couldn't see or receive them, despite having physically received shipments at the location.

(Issue **37619360**)

An error occurs with the CTMS integration when the visit completion date is removed

Updating data in a completed visit results in the removal of the visit completion date. When this occurs, the Oracle Siebel Clinical Trial Management System (CTMS) Subject Visit (SV) integration successfully propagates the update to CTMS. Previously, a library conflict involving the removal of the visit completion date would cause the integration to fail.

(Issue **37160455**)

Oracle Clinical One Analytics

Unexpected form items are now displayed

All form data is now correctly displayed in Oracle Clinical One Analytics and Oracle Life Sciences Data Management Workbench (DMW). Previously, some form items appeared incorrectly in both platforms after updating the Oracle Clinical One Analytics system. This issue occurred because some study version changes were not properly filtered out before being shared with these platforms.

From now on, only the finalized changes that are part of a study version are displayed as expected.

(Issue **37925063**)

Differences in metadata prevent data from being integrated

You can now integrate study data from the Clinical One Cloud Service to Oracle DMW. Previously, issues with calculations identifying clinical tables and items within Clinical One Cloud Service caused some items to be mislabeled, leading to integration problems.

(Issue **37924980**)

Some form items display multiple columns with different titles in Oracle DMW

All data related to form items in your Clinical One Cloud Service is now displayed correctly in Oracle DMW. If available, the SAS Variable is displayed. If not, the Reference Code is displayed, but not both. Previously, you may have noticed that some form items had two columns listed – one was named after the form item's SAS Variable, while the other was named after the form item's Reference Code.

(Issue **37925071**)

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ROW_ID data element displays different data

Clinical One Cloud Service study data that's integrated with Oracle DMW displays the correct ROW_ID elements in Oracle DMW. Previously, there were discrepancies between these IDs despite no changes having been made in the study before integrating its data into Oracle DMW.

(Issue **37924902**)

COUNTRY_NAME and INVESTIGATOR data elements aren't displayed in datasets

Now, you can properly view data being populated for the COUNTRY_NAME and INVESTIGATOR data elements whenever you include them in your datasets or dashboards. Previously, these data elements weren't displaying the expected data.

(Issue **37756629**)

Not-yet-triggered dynamic forms appear in Oracle Clinical One Analytics datasets (former Known Issue)

Only dynamic forms that are triggered are now included in the *Subject Forms dataset*, as expected. Previously, dynamic forms that have not been triggered were incorrectly included in the dataset. These forms were categorized as missing and assigned a status of Scheduled, even though they should not have been present. This issue occurred when a single show-form rule was configured to trigger multiple forms, leading to the unintended inclusion of untriggered forms in the dataset.

Retracted recommended action: Create one show form rule per form.

(Issue **36976923**)

Randomization and kits

Permissions for dispensation exceptions may be unblinding

Now, the two permissions related to dispensation exceptions (*Create and Manage Dispensation Exceptions* and *View Dispensation Exceptions*) are properly labeled as **Unblind** in both the application's User Inteface (UI) and in the documentation, as well.

For more information on the unblinding effect of these permissions, see the warning included on the following page: Inventory Management permissions.

(Issue **37813937**)

Full descriptions are not visible in the Upload Randomization List dialog

The full description of a stratum group in the Upload Randomization List dialog is visible when you hover the cursor over the title.

(Issue **36797483**)

Unable to update kit statuses on the Depot Inventory tab

Now, on the Depot Inventory tab, the checkbox next to kits with any status (including *Pending Destruction* and *Expired*) can be selected, and the status of the selected kits can be updated.

(Issue **37386222**)

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Reports, archives, extracts, and notifications

Incorrect Subject Data Extract file name format prohibits third-party vendor pickup

Now, the date portion of the filename format is generated correctly, allowing a third-party tool to successfully retrieve the Subject Data Extract file from the Oracle sFTP server. Previously, the file name format generated a file name with a date string that was not expected.

(Issue **38071927**)

Auto-lock failure notifications were triggerred without auto-lock set

The system now correctly avoids sending Auto-lock failure notifications when no auto-lock is set up for a visit. Previously, the system mistakenly triggered these notifications even when there was no auto-lock rule configured in a visit, due to an error that wasn't properly handled. This caused unnecessary failure alerts under those conditions.

(Issue **37664506**)

Auto-lock failure notifications sent due to insufficient retries

Now, the application tries 3 times to determine whether there are any Auto-lock validation rules configured for a visit. Previously, if no rules were configured for a visit the application was sometimes unable to determine this with only a single retry and would send an Auto-lock failure notification to designated users.

(Issue **37644881**)

Some Auto-lock failure notifications may be sent to the wrong users

> **Note**
>
> This issue did not generate any unblinding risks in your study.

Going forward, Auto-lock failure notifications will only be sent to users with the *Lock Subject Data* permission who are specifically assigned to a site in the corresponding study mode (Testing, Training, or Production). Previously, these notifications were sent to a broader group of users, including those not directly associated with the site in the specific study mode. For example, a user with the appropriate permission, assigned to site A in Production mode also received an Auto-lock failure notification for site A in Testing mode.

(Issue **37669116**)

The User Assignment report retrieves incorrect data when generated

Now, when you generate the User Assignment report, it retrieves all the correct data and does not include duplicate data.

(Issue **37330486**)

Submission PDF archives generate with failures

Users no longer encounter system errors, and Submission archive requests complete successfully. Previously, the blank forms included in the request could cause a max connection limit to be reached, leading to submission requests failing.

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(Issue **37538595**)

CO:extension data isn't visible in the clinical data and metadata extracts

We fixed an issue where CO:extension data was not showing up in the clinical data and metadata extracts, even when the include Co:Extension flag was set to True. The applied fix ensures that CO:extension data is visible and you can successfully extract data in an ODM-XML format.

(Issue **37522360**)

The Kit Chain of Custody (Blinded and Unblinded) reports are failing

The **Kit Chain of Custody (Blinded)** and **Kit Chain of Custody (Unblinded)** reports now generate successfully when kit numbers contain alpha and numeric characters. Previously, the reports would fail due to the alpha characters.

(Issue **37257750**)

Training reminders are being sent when training is disabled

Only when you enable the **Product User Training** toggle under Global Settings will Clinical One Cloud Service training reminders be sent. Previously, automatic training reminders were sent to study users even with the toggle turned off.

(Issue **36515001**)

Oracle CRF Submit shared server bug fix details

We fixed the following shared server bugs in Oracle CRF Submit.

- 37202944 - To address issues with Custom Blank PDF requests.
- 37273642 - To address broken links when a subject PDF is larger than 15 MB.
- 37273688 - To address missing page headers.

For more information about each bug, see the Oracle CRF Submit Release Notes on My Oracle Support (MOS) (DOC ID 2884571.1).

> **Note**
>
> The content related to these bugs will be available on 11-February-2025 after the shared server upgrade completes.

Site users and subject data

Characters are missing when typing quickly in text fields

When typing quickly in text fields, all characters are now captured correctly. Previously, some characters would be lost when typing at high speeds, especially when the network connection was slow. This issue only occurred when typing quickly and was not reproducible with normal or moderate typing speeds.

(Issue **35763244**)

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Subject History timezones display incorrectly

The Subject History sidebar no longer displays time zones for actions related to screen failures.

(Issue **36836388**)

Indication and Route of Administration are not present in Oracle Central Coding (former Known Issue)

The Indication and Route of Administration values are now available in Oracle Central Coding.

Retracted recommended action:

1. A site user must do one of the following to resolve the immediate issue of missing context item values in Oracle Central Coding:
    a. Clear and **re-select** the option (accept Other, see option 2) originally selected from the drop-down.
    b. Clear and **re-enter** the value entered manually when **Other** was originally selected from the drop-down. You do not need to re-select **Other**.
2. To ensure you don't encounter the same issue, implement the following study design change:
    a. Create a new calculation rule to populate a new read-only field for the verbatim term.
    b. Map the new read-only field as a Oracle Central Coding question on the **Advanced** sidebar. For more information, see task 1 in Create a coding question and coding target field.
    Doing this ensures the data entered for the verbatim and context values are copied to the read-only fields at the same time, resulting in all data being collected when the Oracle Central Coding integration process runs.

(Issue **37044789**)

Incorrect user role displays on the Query List page for closed queries

Now, the Query List page displays the correct user role for manually closed queries. Previously, when a query was closed, the role of the user that answered the query was displayed..

(Issue **37649070**)

Coding target items are not cleared when the verbatim term is cleared

Now, when a verbatim term is cleared, the data populated in the coding target items is cleared as well.

(Issue **37570275**)

Subjects are left unsigned due to Sign API code

Now, all items for a subject are signed and remain signed when a signature is applied. Previously, the API code responsible for signatures was referring to the Study Version instead of the Associated Study Version, causing newly added items for a subject to be left unsigned.

(Issue **37330940**)

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An error occurs when attempting to update the subject status to withdrawn for a previously withdrawn subject

When users attempt to change a previously withdrawn subject's status to Withdrawn, they encounter a new validation error, indicating an invalid subject state transition.

New validation error text: Invalid State Transition from Withdrawn to Withdrawn.

Previously, the system presented an incorrect error, causing confusion.

(Issue **36180645**)

Users encounter system errors when submitting data meant to trigger dynamic forms

Now, only one form-level SDV status record exists per form, so there is no longer a conflict when a dynamic form is hidden. Previously, if a user navigated between visits for a subject too quickly, duplicate form-level SDV status records could be created. These duplicate records would cause an error in Clinical One Cloud Service if a dynamic form with duplicate records was subsequently hidden.

(Issue **36113979**)

Release impact on other applications

This document describes the known impact and limitations that new features and enhancements introduced in Clinical One Cloud Service 25.1. may have on downstream applications.

Oracle Clinical One Analytics also known as Data Hub

Sequence numbers in Oracle Clinical One Analytics is an enhancement planned for a future release. For more information on sequence numbers used in randomization, see Add a sequence number to a randomization list.

Clinical One Digital Gateway configured integrations

For this release, no impact over Clinical One Digital Gateway is expected.

- Patch set impact on other applications
  This document describes the known impact and limitations that new features and enhancements introduced in Clinical One Cloud Service 25.1.1 may have on downstream applications.

Patch set impact on other applications

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Oracle Clinical One Analytics also known as Data Hub

Some new features and enhancements in this release impact datasets in Oracle Clinical One Analytics as follows:

- For this release, Oracle Clinical One Analytics is enhanced with a new architecture, using a new data processing model that refreshes data more frequently in Oracle Clinical One Analytics than before. Besides the improved performance, we have brought other enhancements that may impact your workflow if you are working with Oracle Clinical One

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Analytics datasets. For more information, see Improved performance in Oracle Clinical One Analytics with new data elements to track data reliability.

- EHR data and any configurations related to this new feature are displayed in Oracle Clinical One Analytics datasets, as expected. For more information on the new feature, see Import Electronic Health Record (EHR) data.
- With the improved workflow for withdrawal, completion, and screen fail visits, related data is displayed in both Oracle Clinical One Analytics datasets and standard reports. For more information on this new enhancement, see Manage subject event related data and visits better.
  The following data points will be introduced in a future release in the Oracle Clinical One Analytics datasets:
  - WITHDRAWAL_REASON
  - WITHDRAWAL_COMMENT
  - SCREEN_FAILURE_COMMENT
  - SCREEN_FAILURE_DATE

  Moreover, whereas this new feature allows users to capture and update events such as a subject's study completion or withdrawal date, along with the reasons for making these updates, these reasons will only be propagated to downstream systems in a future release.
- You can now exclude or include screen failed subjects from the Source Data Verification (SDV) pool. Data related to included or excluded subjects from the SDV pool is refreshed in the appropriate Oracle Clinical One Analytics datasets. For more information on this new enhancement, see Include or exclude screen failed subjects from Source Data Verification.
- You can now make Advanced Study Version changes to forms with label questions. Changes you make in your tabular forms are now reflected reflected appropriately in Oracle Clinical One Analytics. For more information on this new enhancement, see Update tabular forms included in live studies.
- Should your study use a SAP integration to ship pooled kits, data related to the Material ID is sent to Oracle Clinical One Analytics, as expected. For more information on this new enhancement, see Enhanced kits pooling for the quantum shipment model.

Clinical One Digital Gateway configured integrations

Some new features and enhancements in this release impact Clinical One Digital Gateway integrations as follows:

- Data related to a subject's Withdrawal, Screen Failure, and Study Completion events, as well as updates to these events, is now supported by the integrations with Oracle InForm, Medidata Rave, and Oracle's Siebel Clinical Trial Management System (CTMS). For more information, see Support for undoing subject events.
- With this release, should your study use a SAP integration to ship pooled kits, you may need to perform certain updates on your integration configuration file. For more information, see Enhanced kits pooling for the quantum shipment model.

Oracle Life Sciences Data Management Workbench integrations

Some new features and enhancements in this release impact Oracle DMW integrations as follows:

- Electronic Health Record (EHR) data imported into your study is now supported in Oracle DMW. For more information on this new feature, see Import Electronic Health Record (EHR) data.

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- With the improved workflow for withdrawal, completion, and screen fail visits, related data is displayed in Oracle DMW. For more information on this new enhancement, see Manage subject event related data and visits better.
  The following data points will be introduced in a future release in Oracle DMW:
  - WITHDRAWAL_REASON
  - WITHDRAWAL_COMMENT
  - SCREEN_FAILURE_COMMENT
  - SCREEN_FAILURE_DATE

  Moreover, whereas this new feature allows users to capture and update events such as a subject's study completion or withdrawal date, along with the reasons for making these updates, these reasons will only be propagated to downstream systems in a future release.
- Numeric ordering tags for queries will not be reflected in Oracle DMW. For more information on this enhancement, see Trace queries for a target question.
- Data related to included or excluded subjects from the SDV pool is supported in Oracle DMW. For more information on this new enhancement, see Include or exclude screen failed subjects from Source Data Verification.

Rest API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.1.

Services updates

The following services are updated:

- Data Hub
- Designer
- Randomization and Supplies
- Sites and Depots
- Users, Permissions and Roles

Data Hub

Change	Endpoint
New	• POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits

Designer

Change	Endpoint
New	• GET /v4.0/studies/{studyId}/statusessummary

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Randomization and Supplies

Change	Endpoint
New	• POST /v2.0/studies/{studyId}/{mode}/resupply/depotmanual • GET /v3.0/studies/{studyId}/{mode}/randlistdesigns • POST /v3.0/studies/{studyId}/{mode}/{studyVersion}/randlist/generate • GET /v5.0/studies/{studyId}/{mode}/randlists/{rndlistid} • GET /v5.0/studies/{studyId}/{mode}/randlists/{rndlistid}/randnumbers • POST /v5.0/studies/{studyId}/{mode}/reports/unblindedrandreport • GET /v6.0/studies/{studyId}/{mode}/randlists • GET /v7.0/studies/{studyId}/{mode}/shipments

Sites and Depots

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId}
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/labs • GET /v1/studies/{studyId}/{mode}/country • GET /v1/studies/{studyId}/{mode}/country/{countryId}/states • POST /v1/studies/{studyId}/{mode}/regions • GET /v1/studies/{studyId}/{mode}/regions • GET /v1/studies/{studyId}/{mode}/regions/filter/countries/{countryId} • GET /v1/studies/{studyId}/{mode}/regions/{regionId} • PUT /v1/studies/{studyId}/{mode}/regions/{regionId} • GET /v1/studies/{studyId}/{mode}/regions/{regionId}/countries • GET /v1/studies/{studyId}/{mode}/sdfcountry • GET /v1/studies/{studyId}/{mode}/sdfs • GET /v1/studies/{studyId}/{mode}/sdfs/all • GET /v1/studies/{studyId}/{mode}/sdfs/countries • GET /v1/studies/{studyId}/{mode}/sdfs/pinaddr • GET /v1/studies/{studyId}/{mode}/sdfs/search • GET /v1/studies/{studyId}/{mode}/sdfs/searchSite • GET /v1/studies/{studyId}/{mode}/sdfs/siteFilterPaginated • GET /v1/studies/{studyId}/{mode}/sdfs/tenant/{sdfId} • GET /v1/studies/{studyId}/{mode}/sdfs/{sdfId} • GET /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property • GET /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId} • GET /v2/studies/{studyId}/{mode}/country • GET /v2/studies/{studyId}/{mode}/regions • GET /v2/studies/{studyId}/{mode}/regions/{regionId} • GET /v2/studies/{studyId}/{mode}/regions/{regionId}/countries • GET /v2/studies/{studyId}/{mode}/sdfcountry • GET /v2/studies/{studyId}/{mode}/sdfs/countries • GET /v2/studies/{studyId}/{mode}/sdfs/paginated • GET /v2/studies/{studyId}/{mode}/sdfs/{sdfId} • GET /v3/studies/{studyId}/{mode}/country • GET /v4/studies/{studyId}/{mode}/country

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Users, Permissions and Roles

Change	Endpoint
New	• GET /v1.0/authusers/{userid}/studies/{studyId}/usersupdatetemplate
Deprecated	• GET /v2.0/authusers/{userid}/studies/{studyId}

- Rest API patch updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.1.1.

Rest API patch updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 25.1.1.

Services updates

The following services are updated:

- Codelist
- Data Collection
- Data Hub
- Data Integration
- Designer
- Designer EDC
- Notifications
- Randomization and Supplies
- Sites and Depots

Codelist

Change	Endpoint
Deprecated	• GET /v2.0/codelist/values/{fieldName} • POST /v3.0/codelist/code • PUT /v3.0/codelist/code/{codeId}

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Data Collection

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/ehrdata • GET /v1.0/studies/{studyId}/{mode}/ehrdata/medicalrecordnumber/{siteId}/{medicalRecordNumber} • GET /v1.0/studies/{studyId}/{mode}/ehrdata/subjects/{subjectId}/visit/{eventId}/studyversion/{studyVersion}/{category} • POST /v1.0/studies/{studyId}/{mode}/ehrdata/subjectslinkstatus • DELETE /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/linkehr • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/linkehr/{mrn} • GET /v1.0/studies/{studyId}/{mode}/mrn/{medicalRecordNumber} • POST /v4.0/studies/{studyId}/{mode}/subjects • GET /v5.0/studies/{studyId}/{mode}/subjects • PUT /v5.0/studies/{studyId}/{mode}/subjects/{subjectId} • POST /v6.0/studies/{studyId}/{mode}/subjects/visitschedule • GET /v6.0/studies/{studyId}/{mode}/subjects/{subjectId} • GET /v3.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata • GET /v7.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items • GET /v8.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements • GET /v10.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v12.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • POST /v14.0/studies/{studyId}/{mode}/visitstatus/subjects

Data Hub

Change	Endpoint
New	• POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v10.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits • POST /v6.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v7.0/studies/{studyId}/{mode}/odm/metadata • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • GET /v8.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v8.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • GET /v9.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v9.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded

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Data Integration

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/subjects/{subjectId} • GET /v2.0/studies/{studyId}/{mode}/visitstatus/dateRange/{subjectId} • GET /v3.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v4.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Designer

Change	Endpoint
New	• POST /v9.0/studies/{studyId}/studyDesign/paginated • GET /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • POST /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • PUT /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • DELETE /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • GET /v8.0/studies/{studyId}/versions/{version}/visitschedules

Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/ehrmapping • GET /v1.0/studies/{studyId}/ehrmapping/all • POST /v1.0/studies/{studyId}/visitsforms/ehrmapping • POST /v18.0/studies/{studyId}/versions/{version}/forms • GET /v18.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v18.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • PUT /v18.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v18.0/studies/{studyId}/versions/{version}/forms/{formId}

Notifications

Change	Endpoint
Deprecated	• POST /v1.0/email/{templatetype} • POST /v2.0/email/{templatetype} • GET /v2.0/studies/{studyId}/{mode}/notificationlog

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Randomization and Supplies

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/lotsbykittype/sdfs/{sdfType}/{sdfId} • POST /v1.0/studies/{studyId}/{mode}/reports/depotresupply • POST /v1.0/studies/{studyId}/{mode}/reports/minmaxresupply • POST /v1.0/studies/{studyId}/{mode}/reports/predictiveresupply • POST /v1.0/studies/{studyId}/{mode}/reports/siteresupply • POST /v2.0/studies/{studyId}/{mode}/reports/partialdispensations • POST /v2.0/studies/{studyId}/{mode}/reports/projectedsupplies/countrycounts • POST /v2.0/studies/{studyId}/{mode}/reports/projectedsupplies/depotcounts • POST /v2.0/studies/{studyId}/{mode}/reports/projectedsupplies/sitecounts • POST /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots • PUT /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • POST /v3.0/studies/{studyId}/{mode}/reports/doseholdsettings • GET /v4.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v4.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • GET /v9.0/studies/{studyId}/{mode}/orders • GET /v9.0/studies/{studyId}/{mode}/orders/{shipmentId}

Sites and Depots

Change	Endpoint
New	• GET /v1.0/EHRConnectors • GET /v1.0/studies/{studyId}/{mode}/sdfs/locallySourcedKitsBySite

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7

Clinical One Cloud Service and Clinical One Digital Gateway 24.2

- Patch log
- What's new in 24.2.1
- What's new
- Fixed issues
- Rest API updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 24.2.
- Release impact for other applications
  This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic describes the history of patches and patchsets we have applied to the 24.2 release.

Table 7-1 Patch log

Release Number	Release Date	Notes
24.2.1.2	20-December-2024	For this release, we applied required security updates. Also, we addressed an issue related to the application's performance on the Subjects and Sites & Labs pages, Oracle InForm MedML integration, and calculated rules. • For more information about the issue **37309578**, see Site users and subject data. • For more information about the issue **37331077**, see Integrations. • For more information about the issue **35968040**, see Forms, visits, and rules.

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Table 7-1 (Cont.) Patch log

Release Number	Release Date	Notes
24.2.1.1	26-November-2024	For this release, we applied required security updates. Additionally, we addressed issues related to Lab Normal Ranges, queries, forms, Analytics, and kit inventories. • For more information about issues **37222861** and **36297924**, see Forms, visits, and rules. • For issue **37213859**, see Site users and subject data. • For issue **37253372**, see Randomization and kits. • For issue **37111618**, see Oracle Clinical One Analytics.
24.2.1	29-October-2024	For this release, we introduced a new type of report and other enhancements, as well as fixed several issues related to user management, reports, integrations and Oracle Clinical One Analytics. • For the new report and other enhancements, see What's new in 24.2.1. • For issues **36983545** and **37133069** see Facilities, settings, and user management. • For issues **36730673**, **36440930**, **36824952**, **36779220**, **37106112** and **36784681**, see Reports, archives, extracts, and notifications. • For issues **36999348**, **36958248** and **36249843**, see Oracle Clinical One Analytics. • For issues **36728924** and **36728502**, see Integrations. • For issue **36791783**, see All users.
24.2.0.1	18-September-2024	For this release, we fixed one issue related to reports. For more information, see issue **37008259** in Reports, archives, extracts, and notifications.

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What's new in 24.2.1

- New Projected Supply (Unblinded) report
  You can now generate a new unblinded report that gives you an overview of your projected supply needs for a certain period of time.
- Removed subjects no longer included in Subject PDFs for Oracle CRF Submit archives
  Subjects removed from a study by the **Undo Add Subject** action, are no longer included in Subject PDFs of Oracle CRF Submit archives.
- Configure subject number integrations to Oracle InForm using the randomization number
  You can now configure an integration to send subject numbers to Oracle InForm using a format that concatenates the site ID with the subject's randomization number.

New Projected Supply (Unblinded) report

You can now generate a new unblinded report that gives you an overview of your projected supply needs for a certain period of time.

The new Projected Supply (Unblinded) report is especially useful to monitor inventory availability. For example, if you need to ensure that sites and depots in your study have enough investigational product to account for shutdown, or non-shipment periods, when scheduled drug shipments typically stop.

Before working with this feature

This report is available to users assigned the *Run the Supply Prediction (Unblinded) Report* permission. For more information about this permission, see *Descriptions of permissions in Clinical One* in the *Add Users Guide*.

Details for clinical supply managers

The report contains data on the count of available or unavailable kits for dispensation. It also displays the projected need for kits during a given period of time that you can specify. However, the projected time period cannot be longer than one year from the current date. Data is displayed by site, country, and depot.

You can run or schedule the Projected Supply report, but you can only generate it in an XLXS format.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Removed subjects no longer included in Subject PDFs for Oracle CRF Submit archives

Subjects removed from a study by the **Undo Add Subject** action, are no longer included in Subject PDFs of Oracle CRF Submit archives.

This impacts the following archives:

- Submission PDF
- Archival PDF
- Custom PDF

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This enhancement does not impact the Subject Data report or any other downstream applications that need to include the removed subjects.

For more information about these archives, see *Oracle CRF Submit archives and reports* in the *Reporting Guide*.

Configure subject number integrations to Oracle InForm using the randomization number

You can now configure an integration to send subject numbers to Oracle InForm using a format that concatenates the site ID with the subject's randomization number.

The setting **Replace Subject Number with Randomization Number** was introduced in a previous Clinical One Cloud Service release. When enabled, the randomization number replaces the subject number throughout the study after randomizing a subject. And when this happens, the subject is no longer identified with the screening subject number.

To support this configuration, the Clinical One Cloud Service integration with Oracle InForm can be set to specify the subject number in Oracle InForm as the <*Site ID*> + <*Randomization number*>.

More information about this setting is available in the *Sponsor and CRO User Guide* under *Specify study, enrollment, and visit settings*. For more details about the integration refer to *Oracle Clinical One Platform to Oracle InForm* in the *Digital Gateway User Guide*.

What's new

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

> **Note**
>
> The Release Notes available for the Assessment Environment release represent a draft version and are subject to change before the Production release.

- Data collection
- Integrations
- Notifications
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management
- User experience

Data collection

- **Easily include lab normal updates in existing forms**
  The process of updating lab normal ranges for existing lab forms is now more seamless.

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- Design questions with an auto-lock
  Study designers can now restrict site users from editing subject data after subject screening, randomization, dispensation, or visit completion.

Easily include lab normal updates in existing forms

The process of updating lab normal ranges for existing lab forms is now more seamless.

> **Note**
>
> Any automatic updates to lab normal ranges in lab forms do not impact a question's Signed or Verified status, while lab normal updates are still pushed to lab forms even when their data is locked.

Now that lab normal updates are more seamlessly included in existing lab forms, you can ensure that the most up-to-date normal range values are associated with all subject data without requiring visit-level interaction.

For example, if you identify data entry errors for a local lab's normal ranges during a peer review session, and you proceed to correct those errors in the application, those changes are automatically displayed in the existing lab forms included in a study, including forms that have already been completed or locked.

Details for all users

If you work with local labs, upon updating and saving a lab's normal ranges from the **Sites & Labs** tab, your updates are automatically refreshed in the existing lab forms associated with the updated lab, irrespective of the study version, subject, or visit. To ensure that all of your updates are properly reflected in a form, it may take only a couple of minutes for the data to be refreshed.

> **Tip**
>
> Want to view an audit trail of your lab normal updates? Either check the Answer & Visit History sidebar for a specific lab form row or run the new Lab Normal Range report. For more information on this new report, see New Lab Normal Range report.

Impact on reports, extracts, or data sets

Any lab normal updates that are automatically applied to existing lab forms are displayed as follows:

- In the following reports in the Clinical One Cloud Service: the Subject Data report, the Subject Data Extract, and the Lab Normal Range report.
- In all of the expected datasets in Oracle Clinical One Analytics where lab normal updates are refreshed appropriately.

Already working in a live study?

Whether you're working in a live study or you're getting ready to set up a new study, you should know that this enhancement is available for new and existing studies and for new and existing labs, sites, and subjects.

For existing lab forms, any lab normal updates you made before this release (release 24.2) will not be applied retroactively. If you completed a lab form prior to this release, your lab normal

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updates are not automatically reflected in these past forms. Any updates you made to lab normals after this release (24.2) will be reflected in existing lab forms. For more information on how to enable your past lab forms to display your lab normal updates automatically, contact your Oracle point of contact.

Design questions with an auto-lock

Study designers can now restrict site users from editing subject data after subject screening, randomization, dispensation, or visit completion.

Study designers can now configure a new predefined rule when configuring a question's settings. The **Auto-lock** rule option restricts site users from modifying questions once a subject has completed a key event during the study, such as screening, randomization, drug dispensation, or when the visit has been completed.

Locking subject data during the study conduct period allows sponsor users to protect essential data used in system decision-making from updates made by the site users without sponsor intervention. A site user can request the unlocking of a question from a sponsor user for editing. The sponsor user must first manually unlock the item to edit, which will be modified, and then locked again.

Details for study designers

If you're assigned to a study role that includes the *Design Forms* permission, you can now add an **Auto-lock** rule to a question in a form's design.

Upon selecting the Auto-lock predefined rule, you can specify the condition of when the auto-lock of a question should occur. The following four options are available:

- **Subject Screened**: a question should be automatically locked after a subject is screened.
- **Subject Randomized**: a question should be automatically locked after a subject is randomized.
- **Subject Dispensed**: a question should be automatically locked after a subject is dispensed the kit in the current visit.
- **Visit Completion**: a question should be automatically locked after a visit is completed.

In a live study, when the rule is applied, data related to the question with the auto-lock rule becomes read-only for site users after the defined condition is completed.

The auto-lock rule can be applied to one-section, two-sections, and lab form types, and all question types (including hidden questions), whether they're optional or required. However, instructional text items and clinical supplies forms do not support auto-lock rules.

> **Note**
>
> After completing a one-section, two-section, and or lab form, at least one flat form must be completed and added to the visit in order for the items to auto-lock.

You can add, delete or update an auto-lock rule as part of a study version change or when using the Advanced Study Versioning (ASV) feature. Only data where the precipitating event has not already occurred will be locked. Data where the precipitating event occurred before the ASV is applied will need to be manually locked.

Sponsor users will receive the Auto-lock failure notification if the rule locking is unsuccessful.

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Details for site users

If you need to update a question that was automatically locked, this is what you should know:

> **Note**
>
> The details listed below describe a workflow that occurs outside of the Clinical One Cloud Service. You can contact your sponsor team through other means to request an approval for updating an automatically locked question.

- You need to request approval from a sponsor user, sponsor support representative, CRA, data manager, or medical monitor to indicate that you need to update a locked question.
- In the change request, you must follow the process defined by the sponsor user.

You can find additional information in the Frequently Asked Questions section from the *Site User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Impact to reporting and analytics

Updates to the following reports are introduced to support auto-lock rules:

- **Study Design Report** shows the auto-lock rule changes in the Action Rules column.
- **Annotated Case Report Form** shows the auto-lock rule changes in the Validations column as an Action item.
- **Subject Data Report** shows the auto-lock rule changes in the Type of Change column.

You can find additional information in the *Reporting Guide* and the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Integrations

- Configure Clinical One Digital Gateway integrations to integrate data as of a specific date
  A new Clinical One Digital Gateway setting lets you control what data gets integrated for your studies.
- Support for non-serialized inventory for integrations
  The supply and dispensation of non-serialized inventory is now supported for select Clinical One Digital Gateway integrations with Clinical One Cloud Service studies.

Configure Clinical One Digital Gateway integrations to integrate data as of a specific date

A new Clinical One Digital Gateway setting lets you control what data gets integrated for your studies.

Details for integration managers

A new scheduling setting (**Only transfer data after specific date**), available in Clinical One Digital Gateway, lets you determine how far back an integration should look (in a study) when creating jobs for outbound data integrations. This enables you to control what data gets integrated for your studies.

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By default, the setting is configured to send all data from the start of the study, which is the most common integration process. However, limiting the data you integrate can enhance the efficiency of your integrations.

The most common uses cases include:

Table 7-2 Use case details

Use case	Example
Limiting the test data being integrated	You created an integration for testing purposes. You did this two years ago and never deleted the test integration, as you may need it again. Today, you want to implement one change to the integration, and you need to test it. In this scenario, you'd set **Only transfer data after specific date** to a date that aligns with the day you changed the integration. This ensures your new testing does not include the older data.
After migrating a study to a new tenant	You wouldn't want to re-integrate data already integrated before the study migrated; you'd only want to integrate data since the day the study completed the migration process. In this scenario, you'd set **Only transfer data after specific date** to a date that aligns with the day the study completed migration.

You can find additional information in the *Digital Gateway User Guide* after the Production upgrade.

Support for non-serialized inventory for integrations

The supply and dispensation of non-serialized inventory is now supported for select Clinical One Digital Gateway integrations with Clinical One Cloud Service studies.

Details for integration managers

Non-serialized kits are tracked by lot number and quantity and not by the kit number. For more information about this new feature, see Distribute non-serialized inventory.

The following integrations now support the transmission of data related to non-serialized kits:

> **Note**
>
> If your study is using an integration with Clinical One Digital Gateway which is not listed below, your study will not support the transmission of data related to non-serialized inventory.

- The integration with Almac Global Depot Network

  > **Note**
  >
  > The integration with Almac Global Depot Network only supports a single kit type or description per lot. When using the Almac integration with non-serialized investigational product, a kit type must be mapped to an individual number.

- The integration with Oracle InForm

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- The integration with Medidata Rave

How to update current integrations

Reach out to your Oracle point of contact if you would like to update the integration configuration to support non-serialized inventory.

Notifications

- New notification for report server limit exceeded
  This new notification informs users when a generated report exceeds the report storage server space.

New notification for report server limit exceeded

This new notification informs users when a generated report exceeds the report storage server space.

Each study mode is allocated 200 GB on the report storage server. When a report is generated that exceeds this limit, users are informed by the new **Report Space Limit Exceeded** notification.

When a report exceeds the limit, the report fails, and the person generating the report receives the notification. For scheduled reports, the person who scheduled the report gets the notification.

> **Note**
>
> The system does not notify users if one of the following global-level reports exceeds the limit:
>
> - Global Study Roles report
> - Life Sciences Learn Training Report
> - Study Roles Report by Study
> - User Assignment Across Studies report

More information can be found in the *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- Allow depot-to-depot shipments for staging kits
  Clinical supply managers can now allow depot-to-depot shipments to stage kits for a country prior to a blinded lot being approved in a study.
- Distribute non-serialized inventory
  Clinical supply managers can now provide sites with the ability to distribute non-serialized inventory to subjects and define a resupply process to ensure product availability when needed.

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Allow depot-to-depot shipments for staging kits

Clinical supply managers can now allow depot-to-depot shipments to stage kits for a country prior to a blinded lot being approved in a study.

With the introduction of a new setting for blinded lots, you can better plan and control a study's supply strategy and configurations. By allowing depot-to-depot shipments before a lot is approved for release in a certain country, you give your team the possibility to ship the kits to the depot and stage them just in time for them to be shipped to the country-specific sites.

For example, a new blinded lot A is created for your study. Kits in lot A will be dispensed in three countries (Germany, France, and Spain) and each country has its own release process for these kits, as well as different intervals for releasing these new kits. Even though your study team cannot ship the kits to the sites in all three countries at once, they can now ship those kits to the depot (via a depot-to-depot shipment) to have them ready in due time for when the release of the kits can begin.

Details for clinical supply managers

> **Note**
>
> This feature doesn't impact any other components, such as study design, data collection, reports, integrations, or notifications.

Here's what's new in your workflow:

- On the **Study Inventory** tab, when you edit a blinded lot, a new toggle is displayed on the Edit Blinded Lot dialog. This new toggle is called **Release for Depot to Depot**.
- By default, the **Release for Depot to Depot** toggle is turned off. When you turn on the toggle, and a depot-to-depot shipment is created, this shipment will be delivered regardless of the DNS (Do Not Ship) settings specific for a lot or a country.

You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Distribute non-serialized inventory

Clinical supply managers can now provide sites with the ability to distribute non-serialized inventory to subjects and define a resupply process to ensure product availability when needed.

The use of non-serialized inventory can be helpful in numerous scenarios, especially in studies with a large number of subjects that require a larger supply. Because non-serialized inventory is not tracked, this leads to easier reconciliation, depending on the type of investigation product.

For example, if ten (10) kits are dispensed for a subject, but two (2) of the kits were damaged, all 10 kits are marked as *Damaged By Subject*. The eight (8) kits are still dispensed, but it is not specified which 2 kits are damaged because they are not tracked by kit number.

Details for clinical supply managers

When it comes to your workflow, here's what's new for you:

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- On the **Study Inventory** tab, you can now manage both serialized and non-serialized kits. To easily identify any of these kit types, you can use the new Kit Type filter options: Serialized, Non-Serialized, or All.
- On the **Study Inventory** tab, you can now add kits to a lot by selecting the **Add to Lot** drop-down and entering the required information in the Add Non-Serialized Kit to Lot dialog.
- When specifying resupply settings, a min/max or predictive resupply strategy can be used for non-serialized kits.
- Non-serialized kits can be partially dispensed, locally sourced, and selected for a dose hold.
- Non-serialized kits *cannot* be individually ordered.
- Dispensation of reusable kits, site confirmation for dispensation, temperature excursion numbers, site and depot kit reconciliation are *not* available for non-serialized kits when both serialized and non-serialized kits are present in a study.
- On the **Depot Inventory** tab, non-serialized kits display by lot number and as unblinded.
- On the **Depot Inventory** tab, when a single lot is selected with the status of *Quarantined*, Quarantined Shipment Details appears in the side panel.

More information on non-serialized kit design and configuration can be found in the *Sponsor and CRO User Guide* and *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

As a site user, here's what's new for you:

- Details on non-serialized kits appear on the **Site Inventory** tab.
- Under **Kit Types**, you now have options to view **All**, **Serialized**, or **Non-Serialized** kits.
- For non-serialized kits, instead of a kit number, the lot number and quantity is displayed in the following user interface (UI) areas:
  - **Shipments** tab
  - **Site Inventory** tab
  - Add Shipment to Inventory dialog (when you register a shipment at a site)
  - Release Quarantined Kits dialog (when you quarantine kits at a site)
  - Dispense Kits dialog (after you dispense a non-serialized kit to a subject)
- When adding non-serialized kits to your inventory, you can enter an exact quantity of kits from the received lot you would like to add.

More information and step-by-step instructions on managing non-serialized inventory at the site level can be found in the *Site User Guide* after the RAE upgrade.

Impact on reports

Once the RAE upgrade is complete, additional details on non-serialized lots and counts of kits can be found in the following reports:

- Kit Inventory (Blinded) report
- Kit Inventory (Unblinded) report
- Kit Dispensation report

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- Shipment Order Summary report
- Subject Events Report
- Study Design report
- Subject Visits (Blinded) report
- Subject Visits (Unblinded) report
- Titration Summary (Blinded) report
- Titration Summary (Unblinded) report

For more information, see the *Reporting Guide*.

> **Note**
>
> Kit numbers display as lot numbers for non-serialized inventory.

Individual barcodes and tracking are not available in Oracle Clinical One Analytics for non-serialized kits. Because all tracking is removed, Oracle Clinical One Analytics datasets display the most recent view of kits by groups and quantity based on their status. Updates to the Blinded and Unblinded Kits datasets can be found in the *Analytics User Guide* after the RAE upgrade.

Impact on notifications

The following notifications include additional details on non-serialized inventory when non-serialized kits are dispensed:

- **Unblinded dispensation notification**
- **Study inventory notification**
- **Kits quarantined notification**
- **Kits released from quarantine notification**
- **Kit status changed to "Misallocated" notification**
- **Kit status changed to "Not Dispensed to Subject" notification**
- **Subject dispensation notification**

For more information, see the *Notifications and Permissions Guide*.

Impact on integrations

To learn more about the impact of this new feature on your existing or future integrations, see Support for non-serialized inventory for integrations.

Already working in a live study?

When the upgrade for this release is complete, to start working with non-serialized kits you must update the study design adding a non-serialized kit type. Functions for non-serialized kits in existing studies will be available, such as new filter and field options, and kit status information on the **Study Inventory**,**Site Inventory**, and **Depot Inventory** tabs.

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Reporting, archives and analytics

- New Lab Normal Range report
  The new Lab Normal Range report provides information about all the lab normal ranges entered for your studies.
- Report data gets automatically purged
  Reports are now automatically purged to optimize report storage.
- Enhancements to Oracle CRF Submit archives and reports
- Control authoring access in Oracle Clinical One Analytics
  New global roles are available to control authoring and read-only access to Oracle Clinical One Analytics. With these roles, you can control which users can create or edit reports and dashboards and which users are restricted to only viewing and running existing reports.
- Audit Trail dashboard in Oracle Clinical One Analytics
  Sponsor users can now use the Audit Trail Dashboard, available in Oracle Clinical One Analytics to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.
- Support for queries on visit dates in Oracle Clinical One Analytics
  Data related to queries raised on visit dates now populate in Oracle Clinical One Analytics in all applicable datasets.
- Oracle Clinical One Analytics supports replacing a subject number with a randomization number
  Replacing a subject number with a randomization number in an Clinical One Cloud Service study is now supported in Oracle Clinical One Analytics datasets.

New Lab Normal Range report

The new Lab Normal Range report provides information about all the lab normal ranges entered for your studies.

By having all the existing data now available in one place within the **Lab Normal Range** report, you can regularly can verify the accuracy and completeness of the normal ranges entered for labs in the study, troubleshoot and minimize errors at a specific lab and across all labs in a study.

Before you work with this feature

- Users who are assigned to a study role that includes the *Add and Update Lab Normal Ranges* permission or are assigned to the View Only Unblinded Support template study role can run this report.
- As a user administrator, you can also assign the new permission *Run the Lab Normal Range Report* to a role, so that the user assigned to that role can generate the report.
- Users assigned to a study role that includes the *Run the Lab Normal Range Report* permission, who are not assigned the *Add and Update Lab Normal Ranges* permission, can only view normal ranges for the sites for which they have permission.

What data does this report show?

In a study, on the **Reports & Archives** page you will see a new report called **Lab Normal Range**.

When you select that report, you can use the **Settings** sidebar on the right to filter the data included in your report. Or you can schedule the report to run at a specific date and time.

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This report will be available for new and existing studies as soon as the upgrade completes. The report contains the normal ranges for each lab, including:

- Low and high lab ranges
- Normal test results
- Fasting
- Effective date
- Entered, or last updated date information
- User identification details that performed the actions (first and last updated information)
- Action performed (created, modified or deleted)
- Associated sites to the lab
- Lab unit, test name, and ID

You can find additional information in the *Reporting Guide* once the Release Assessment Environment (RAE) upgrade completes.

Report data gets automatically purged

Reports are now automatically purged to optimize report storage.

Details for all users

Starting with this release, each time you generate a study-level standard report in any study mode, a system check runs to see if any previously generated reports (in that study and mode only) are 120 days old or older; if found, the system automatically deletes them. This optimizes report storage and ensures smooth study export during the decommissioning process.

> ⚠ **Caution**
>
> The system check will be active after the Clinical One Cloud Service Production upgrade is complete. The first time a user generates a report, the check will run, and reports will be purged.

Details for sponsor users

The system check includes the **Drug Order** and **Drug Reconciliation** forms, considered reports in Clinical One Cloud Service studies. They are also automatically deleted when they are 120 days old.

Applicable shipment details for an auto-purged form are still available on the Shipment Details side panel in the UI (User Interface), even after the system deletes a form.

> ⓘ **Note**
>
> You should not resend an auto-purged drug order or drug reconciliation form, as it will be resent to the depot, potentially causing confusion. This may trigger the depot to send shipments to sites that are not needed.

You can find additional information in the *Reporting Guide* and the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

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Enhancements to Oracle CRF Submit archives and reports

The shared servers now use the Chrome Engine to generate PDFs

This move leverages Chrome Engines' ability to optimize PDF generation when converting clinical trial data into PDFs. The result? A noticeable performance improvement when using Oracle CRF Submit.

Also, using the Chrome Engine to generate PDFs results in better PDF rendering, which reduces the number of pages in your requests' output.

> **Note**
>
> Moving to this technology does not result in any layout changes in the PDFs.

We've made it easier to locate RTSM data in the PDF output of an Archive

The PDF output for Submission, Archival (site and sponsor), and Custom Archive requests now include a new heading, Subject Randomization History. This was previously called Subject History.

The PDF output includes this section when you set the Advanced Setting, **Include RTSM Data**, to **Yes**.

For more information about this setting, see Available archive types and reports in the *Reporting Guide*.

In-product filters are now available for the Site Confirmation report

The Site Confirmation report now includes in-product filters. Before introducing these filters, site, and sponsor users were required to generate the report for all data, only then being able to filter data directly in the output file, which can be cumbersome for studies with many sites.

A new set of filters is available under the Settings side panel in the user interface, allowing users to apply filters before generating the report.

The new available filters are:

- **Request Name**
- **Request Type**
- **Published Date**
- **Site Name**
- **Confirmed By**
- **Confirmation Date**
- **Confirmation Status**

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

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Control authoring access in Oracle Clinical One Analytics

New global roles are available to control authoring and read-only access to Oracle Clinical One Analytics. With these roles, you can control which users can create or edit reports and dashboards and which users are restricted to only viewing and running existing reports.

Details for user administrators and global user managers

The existing study-level permissions to run a specific dataset are still available, but now they provide read-only access to Oracle Clinical One Analytics for a given dataset. These dataset permissions allow a user to view and run existing reports and dashboards, viewing only data related to the given dataset. Without authoring access at the global level, a user cannot modify reports or create new ones.

To have authoring access, a user must be assigned any of the new Analytics global roles. The Analytics global user roles, now available on the Global Settings page in Clinical One Cloud Service, are:

- *Analytics: Data Visualizer Authoring*: this role lets you create and modify reports and dashboards in the Oracle Clinical One Analytics Data Visualizer interface.
- *Analytics: BI Publisher Authoring*: this role provides access to the Oracle Business Intelligence (BI) Publisher functionality to create or customize pixel-perfect reports.

As a user administrator or global user manager, if you want a study team member to have authoring access to Oracle Clinical One Analytics, you must assign them the appropriate permissions at the study level and the appropriate new global user roles together. For example, if you only assign a user with any study-level dataset permission, like the *Run the Unblinded Kits Dataset* permission, they will only have read-only access to that specific dataset in Oracle Clinical One Analytics. If you assign a user with the *Run the Unblinded Kits Dataset* permission and the *Analytics: Data Visualizer Authoring* global role, they will have the ability to create, view, and update reports and dashboards that use this specific dataset.

You can find additional information in the *Analytics User Guide* once the Release Assessment Environment (RAE) upgrade completes.

Details for users working with Oracle Clinical One Analytics

Given that not every user with access to Oracle Clinical One Analytics has authoring privileges, the landing page is changing. When you access Oracle Clinical One Analytics from Clinical One Cloud Service, you are now redirected to the catalog page. On the catalog page, you can find all the reports available to you, and from here, you can open and run any report to work with it.

Browse the *Analytics User Guide* to learn how to navigate through Oracle Clinical One Analytics based on your permissions.

Already working in a live study?

As soon as this release is available, a current Oracle Clinical One Analytics user will only have read-only access. To provide authoring access to a study team user, make sure they are included in Clinical One Cloud Service as a global user for your organization and that you assign them with the appropriate Analytics global roles.

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Audit Trail dashboard in Oracle Clinical One Analytics

Sponsor users can now use the Audit Trail Dashboard, available in Oracle Clinical One Analytics to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.

> **Note**
>
> Whether you are working in a live study (and are already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle point of contact for more information about Oracle Clinical One Analytics training and mentoring.

With the new Audit Trail dashboard, the auditing process has become more efficient. You can now pick between several reports, each addressing a particular scenario, which makes it easier to obtain precise data for a specific part of the auditing process. To further improve the efficiency of your work, the visualizations available in each of these reports are specifically selected to best illustrate the data. Some visualizations you can also interact with, giving you the option to dynamically adjust them to better suit your needs.

The Audit Trail dashboard comes pre-packaged with a set of options, which facilitate your auditing process. This means you can save time on creating a dashboard from scratch. Nonetheless, you can still customize the Audit Trail dashboard to better meet your needs. You can find additional information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Before you work with this feature

> **Note**
>
> Even though this dashboard is intended to assist sponsor users, the Audit Trail dashboard is available to any user with the appropriate permissions.

The Audit Trail dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the **Subject Form Items Dataset** before viewing data in a corresponding dashboard.

Access to a dataset is based on the permission assigned in the Clinical One Cloud Service. To access the Subject Form Items dataset and, consequently, the Audit Trail dashboard, make sure you have the *Run the Subject Form Items Dataset* permission assigned.

> **Note**
>
> New permissions have been introduced to manage read-only and authoring access to Oracle Clinical One Analytics. You can find additional information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Details for sponsor users

As a sponsor user, you can have better control of how you view your study's data using the new Audit Trail dashboard. This new dashboard provides insights on data operations that have

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occurred in Clinical One Cloud Service, structured around reports including initial data entry, updates to data, or the clearing and verifying of data. You can also track changes in your study's data on a form by form or a subject by subject basis, and adjust the granularity of these reports according to your needs.

Each of the reports features appropriate visualizations for your data. For instance, the volume of data transactions in your study is illustrated using a heat map, while data modifications on a form-by-form basis are represented using a pivot table.

In the new Audit Trail dashboard, you can switch between the following reports:

- Data Operations Summary: provides object-level summaries of all the data operations that have occurred.
- Data Operations Evolution: provides a view of trends in data operations at an item-level over time.
- Data Operations Analysis: provides summary views of data operations, pivoting and grouping them by properties such as **Country**, **Site**, **Role**, **Visit**, and **Form**.
- Data Modification Analysis: identifies the countries, sites, users, subjects, forms, and items that are most frequently modified.
- Form data Modifications Analysis: provides form-level visualizations of the volume of data modifications across a trial.
- Subject Audit Trail Data: consists of a listing table that provides all of the subject data operations that occurred in a study.

You can find additional information regarding this and other dashboards in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Support for queries on visit dates in Oracle Clinical One Analytics

Data related to queries raised on visit dates now populate in Oracle Clinical One Analytics in all applicable datasets.

Given that raising queries on visit dates is possible in Clinical One Cloud Service, you can now view and analyze this data in Oracle Clinical One Analytics. All datasets that include query data now include queries on visit dates, too. With this, you can also visualize the visit date alongside any queries raised against it.

> **Note**
>
> Queries on visit dates appear assocaited to the form called "Visit Date".

To further support this data, new data elements are now available in the following datasets:

- Query dataset
- Study Design dataset

Similarly, new versions of the applicable Oracle DMW views and updates to the ODM-XML extracts are available to support queries on visit dates.

You can find additional information in the *Analytics User Guide* and the *REST API for Clinical One Platform* guide once the Release Assessment Environment (RAE) upgrade completes.

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Oracle Clinical One Analytics supports replacing a subject number with a randomization number

Replacing a subject number with a randomization number in an Clinical One Cloud Service study is now supported in Oracle Clinical One Analytics datasets.

Details for Oracle Clinical One Analytics users

The setting, **Replace Subject Number with Randomization Number**, was introduced in a previous Clinical One Cloud Service release. When enabled, the randomization number replaces the subject number throughout the study after randomizing a subject.

More information about this setting is available in the *Sponsor and CRO User Guide* under *Specify study, enrollment, and visit settings*.

This enhancement impacts the following Oracle Clinical One Analytics datasets, starting with this release:

- Blinded Kits dataset
- Blinded Subject Event dataset
- Queries dataset
- Subject dataset
- Subject Form Items dataset
- Subject Forms dataset
- Unblinded Kits dataset
- Unblinded Subject Event dataset

Impact to datasets

A new column, SCREENING_NUMBER, is available in the Subject folder for each dataset.

For a new subject, the values displayed under SUBJECT_NUMBER and SCREENING_NUMBER match after you create a subject, as seen in the table below.

Table 7-3 Example dataset output before randomization

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_NUMBER	SCREENING_NUMBER
001-001	Screened	*This cell is initially blank*	001-001

If the **Replace Subject Number with Randomization number** setting is enabled and you randomize a subject:

- SUBJECT_NUMBER displays the randomization number.
- PREVIOUS_SUBJECT_NUMBER displays the original subject number.
- SCREENING_NUMBER remains unchanged, as it always displays the original screening number for a subject.

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Table 7-4 Example dataset output after randomization, where 123456 is the randomization number

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_NUMBER	SCREENING_NUMBER
123456	Active	001-001	001-001

If you re-randomize a subject:

- SUBJECT_NUMBER displays the new randomization number.
- PREVIOUS_SUBJECT_NUMBER displays the initial randomization number.
- SCREENING_NUMBER remains unchanged, as it always displays the original screening number for a subject.

Table 7-5 Example dataset output after re randomization, where 789101 is the new randomization number

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_NUMBER	SCREENING_NUMBER
789101	Active	123456	001-001

You can find additional information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- Clear values on a form using custom rules
  With the new `clearValue()` helper function you can clear data in a target question for a calculation rule, whether it is a text, number, or choice question.

Clear values on a form using custom rules

With the new `clearValue()` helper function you can clear data in a target question for a calculation rule, whether it is a text, number, or choice question.

With the introduction of the `clearValue()` helper function, rule developers can now clear a form question using a custom calculation rule. This function can only be called as part of the return statement of a calculation rule, which means you can only use this helper function with question types that can be used as the target for a calculated value, such as:

- Text
- Number
- Choice-type controls (drop-down, checkboxes, or radio buttons)

The `clearValue()` helper function allows you to perform a "true clear", which is different from simply removing an item's data and replacing it with an empty string. Data clear is a more complex process that occurs in the backend, and by using this function you are actually returning an indicator to the rule process to start a data clear. When data is cleared, the given item state is as if it has never been answered. With all items in an unanswered state, a form can return to a status of *New*. This is important for site users so they can skip visits whenever necessary or avoid having false incomplete visits on a subject's record.

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> **Note**
>
> Even if you clear a question's data, the whole answer history is preserved. All actions on a question are listed on the Answer & Visit History sidebar and in the audit trail. In there, you can also see which actions result from rule execution.

You can find additional information in the *Rules Developer Guide* once the Release Assessment Environment (RAE) upgrade completes.

User experience

- Study roles and permissions are now translated
  Study roles with their assigned user permissions and data classifications are now localized when you operate theClinical One Cloud Service in any of the available languages.

Study roles and permissions are now translated

Study roles with their assigned user permissions and data classifications are now localized when you operate theClinical One Cloud Service in any of the available languages.

Whenever you set your language preference to a language other than English, you can now see study roles and permissions translated into the selected language. This localization is applicable to every task that involves study roles, permissions, and data classifications. This includes study role management (at the global and study levels), study user management, and reporting.

> **Note**
>
> While both template and custom study roles information is localized, user-entered data is never translated. This means that study role names and descriptions are only localized for template roles. For custom roles, this data is manually entered and always displayed as it was originally entered.

Impact on study role management

Study role management refers to the process of viewing, creating, and modifying study roles and their assigned data classifications. This can be either at the global level from the Global Settings page or at the study level from the study's settings. In both cases, if you are working on the **Study Roles** tab, the following UI areas display study role details, permissions, and data classification information, localized according to your language preference settings:

- On the main screen of the **Study Roles** tab, you can see the list of available study roles. The names for the template study roles are localized, as well as the role type (*Design*, *Sponsor*, or *Site*) for all study roles (template and custom).
- For each study role, upon selection, you can view the study role's localized permissions in the Permissions section on the sidebar. From this section, you can also view the study role's description, which gets localized but only for template study roles.
- Similarly, upon selection, you can view the localized data classifications assigned for each study role on the Data Classifications section of the sidebar.
- When you create a study role, in the Create Study Role dialog, you get localized options for the **Type** drop-down, and localized permissions to select and assign to the study role being created.

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Additionally, the Study Role Name field now supports international characters, in the same way they were supported in the description field. With this, you can create or update custom study roles with a preferred name and language.

Impact on study user management

When working on the **Users** tab within a study's settings, the following UI areas display localized study roles, according to your language preference settings:

- Upon selection, you can view the assigned study roles for each study user in the corresponding section on the sidebar.
- When you create or edit a user, in the Create User or Edit User dialogs respectively, you get localized options for the template study roles on the **Study Roles** drop-downs available for each mode.

Impact on reports

Similarly, template study roles, study role types, and permissions included in reports are also localized. These reports include:

- User Assignment report
- User Assignment Across Studies report (global level)
- Study Roles Report by Study (global level)
- Global Study Roles Report (global level)

Fixed issues

- All users
- Oracle Clinical One Analytics
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Reports, archives, extracts, and notifications
- Site users and subject data
- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

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All users

Removed subjects are incorrectly listed in subject number list drop-downs across studies

Subjects removed from a study by the **Undo Add Subject** action, are no longer listed in the different subject number drop-downs across a study, and duplicates are no longer observed.

Previously, subjects who were removed from a study were included on subject number lists. Given that the subject number that was originally assigned to a removed subject can be later assigned to a subsequently enrolled subject, this sometimes resulted in duplicates.

The processes that were previously impacted are:

- Manage kit inventory
- Manage site inventory
- Update subject number
- Manage queries on the Query list page
- Filter by subject number in the subject visits page

(Issue **36791783**)

Users logged out while actively working in a study

Users no longer experience inactivity time-out issues while actively working in a study. Previously, users received inactivity timeout messages and were forcefully logged out when the defined inactivity time had not been reached.

(Issue **35900433**)

Facilities, settings, and user management

System error when updating a study role

You can now successfully save changes to custom study roles at the study level. Also, study-level custom study roles are no longer being renamed according to study roles at the global level.

Previously, custom study roles at the global level that were renamed within a study were being renamed back at the study level with the names they had at the global level. This was sometimes causing duplicate names for study roles within a same study. Additionally, when trying to update these custom study roles, update attempts were failing and changes were not being saved.

(Issue **37133069**)

Unable to create new users with hyphens in their user names

Hyphens are now permitted in user names when you create user accounts in Clinical One Cloud Service and add them to your studies, individually or when using the bulk upload process. User names can be an email address, must be case-insensitive, and can only contain letters, numbers, underscores, dots, or hyphens.

For more information about the template and step-by-step instructions, see the *Add Users Guide*.

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(Issue **36983545**)

Only the first 20 sites are displayed on the Sites & Labs tab

For any study mode, if your study contains more than 20 sites, you can now view all sites on the Sites & Labs tab. Previously, if your study contained more than 20 studies, not all of them may have been visible in the UI, although you could still search for them.

(Issue **36484968**)

Filtering by a query creator's name isn't preserved

On the Query List page, when you filter queries by their creator's name and navigate to other sections of the Query List page, the filter you previously configured is preserved. Previously, the filter would get deselected once you viewed a specific query's details and then navigated back to the main page of the Query List.

(Issue **36836143**)

A study version is not deselected for all sites displayed in the UI

On the Sites & Labs tab, when you remove or update the study version associated with sites from the **Study Version** drop-down, your update is applied to all sites in your study, as expected.

(Issue **36730703**)

A source data verification checkbox appears for forms and questions when it should not

Source Data Verification (SDV) checkboxes no longer appear next to all forms and questions when you select **No** for the Source Data Verification setting, **Allow SDV Overrides**. Instead, checkboxes only appear next to questions that require SDV based on study settings.

For more information about the setting, see *Understanding source data verification* in the *Sponsor and CRO User Guide*.

Retracted recommended action:

1. Go to Study Settings and select the **Source Data Verification** tab.
2. Set **Allow SDV Overrides** to **Yes**.

(Issue **36766556**)

Unable to create new users using the bulk upload process when user names contain an underscore

Underscores are now permitted in user names when you create user accounts in Clinical One Cloud Service and add them to your studies, individually or using the bulk upload process.

For more information about the template and the process, see *About creating user accounts using the upload template* in the *Add Users Guide*.

(Issue **36676631**)

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Forms, visits, and rules

Calculation rule target not updating without refresh

Now, the updated value in at least one open query in a visit displays without the need for a refresh. Previously, when a question was used as a variable in more than one calculation rule and there was at least one query open in the visit, the calculation target questions would not display the updated value until the visit was refreshed.

(Issue **35968040**)

Inline saving for some repeating forms took too long

Repeating forms that are referenced by multiple custom rules will now save more quickly. Previously, the data submission could be slowed due to rules needing to be processed for all repeating form instances.

(Issue **36297924**)

Lab normals now populate regardless of the associated study version

Now, the lab normal range is set properly, regardless of the study version used to start the demography form. Previously, lab normal ranges were sometimes cleared if the demography form was started on a different study version than the lab form.

(Issue **37222861**)

Improved performance for Advanced Study Versioning (ASV) updates

When you apply changes to multiple forms through Advanced Study Versioning (ASV), you will notice an improvement in the performance of those updated forms. Previously, the system may have been slower when data was collected through forms that were modified or added through an ASV update.

(Issue **36771040**)

Integrations

Configured Subject Identifier not being sent for kit replacement in the Oracle InForm MedML Integration

Integration managers can now configure a <Site ID> + <Randomization Number> as the subject identifier to be integrated to Oracle InForm for the kit replacement template. We optimized all APIs associated with the MedML integration to now correctly display the full 12-digit patient number when a kit is replaced. Previously, when performing a kit replacement, the subject number was displayed instead of the concatenated <Site ID> + <Randomization Number>, which represents a patient's 12-digit number in Oracle InForm.

(Issue **37331077**)

The Data Intake integration fails to integrate data into a visit that was completely cleared

The Data Intake integration now completes successfully when integrating items into a visit that was completely cleared in Clinical One Cloud Service. Previously, this integration failed to complete for cleared visits. In particular, this issue was observed when a study version update occurred at any point after the visit was originally created, and before the integration's attempt to send data.

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(Issue **36728502**)

The Data Intake integration fails to integrate items added via Advance Study Versioning (ASV) (former known issue)

The Data Intake integration now completes successfully when integrating items introduced in a study version via ASV.

For more information about the integration, see *Data Intake integration* in the *Digital Gateway User Guide*.

(Issue **36728924**)

Oracle Clinical One Analytics

Duplicate records created for a site, depot, or lab

Now, when you create or modify a site, depot or lab facility in the Clinical One Cloud Service, data related to these facilities is provided to Data Hub with a unique identifier. Previously, creating or updating sites in the Clinical One Cloud Service would generate duplicate active records due to the lack of a unique identifier for a lab facility. This impacted the integration of downstream services such as Oracle Life Sciences Data Management Workbench.

(Issue **37111618**)

Two active records for the same inventory ID in the Blinded and Unblinded Kits datasets

There are no longer duplicate rows for the same inventory ID in the Blinded and Unblinded Kits datasets in Oracle Clinical One Analytics. Previously, two different records were incorrectly created at the same time for a new inventory ID: one for the `CREATED` action and another one for the `REMOVED` action. Both records were displayed in the Oracle Clinical One Analytics tables, creating a data mismatch.

Due to a primary key violation, this issue was also causing a data load failure in Oracle DMW which is now corrected along with this fixed issue.

(Issue **36999348**)

Two active records for the same site after a change of primary address

Oracle Clinical One Analytics datasets now display the correct new primary address for a site and no duplicate records are observed. Previously, with the introduction of multiple primary addresses for sites, a duplicate entry for the same site's address was created when there was a change of primary address. This was particularly observed for sites created before Clinical One Cloud Service 23.3 as part of a backward compatibility issue.

Due to a primary key violation, this issue was also causing a data load failure in Oracle DMW which is now corrected along with this fixed issue.

(Issue **36958248**)

Oracle Clinical One Analytics data refresh event completes with errors (former known issue)

The Oracle Clinical One Analytics data refresh event, to synchronize data entered in Clinical One Cloud Service with Oracle Clinical One Analytics tables, now completes successfully. This makes all kit dispensation details to be available and accurate in Oracle Clinical One Analytics datasets.

All previously impacted data elements now populate correctly.

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Impacted dataset	Impatcted data elements
Unblinded Subject Event dataset	• INSTANCE_NUMBER • INVENTORY_ID • KIT_NUMBER • KIT_TYPE_SRC_ID • INVENTORY_STATUS_ID • INVENTORY_STATUS • DISPENSATION_DATE • MHEALTH_DEVICE_ID • DOSAGE • BAR_CODE • DISPENSATION_CONFIRMED • MEASUREMENT • FREQUENCY • RETURNED_UNITS • MISSING_UNITS • CONSERVED • KIT_DESCRIPTION
Blinded Subject Event dataset	• KIT_NUMBERS
Unblinded Kits dataset	• DISPENSATION_DATE • DOSAGE • MEASUREMENT • FREQUENCY • CONSERVED • QUANTITY • INSTANCE_NUMBER
Blinded Kits dataset	• DISPENSATION_DATE • DOSAGE • MEASUREMENT • FREQUENCY • CONSERVED • QUANTITY • INSTANCE_NUMBER

Retracted recommended action: Verify the information of the impacted data elements in your study in Clinical One Cloud Service.

(Issue **36249843**)

The Blinded Kits dataset does not include blinded kit records (former known issue)

The Blinded Kits dataset, used to analyze and visualize supply data, now includes details for both blinded and unblinded kit types. Previously, this dataset only displayed data for unblinded kits.

(Issue **36131614**)

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Randomization and kits

GET API endpoints limit kit data

The list of kits of a particular type can now be configured to retrieve over 100 entries when using the following API endpoints:

- `ec-ors-svc/v1.0/studies/{id}/{mode}/inventory/kit-types/{id}/kits`

Previously, this list would be limited to 100 entries, with no possibility for expansion.

(Issue **37253372**)

Kit status options aren't the same for individual kits and kit types

On the Study Inventory tab, when you alternate between selecting a specific kit type and selecting an individual kit of a specific type, you now see the same kit status options in the **Status** drop-down, on the **Kit Settings** sidebar. Previously, when you selected a type of kits (of the same status) and then selected a specific kit from that kit type, you may have noticed that the displayed statuses were different as you navigated from selecting a kit type to selecting an individual kit.

(Issue **36944615**)

Randomization lists are not automatically associated with a study version when moved from Draft to Test

When you move a study version from the Draft container to the Test container, randomization lists remain associated with it. Previously, they were not, and users encountered issues when attempting to associate a list manually after the move.

(Issue **36127185**)

The predictive resupply strategy only considers one-cycle visits for a branch defined with unlimited cycles

A predictive resupply strategy now considers all cyclic visits when you define a branch with unlimited cycles in designer. Previously, predictive resupply only considered the next cyclic visit instance.

(Issue **35476474**)

Reports, archives, extracts, and notifications

Subject Data Extract includes incorrect data for different study versions and modes

The Subject Data Extract, when generated in Production mode, now contains entries only for the questions associated with an approved study version. This includes the study version in the Approved container, as well as any study version in the Archived container that was previously in the Approved container. Previously, this extract included questions added in a subsequent testing version as `DeletedQn` entries.

In addition, hidden questions are now included as expected, considering user permissions and data classifications.

(Issue **36730673**)

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User Assignment and User Assignement by Site reports fail to generate or have slow performance

The processing for the User Assignment reports has been optimized and safety checks for null values have been implemented so that the User Assignment and User Assignment by Site reports now generate successfully, for both current and historical data. This fix reduces processing time and effort, allowing these reports to generate in an acceptable time frame, according to the amount of data being returned.

Previously, these reports were failing for some studies due to a backward compatibility issue with particular data setup and conditions. This was observed in complex studies with high data volumes and when different filter configurations were applied.

(Issue **36440930**)

Sites and Depots report with historical data fails to generate for large amounts of data and makes the system unresponsive

The Sites and Depots report now generates successfully, for all file types and regardless of data volume. Previously, the Sites and Depots report failed to generate for large amounts of data when historical data was included, causing the reporting system to become unresponsive. This was particularly observed when the report was generated in PDF format.

(Issue **36824952**)

Subject Queries report with audit trail data fails to generate

The processing needed to generate the Subject Queries report has been optimized to reduce processing time and effort. Now, the Subject Queries report generates successfully, for all file types and regardless of data volume.

Previously, generating the subject queries report would time out and fail when processing large volumes of data. This would typically happen when filters were set to **Include Audit Trail**, **All locations**, and particularly observed when the report was generated in **CSV format**.

(Issue **36779220**)

Blinded Kit Chain of Custody report groups kit numbers by kit type which is potentially unblinding

The kit numbers in the Blinded Kit Chain of Custody report are now in complete ascending order, irrespective of kit type, and regardless of applied filters.

Previously, when you filtered a Blinded Kit Chain of Custody report by a single shipment, kit numbers were listed in ascending order but grouped by kit types. This exposed partially unblinding information by revealing the kit numbers for the kits that belong to a same kit type.

(Issue **37106112**)

The Study Role report does not show permissions data

The Study Role report now includes the permissions assigned to a study role. Previously, the permissions column would populate with *N/A*.

(Issue **36784681**)

The Subject Data Extract fails to generate

The Subject Data Extract now generates successfully when generated by a blinded user, allowing blinded data to be extracted for review outside the system.

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(Issue **37008259**)

No line breaks in the Life Sciences Learn Training Report

The CSV version of the Life Sciences Learn Training Report now contains proper line breaks between each record, ensuring that you can properly view your learning data.

(Issue **36442280**)

Some users might not be able to generate the Subject Visits (Unblinded) report

As long as you have the appropriate permission (*Run the Unblinded Subject Visit Schedule Report*), you can successfully generate the Subject Visits (Unblinded) report. Previously, running this report may have resulted in a failure due to an API issue.

(Issue **35528180**)

Some reports won't generate successfully for certain custom sponsor study roles

Users assigned to a custom study role that includes either the *View Sites* or *View Depots* permission can now successfully generate reports. Previously, report generation would fail if the study role did not also include either the *Create and Manage Sites* or *Create and Manage Depots* permissions.

Previously impacted reports:

- Subject Queries report
- Subject Events report
- Subject Visits (Blinded) report
- Subject Enrollment report
- Subject Data report
- Kit Chain of Custody (Blinded)
- Kit Inventory (Blinded) report
- Randomization List (Blinded) report

(Issue **36741692**)

Oracle CRF Submit Archives Settings, configured for Testing Mode, are incorrectly applied to Production Mode

The email notification settings initially defined under Testing Mode (on the Study Settings—Archives Settings tab) are no longer applied to Production Mode.

> **Note**
>
> For more information about Archives Settings, see Email and in-application notifications.

(Issue **35987053**)

Oracle CRF Submit Archives Blank Form PDF displays an incorrect question option

The Blank Form PDF displays the correct options associated with each question.

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The issue occurred because two questions on different forms were designed with the same refname (SAS Label) value. This led to a conflict when Oracle CRF Submit pulled the questions into the archive, as it could not determine the correct options due to the duplicate question refnames. As a result, options associated with the other question were displayed.

(Issue **36395284**)

Oracle CRF Submit Archives display the incorrect form status for the Date of Visit form

After clearing all data on forms in a dynamic visit and untriggering the dynamic visit, the correct form status, Not Started, displays instead of Completed in Oracle CRF Submit archives for the Date of Visit form.

(Issue **36393008**)

The Oracle CRF Submit Kit Chain of Custody report Table of Contents is empty

When you generate the Kit Chain of Custody (Blinded) report on the Archives tab, the Table of Contents (TOC) includes the expected details instead of being blank.

(Issue **36380339**)

Oracle CRF Submit Archives status shows Created when, in fact, they fail due to exceeding the storage server limit

When you generate any Oracle CRF Submit Archive, and the request exceeds the storage server limit, the system presents you with the failure message, Failed Out of storage.

Previously, the status in the Download Archives side panel incorrectly indicated it was generated successfully by displaying the status Created.

> **Note**
>
> In a previous release, the storage server allocation per customer was increased from 100 GB to 1000 GB to minimize issues with storage server errors.

(Issue **36110325**)

The Oracle CRF Submit Storage limit has exceeded notification is being sent every 30 Minutes

The **Storage limit has exceeded** notification, which is used to notify sponsor users when a request generated for a study exceeds the allocated storage server limit for a tenant, is no longer sent every 30 minutes when the email list exceeds 255 characters, and the notification status is successfully updated to *Processed*.

For more information about Oracle CRF Submit notifications, see *Email and in-application notifications* in the *Reporting Guide*.

(Issue **36744636**)

The Kit Chain of Custody (Blinded) report contains empty rows

The Kit Chain of Custody (Blinded) report output file no longer contains additional empty rows when you select **All** under the **Location** filter. This occurred because some sites (Locations) included in the report had no kit-related data entered. The report now ignores these sites (Locations) when generating.

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> **Note**
>
> This issue concerns the Kit Chain of Custody (Blinded) report, available under the **Archives tab** after clicking **Reports & Archives**.

(Issue **36367831**)

Site users and subject data

Performance issues with the Subjects and Sites & Labs pages

The Subject List page and the Subject Visit page in Study Settings now load successfully in all study modes. We optimized all APIs associated with these pages to ensure that the pages load in an acceptable time frame and according to the amount of study data being displayed. Previously, these pages would load slower than expected, particularly due to a complex study design involving visit branches.

(Issue **37309578**)

The query list fails to display all expected queries

The query list now displays all of a study's queries, even when the study has a larger number of active sites. Previously, the query list would sometimes display an incomplete number of entries.

(Issue **37213859**)

The Closed status of queries in an unscheduled visit isn't reflected in the Answer & Visit History side panel

The Answer & Visit History side panel now displays the status Closed for queries closed on the All Subjects page and at the form level (for unscheduled visits).

Previously, the status was displayed correctly in other areas of the user interface and in the Subject Queries report, but was not reflected in the side panel. An incorrect data element ID in the database caused this issue.

(Issue **36847101**)

Data does not save when using the right-click-paste function of a mouse

Data successfully saves when you use a mouse's right-click-paste function.

Retracted recommended action: Use Ctrl + V to paste the text into the text field.

(Issue **36455509**)

Users are unable to skip a visit after clearing all data

The visit status gets updated to New, allowing users to skip the visit. The issue occurred because the visit's status remained as In Progress after clearing the Visit Date field, which triggered rules to clear all other visit data.

(Issue **36459552**)

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Visit Data Verification forces users back to the All Subjects page

Selecting the **Ready to Verify** or **Verified** filters under the **All reviews** drop-down on the All Subjects page, followed by clicking **Verify Visit Data** on the subject visit details page, no longer results in undesirable behaviors such as infinite loops between the subject visit details page and the All Subjects page.

(Issue **36129949**)

Rest API updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 24.2.

Permissions

- The *ec-designer-ors-svc* permission has been added to access some APIs of the Designer category.

Services updates

The following new service has been added:

- Designer ORS

The following services are updated:

- Data Action
- Data Capture
- Data Hub
- Data Integration
- Designer
- Designer EDC
- Randomization and Supplies
- Reporting
- Sites and Depots

Designer ORS

> **Note**
>
> Designer ORS endpoints are listed under the Designer category.

Change	Endpoint
New	• POST /v10.0/studies/{studyId}/versions/{version}/kits • GET /v10.0/studies/{studyId}/versions/{version}/kits • GET /v10.0/studies/{studyId}/versions/{version}/kits/{kitId} • PUT /v10.0/studies/{studyId}/versions/{version}/kits/{kitId} • DELETE /v10.0/studies/{studyId}/versions/{version}/kits/{kitId} • GET /v6.0/studies/{studyId}/kits

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Data Action

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/subjects/visits/lock

Data Capture

Change	Endpoint
New	• GET /v1/studies/{studyId}/{mode}/subjects/{subjectId}/{studyVersion}/demographicstatus • GET /v7.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements

Data Hub

Change	Endpoint
New	• POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits • POST /v4.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v5.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v6.0/studies/{studyId}/{mode}/odm/metadata • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/dataelements/all • GET /v3.0/studies/{studyId}/{mode}/subjects/history/all • GET /v3.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Designer

Change	Endpoint
New	• POST /v2.0/studies/{studyId}/versions/{version}/forms/copyForms

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Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/visitsforms/actionitems

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Randomization and Supplies

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/nsinventory • POST /v1.0/studies/{studyId}/{mode}/nsinventory/audit • GET /v1.0/studies/{studyId}/{mode}/nsinventory/kit-types/{kitTypeId}/kits • POST /v1.0/studies/{studyId}/{mode}/nsinventory/lots/{lotId} • GET /v1.0/studies/{studyId}/{mode}/nsinventory/lots/{lotId}/quantity • PUT /v1.0/studies/{studyId}/{mode}/nsinventory/{nsinventoryId} • GET /v1.0/studies/{studyId}/{mode}/nsinventorystatuses/allowed/{fromInventoryStatusId} • GET /v1.0/studies/{studyId}/{mode}/orders-nsinventory • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/replaceRand • GET /v10.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • GET /v16.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v2.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • PUT /v2.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • GET /v2.0/studies/{studyId}/{mode}/events/kitreplacement/{eventId} • GET /v2.0/studies/{studyId}/{mode}/orders-inventory/audit • POST /v2.0/studies/{studyId}/{mode}/reports/blinded-titration-summary • POST /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits • POST /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/receive-quarantined • POST /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/removeKits • GET /v2.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/unblinded-disp-history • GET /v3.0/studies/{studyId}/{mode}/events/codebreak/{eventId} • POST /v3.0/studies/{studyId}/{mode}/shipments/{shipmentId}/received • POST /v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codebreak • POST /v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codeview • GET /v4.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits • GET /v4.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits • POST /v4.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits • POST /v5.0/studies/{studyId}/{mode}/reports/subjects • GET /v5.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits • PUT /v5.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits • GET /v5.0/studies/{studyId}/{mode}/unblinded-disp-history • GET /v7.0/studies/{studyId}/{mode}/inventory/kit-types • GET /v8.0/studies/{studyId}/{mode}/orders • GET /v8.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v8.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits

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Change	Endpoint
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits • GET /v1.0/studies/{studyId}/{mode}/inventory/kitDetails • POST /v1.0/studies/{studyId}/{mode}/inventory/kits/audit • GET /v1.0/studies/{studyId}/{mode}/orders • GET /v1.0/studies/{studyId}/{mode}/orders-inventory/audit • GET /v1.0/studies/{studyId}/{mode}/orders/{shipmentId} • POST /v10.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v10.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v11.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v11.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v12.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v12.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v13.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v13.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v14.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v14.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v15.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v16.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v2.0/studies/{studyId}/{mode}/inventory/kit-types • GET /v2.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits • POST /v2.0/studies/{studyId}/{mode}/inventory/kits/audit • GET /v2.0/studies/{studyId}/{mode}/orders • GET /v2.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v3.0/studies/{studyId}/{mode}/inventory/kit-types • GET /v3.0/studies/{studyId}/{mode}/orders • GET /v3.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v4.0/studies/{studyId}/{mode}/inventory/kit-types • GET /v4.0/studies/{studyId}/{mode}/orders • GET /v4.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v5.0/studies/{studyId}/{mode}/inventory/kit-types • GET /v5.0/studies/{studyId}/{mode}/orders • GET /v5.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v6.0/studies/{studyId}/{mode}/orders • GET /v6.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v6.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • GET /v7.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • GET /v8.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history • POST /v9.0/studies/{studyId}/{mode}/visits/subjectvisit • GET /v9.0/studies/{studyId}/{mode}/visits/subjectvisit

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Reporting

Change	Endpoint
Deleted	• GET /v1.0/reportmetadata/downloadList • GET /v1.0/reportmetadata/reportId/{id} • GET /v1.0/reports/download • POST /v1.0/reports/page • GET /v1.0/studies/{studyId}/{mode}/reportmetadata • GET /v1.0/studies/{studyId}/{mode}/reportmetadata/reportId/{id} • POST /v1.0/studies/{studyId}/{mode}/reports • DELETE /v1.0/studies/{studyId}/{mode}/reports • GET /v1.0/studies/{studyId}/{mode}/reports/download • POST /v2.0/reports/page • GET /v2.0/studies/{studyId}/{mode}/reports/download

Sites and Depots

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/labs/{labId}/labnormals/bulkLookUp • GET /v2.0/contacts • GET /v2.0/organizations • GET /v2.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType} • GET /v3.0/studies/{studyId}/{mode}/labs

- Rest API patch updates
  See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 24.2.1.

Rest API patch updates

See the newly added, deprecated, and deleted endpoints in Clinical One Cloud Service 24.2.1.

Services updates

The following services have been updated:

- Data Capture
- Data Integration
- Randomization and Supplies

Data Capture

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/subjects/count • POST /v5.0/studies/{studyId}/{mode}/subjects/visitschedule

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Data Integration

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items

Randomization and Supplies

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/reports/projectedsupplies/countrycounts • POST /v1.0/studies/{studyId}/{mode}/reports/projectedsupplies/depotcounts • POST /v1.0/studies/{studyId}/{mode}/reports/projectedsupplies/generateAsync • POST /v1.0/studies/{studyId}/{mode}/reports/projectedsupplies/sitecounts

Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Oracle Life Sciences Data Management Workbench

- Data specific to non-serialized inventory is not currently supported in Oracle DMW. For more information on the new feature, see Distribute non-serialized inventory.
- Questions with the new auto-lock rule are not currently supported in Oracle DMW. Questions which have self-locked still behave as regular locked items, but this is not reflected in Oracle DMW. For more information on the new feature, see Design questions with an auto-lock.
- While now supported in Oracle Clinical One Analytics, queries created to validate the Visit Date are not available in Oracle DMW. For more information, see Support for queries on visit dates in Oracle Clinical One Analytics.
- For Oracle DMW, the following details apply when a subject number is replaced by a randomization number:
  - If the **Replace Subject Number with Randomization number** setting is enabled and a subject is randomized, clinical data extracts loaded into Oracle DMW display the randomization number as the subject number. A subject's initial number, assigned during their screening in Clinical One Cloud Service, is always displayed in the new SCREENING_NUMBER column. For more information about this behavior, see Oracle Clinical One Analytics supports replacing a subject number with a randomization number.
  - This update occurs for both new and pre-existing clinical data extract records, with existing records being updated with a new DHTIMESTAMP value to reflect this subject number change. The update to the DHTIMESTAMP value for all existing clinical data records can be viewed in other DHVW views loaded into Oracle DMW aside from clinical data extracts. Use the DHVW_SUBJECTS_DATASET_V extract view to inspect a subject's number change.

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Oracle Clinical One Analytics also known as Data Hub

- While the auto-lock validation rule type is supported in Oracle Clinical One Analytics, with data related to it being displayed in the Study Design dataset, data on locked questions, forms, or visits is not yet supported in any datasets. This will be available in a future release. For more information on the new feature, see Design questions with an auto-lock.

Clinical One Digital Gateway configured integrations

- The following are the only Clinical One Digital Gateway integrations which support non-serialized kits:
  - Clinical One Cloud Service and Almac Global Depot Network.
  - Clinical One Cloud Service and Oracle InForm.
  - Clinical One Cloud Service and Medidata Rave integrations.

  For more information on the integrations which support this feature, see Support for non-serialized inventory for integrations. Alternatively, you can reach out to your Oracle point of contact.

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8

Clinical One Cloud Service and Clinical One Digital Gateway 24.1

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See the newly added, deprecated, and deleted endpoints of the Clinical One Cloud Service APIs.
- Release impact for other applications
  This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic describes the history of patches and patchsets we have applied to the 24.1 release.

Table 8-1 Patch log

Release Number	Release Date	Notes
24.1.1.3	10-September-2024	For this release, we fixed one issue related to reports. For more information, see issue **37008259** in Reports, archives, extracts, and notifications.
24.1.1.2	29-August-2024	For this release, we fixed one issue related to the how data is verified in a form. For more information, see issue **36977998** in Fixed issues for site users and subject data.
24.1.1.1	13-August-2024	For this release, we fixed one issue related to the application's performance. For more information, see issue **36862034** in Fixed issues for all users.

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Table 8-1 (Cont.) Patch log

Release Number	Release Date	Notes
24.1.1	03-July-2024	For this release we made the following changes: • Included the following new features and enhancements: – Manage all queries in one place – New Subject Randomization Data Extract – Quickly identify forms that require your attention – Other enhancements • Fixed the following issues: • – Issue **36774406** was fixed for Facilities, settings, and user management. – Issue **36695050** was fixed for integrations. – Issues **36312970**, **36710994**, **36308776**, **36391622**, and **35981904** were fixed for reports, archives, extracts, and notifications.

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Table 8-1 (Cont.) Patch log

Release Number	Release Date	Notes
24.1.0.1	14-June-2024	For this release we made the following changes: • Fixed multiple issues related to Oracle Clinical One Analytics, reports, data extracts, integrations, visits, and permissions. – For issues **36453777**, **36453959**, and **36457894**, see Oracle Clinical One Analytics. – For issues **36528076** and **36275528**, see Reports, archives, extracts, and notifications. – For issue **36176038**, see Integrations. – For issue **36292294** Forms, visits, and rules. – For issue **36488514**, see All users. • Included an enhancement for the Oracle Siebel Clinical Trial Management System (CTMS) - Site integration. For more information, see Site time zone defaults to UTC.

What's new

- Data collection
- Data review
- Integrations
- Randomization and trial supply management
- Reporting, archives, and analytics
- Rules management
- User experience
- Other enhancements

Data collection

- Allow a future date in forms
  Study designers can choose to allow a future date for a Date/Time question by turning the **Allow Future Date** toggle on or off.

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- Add instructional text
  Study designers can now add instructional text to certain forms to provide users with additional information about how to complete a form and its questions.
- Create Drug Reconciliation forms
  As part of the drug reconciliation process, site users can now generate purpose-built drug reconciliation forms, which can be designed with a new self-populating type of field.
- Enhancements to local labs
  Study designers can now let site users enter more than one instance of a lab form at a visit.

Allow a future date in forms

Study designers can choose to allow a future date for a Date/Time question by turning the **Allow Future Date** toggle on or off.

In some cases, you may be required to define a validation rule check for site users when collecting future dates in which they receive a system validation error. For example, if a site user collects the date of Informed Consent. The **Allow Future Date** control allows you to create this kind of validation rule check in these types of scenarios.

Details for study designers

Here is what's new in your workflow when adding Date/Time questions:

- The Details side panel now includes the **Allow Future Date** toggle for every Date/Time question type.

  > **Note**
  >
  > This feature is not available for time-only questions.

  - Turning the toggle **On** allows future dates while **Off** does not.

    > **Note**
    >
    > The user can enter and save a future date while the toggle is set to **Off**, however, the system will alert the user of a validation error.

  - The toggle is set to **On** by default.
- Future dates are determined against the date and timezone of the respective site. For example, when a site user answers a Date/Time question, the application compares the date of the site's timezone with the time that they entered.

  > **Note**
  >
  > A timezone must be specified for your site in order for future date validations to function properly.

- Only one validation rule is triggered at a time if there is more than one configured for a question. If the **Allow Future Date** is set to **Off** and a future date is entered, the system error message appears. Once this is resolved, validation rules that failed appear next.

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- When it comes to partial dates, only the present information is compared to the current date.
- The **Allow Future Date** toggle is not visible for Age Smart objects and is defaulted to off, resulting in a validation error if a future birth date is entered.

> **Note**
>
> You are required to move the study version for the Approved container to implement this option for live studies.

More information on allowing future dates can be found in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Impact on reports

More details on **Allow Future Date** settings in the Annotated Case Report Forms and Study Design report can be found in the *Reporting Guide* after the RAE upgrade.

> **Note**
>
> The **Allow Future Date** toggle settings appear blank in the Study Design Dataset for existing studies in Oracle Clinical One Analytics until a new study version is moved to the container.

Already working in a live study?

When the upgrade for this release is complete, this function will be set to **On** by default for existing studies to keep functionality consistent. If you would like to disallow future dates, then you are required to move your study to Production in order to activate this feature.

You are required to perform an Advanced Study Version update to date questions in your study in order to set the **Allow Future Date** toggle to **Off** for existing studies.

> **Note**
>
> When the **Allow Future Date** toggle is changed from **On** to **Off** for a question as an Advanced Study Version change, the validation is applied to existing dates that were in the future at the time the date was entered, based on the audit trail

Add instructional text

Study designers can now add instructional text to certain forms to provide users with additional information about how to complete a form and its questions.

Details for study designers

When it comes to creating forms, here's what's been enhanced in your workflow:

- Instructional text *cannot* be used in question groups, repeating forms, or repeating tables, including lab forms.

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> **Note**
>
> Instructional text can only be added to the top section of a two-section form.

- When you click **Add** in an appropriate form, the option to include a new question as instructional text is available for forms and can be added anywhere within a form.
- The added text can be formatted for further clarity, if desired. External links and email addresses can also be included.
- Once your study version is approved, the added instructional text can be modified or deleted.
- If the form only contains questions added as instructional text, it cannot be listed for signature configurations.

More information and step-by-step instructions on adding instructional text can be found in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

For information about how instructional text gets displayed in Archives requests, see Enhancements to Oracle CRF Submit archives and reports.

Details for site users

As a site user, there is no change to your workflow. However, be aware that forms may now include read-only instructional text inserted by sponsor users at the time they created a form.

Impact on reports

The Study Design report and Annotated Case Report Forms now include instructional text that has been added to any forms.

Create Drug Reconciliation forms

As part of the drug reconciliation process, site users can now generate purpose-built drug reconciliation forms, which can be designed with a new self-populating type of field.

Before you work with this feature

As part of drug reconciliation, the new purpose-built drug reconciliation forms aim to replace drug order forms. Introduced in conjunction with the new instructional text field, drug reconciliation forms are more customizable and can be designed as part of the standard form design process. For more information on the new instructional text field, see Add instructional text.

To design drug reconciliation forms, study designers must have the *Design Supplies and Dispensation* permission assigned.

Details for study designers

As a study designer, you can now add a new question type to your Drug Reconciliation form called Existing Data. This new type of question uses existing study data to reduce the number of fields a Clinical Research Associate (CRA) needs to complete when using the form to perform drug reconciliation. Existing data fields are only available to drug reconciliation forms.

Drug reconciliation forms have a three-section structure by default, which you can customize according to your needs. These are:

- A flat section, containing study, depot, site, and user details.

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- A repeating section, containing self-populating fields related to kit information.
- Another flat section, with target depot and form information fields.

Details for sponsor users

As part of the drug reconciliation process, CRAs can now access the drug reconciliation form in the **Shipments** tab in the study's Supplies panel. Once kits are marked for destruction, CRAs can select which kits to perform reconciliation for in the site inventory, generate and complete the form, and use it according to the workflow of the study.

You can find additional information in the *Information for CRO and Sponsor Users* guide after the Release Assessment Environment (RAE) upgrade.

Impact on reports

- Drug reconciliation forms are reflected in the Study Design report through a three-section layout:
  1. Questions before the table
  2. Questions inside the table
  3. Questions after the table
- Drug reconciliation forms are also reflected in the Annotated CRF report.

> **Note**
>
> drug reconciliation forms will not be included in Oracle Clinical One Analytics.

Already working in a live study?

To start working with drug reconciliation forms, you must update and go through the entire study versioning process, since Advanced Study Versioning (ASV) is not supported. To apply your changes, update in a draft study version, approve it and assign it to the impacted sites in the appropriate modes.

> **Note**
>
> existing drug order forms which have been used for drug reconciliation will not be affected should a study designer create a drug reconciliation form.

Enhancements to local labs

Study designers can now let site users enter more than one instance of a lab form at a visit.

> **Note**
>
> This enhancement only applies to lab forms.

Details for study designers

If you're a study designer, here's what's new in your workflow:

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- In a lab form, the Details side panel now displays a new toggle called **Allow for Multiple Instances**. By default, this toggle is turned off.
- When you turn the **Allow for Multiple Instances** toggle on, you let a site user enter more than one instance of the same lab form during a visit.
- From now on, you can also hide all questions in the **Questions Before the Table** section, configure, associate lab results to other forms using **Link & Show** rules, and only configure the following predefined rules: **Show Question** and **Show Section**.
- Moreover, for a lab form the **Repeating Form** toggle is turned on by default and inactive, while the **Allow Additional Rows** toggle is turned off by default and active.

Details for site users

If you're a site user collecting lab data, here's what's new in your workflow:

- If you're allowed to add additional instances of a lab form to a subject's visit, you can click **Add** ( ) next to the title of a lab form to include a new instance of the same lab form. Or you can click **Add** next to the lab form's title.
- For each lab form instance you add, you must do the following:
  - Select a lab from the **Select Lab** drop-down so you can collect data associated with the appropriate lab.
  - Collect data for the Sample Collection Date and Fasting questions.

Impact on reports

The following reports and extracts are impacted:

- The Annotated Case Report Forms includes the text **Allow for Multiple Instances** in the header of each lab form that is configured this way.
- The Study Design report includes a new column called **Allow for Multiple Instances** for each lab form. The column displays No or Yes, depending on whether that toggle is turned on or off in a lab form.
- When additional instances of a lab form are included in a study, the following **REPEATNUMBER** column in the Subject Data Extract will display a lab form's instance number.
- In Oracle Clinical One Analytics, the Study Design dataset will display the **Allow for Multiple Instances** design setting. The Subject Form Items dataset will display additional instances of a lab form.

Impact on custom rules

You can use custom rules to compare data between instances of a lab form in the same visit. Moreover, because a lab form now works as a two-section form, you can also start using the same rule helper functions that are available for two-section forms.

Impact on integrations

When it comes to Oracle CRF Submit, you can learn more about the impact on this integration type in our Release Notes. For more information, see Enhancements to Oracle CRF Submit archives and reports.

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Already working in a live study?

As a study designer, you can update existing lab forms to let a site user enter additional instances of a lab form at a visit through a study version change. This update is not supported through Advanced Study Versioning (ASV).

More information about this feature can be found in the following user guides, after the Release Assessment Environment (RAE) upgrade:

- *Study Designer User Guide*
- *Site User Guide*
- *Reporting Guide*

Data review

- Manage all queries in one place
  Using the new Query List page, site and sponsor users can now prioritize and manage queries more efficiently by viewing, filtering, and working on the queries of a study, all in one place.

Manage all queries in one place

Using the new Query List page, site and sponsor users can now prioritize and manage queries more efficiently by viewing, filtering, and working on the queries of a study, all in one place.

The Query List page shortens the time spent by users on tasks such as responding to queries, finding queries raised by users with a specific role, subject data cleanup, query cleanup where queries have been opened erroneously, or other work related to queries.

Details for all users

You can access the new Query List page by selecting the **Queries** icon ( ), on the Home page. You can also access the Query List by selecting the **Query List** button on the Subjects page.

While the queries you can see vary depending on your permissions, the queries are grouped as follows:

- **To Do**: queries that you need to perform actions on. This includes open queries, assigned open queries, answered queries, and candidate queries.
- **Unresolved**: queries that you have permission to see and that do not have a status of **Closed** or **Deleted**. This view includes queries that are pending the action of other users, meaning you may only have permission to see some of these queries.
- **Closed**: all the queries with a **Closed** or **Deleted** status that you have permission to see.

> **Note**
>
> While this new feature doesn't introduce any new permissions, refer to Descriptions of permissions in Clinical One for more information on the existing permissions required to view, create, and manage queries.

To help you quickly find the queries you need to work on, you can filter your list of queries based on criteria such as **Subject Number**, **Status**, **Query Age**, or **Assigned to Role**. The

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queries you are working on can also be sorted in ascending or descending order based on age.

Improved view of a query's history

In order to swiftly gain a detailed understanding of a query, you can now navigate from the list of queries to a page dedicated to the query's detailed, consolidated history. This new page lists all the events related to the query in a reverse-chronological order, along with other fine-grain administrative details.

To further shorten the time spent working with queries, you can either jump to a query's source in a form or, provided you have the necessary permissions, update the value of an answer in a form. Once you're in a form, you can click **Return to Query Details** to easily return to the query management view.

Details for site users

As a site user, your responsibilities on the Query List page revolve around viewing queries and working with their source form questions. Within the dashboard, queries with the following statuses are visible to you: **Opened**, **Answered**, **Closed**.

Using the new feature to directly access the source of a query, you can quickly edit the answers of questions for which queries have been raised. You can also answer a query from its query details page, provided that no update is required for its associated question.

Details for sponsor users

As a sponsor user, your responsibilities on the Query List page are focused around processing the queries associated with a study. You can view questions with all statuses and depending on each status, you can perform the following actions:

- View queries
- Re-open queries
- Close queries
- Delete queries

You can find additional information in the *Sponsor and CRO User Guide*, after the Release Assessment Environment (RAE) upgrade.

Integrations

- Site time zone defaults to UTC when not defined in the source CTMS system

Site time zone defaults to UTC when not defined in the source CTMS system

The Oracle Siebel Clinical Trial Management System (CTMS) - Site Integration runs on a schedule to retrieve a list of sites in a source CTMS system. The integration then creates the sites in Clinical One Cloud Service, where a time zone is required.

If the source CTMS system does not have a time zone defined by the time the integration runs, the Clinical One Cloud Service will default the time zone setting to UTC. This ensures system errors do not occur when calculations run for things like future date validation or dispensation when using titration or when trying to prevent out-of-window dispensation.

For more information, see Site Integration

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Randomization and trial supply management

- Set exceptions to kits with the Do Not Dispense dispensation logic
  Additional options are available to sponsor users, allowing them to control kit dispensation based on protocol requirements and to ensure patient safety.
- Duplicate a randomization list
  Sponsor users can now reproduce an existing randomization list on request for regulatory inspection purposes. After you first generated the randomization list for a study, you can re-run an exact duplicate on demand.

Set exceptions to kits with the Do Not Dispense dispensation logic

Additional options are available to sponsor users, allowing them to control kit dispensation based on protocol requirements and to ensure patient safety.

Clinical supply managers now have the ability to set an exception for kits with the Do Not Dispense (DND) dispensation logic at both the country and site level to adhere to protocol requirements and preserve patient safety.

This feature supports sponsor users in scenarios such as a country or a site that requires a longer expiration timeframe for distributing the investigational product to subjects. Similarly, this can be helpful in emergency situations when there is a shortage in supply at the site and an override of the initial distribution setting is necessary.

Details for sponsor users

When it comes to configuring dispensation schedules for kits, here's what has been enhanced in your workflow:

- You must be assigned the *View Dispensation Exceptions* permission in order to view dispensation exceptions that have been created.
- You must be assigned the *Create and Manage Dispensation Exceptions* permission in order to add, edit, copy, and delete DND dispensation logic exceptions.
- Study designers can still configure the DND (Days) in a study's visit schedule, while a clinical supply manager (or a sponsor user) can configure exceptions to the DND dispensation during the study conduct period, as well.
  For more information on specifying DND dispensation in study design, see Define the dispensation schedule.
- Exceptions to the DND logic are created on the Study Supplies page and can be defined by country, which are included at the time of depot or site creation. Exceptions can be further defined by site within the country, and updated at the site or country level by visit.
- Exceptions can be made for all visits where dispensation occurs.
- The DND logic considers the limit or exceptions at the time of dispensation for a subject's country or site when the subject completes a partial dispensation or removing the subject from a dose hold visit.
- When removing an exception from a site, the site defaults to the country's DND settings. If you remove an exception from a country, the country returns to the study design's default DND settings.

More information and step-by-step instructions can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

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Impact on reports

The Study Design report now includes exceptions set for kits with the DND dispensation logic.

Duplicate a randomization list

Sponsor users can now reproduce an existing randomization list on request for regulatory inspection purposes. After you first generated the randomization list for a study, you can re-run an exact duplicate on demand.

Before you work with this feature

Reproduce a randomization list by copying the same design parameters and adding the same randomization seed number when randomizing multiple lists to ensure the resulting list will be the same as the first.

When reproducing a randomization list with a seed, it's crucial to know that Clinical One Cloud Service will use and maintain the latest active randomization list to re-shuffle the treatment arms in the study. To revert to any previous randomization lists you need to manually unassign the current active list from the study version.

Details for sponsor users

If you need to duplicate a randomization list for auditing purposes, this is what you should know:

When re-generating a randomization list, on the **Randomization** tab, a new field called **Randomization Seed** is available in the Randomization List dialog.

When adding the same seed number and maintaining the same design parameters as the original randomization list, an algorithm can produce a second list as a duplicate of the first. This approach ensures both lists follow the same randomization sequence, maintaining consistency between them.

The process provides proof for regulatory agencies that the study is randomized properly and that the list can be regenerated on request.

More information and step-by-step instructions can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Impact on reports

The following reports will show the randomization seed lists generated under the field of **Randomization List**:

- About the randomization list duplication
- Generate a randomization list
- Study Design report
- Randomization List (Blinded) report
- Randomization List (Unblinded) report

Reporting, archives, and analytics

- Enhancements to Oracle CRF Submit archives and reports

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- Hide randomization details in the Study Design Report
  Sponsor users can now hide randomization details in the Study Design Report.
- New Subject Randomization Data Extract
  Sponsor users can now extract cumulative data including randomization details, such as the subject ID along with its randomization number and associated treatment.

Enhancements to Oracle CRF Submit archives and reports

We've increased the storage server space allocated for each customer

To accommodate the increasing usage of Oracle CRF Submit and to minimize the possibility of encountering issues when generating archives and history reports for large studies, we increased the storage server space allocated for each customer from 100 GB to 1000 GB.

> **Note**
>
> Storage server space is allocated per customer and shared across all your studies.

PDF output supports Instructional Text questions

Study designers can add instructional text to any form to provide users with instructions to complete a form or the questions on it.

The text appears in Submission PDF, Archival PDF (sponsor and site), Blank Form PDF, and Custom PDF request output.

- The PDF reflects the question's location on the form and the instructional text's font format (size, type, and color), as displayed in the user interface, but the PDF does not include a row number.
- Email addresses and hyperlinks in the instructional text appear as plain text in the PDF.

For more information, see Instructional text.

A new pop-up reminds site users to confirm a request after download

After downloading an Archival PDF request, a Custom PDF request, or the Kit Chain of Custody (Blinded) report, a site confirmation required pop-up reminder is presented to site users when the sponsor who generated and shared the request requires confirmation.

The reminder appears for site users assigned to a study role that includes the permission *Confirm download of Archival PDFs and content (Site)*.

After the Release Assessment Environment (RAE) upgrade, you can find additional information in Download an archive or report in the *Reporting Guide*.

The Site Confirmation report is available for site users

Sponsor users can share Archival PDF, Custom PDF, and the Kit Chain of Custody (Blinded) report with site users and require site confirmation after download; confirmation actions get tracked in the Site Confirmation report. For more information about the confirmation process, see Confirm an archive or report after download.

Site users assigned to a study role that includes the permission, *Confirm download of Archival PDFs and content (Site)*, can generate the **Site Confirmation report** for associated sites.

After the Release Assessment Environment (RAE) upgrade, you can find additional information about this report (for site users) in the Site Confirmation report.

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New lab forms now render as two-section forms in PDF output

The PDF layout for lab forms created before this release remains unchanged.

Archives generated after this release render newly created lab forms as two-section forms.

> **Note**
>
> This change impacts the Submission PDF, Archival PDF (sponsor and site), and Custom PDF requests PDF output. There is no impact on Blank PDFs, as lab forms already display as two-section forms.

This change is to support an enhancement in this release that allows multiple instances of a lab form to be associated with the same visit. For more information about this enhancement, see Enhancements to local labs.

Hide randomization details in the Study Design Report

Sponsor users can now hide randomization details in the Study Design Report.

Study Design Report Suppress Randomization is a new permission that conceals critical information from the randomization list such as the **Multiplier for Blocks** that can unblind a blinded user if revealed.

If you are a blinded user who has been assigned this new permission, you can still run the report and you can still use the report filters as intended, but the **Randomization list** details are hidden to you. Specifically, the **Generated Randomization List** section in a **Study Design Report** shows empty for users assigned this new permission, even if they select the **Generated Randomization List** check box option when running the report.

Find additional information in the *Add Users Guide* after the Release Assessment environment (RAE) upgrade.

Updates to the Study Design report can be found in the *Reporting Guide* after the RAE upgrade.

Related Topics

- Edit a study role that is already assigned to users

New Subject Randomization Data Extract

Sponsor users can now extract cumulative data including randomization details, such as the subject ID along with its randomization number and associated treatment.

Details for sponsor users

A new data extract, Subject Randomization Data Extract, is available under **Reports & Archives** for Clinical One Cloud Service studies in any mode. This report contains randomization-related information, including the following:

- Subject metadata
- Visit information for the visit when randomization occurred
- Details about the users who last updated a subject's randomization visit or stratification factors

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- Randomization details
- Assigned treatment
- Stratification data

The stratification data included in this report corresponds to any form question defined as a stratum factor in the randomization design. Only records for randomized subjects are included, and only values that were used for a given subject as stratification factors at the time of randomization are populated for the subject. This means that, even if the site updates this data for a subject after randomization, the values that were actually used to determine randomization are retrieved. Conversely, if stratification factors are not specified, no stratification factors are listed.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Details for user administrators

To support the creation of this new data extract, a new permission is introduced. Any user that's assigned the new *Run the Subject Randomization Data Extract Report* permission can generate this report. However, users can only see the data that they're allowed to, based on their access to classified data.

Similarly, the Subject Randomization Data Extract can contain blinded or unblinded data, depending on the user's permissions within the study. Having at least one of the following permissions makes unblinded data available in the generated extract:

> **Warning**
>
> Extracts generated by unblinded users must be managed carefully when sharing to protect other users blinding.

- *Receive the Unblinded Dose Hold Notification*
- *Upload and Generate Inventory Lists*
- *View Dispensation Exceptions*
- *Create and Manage Dispensation Exceptions*
- *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies*
- *Manage Study Inventory for Unblinded Users*
- *Manage Randomization Lists*
- *Create and Manage Lots*
- *Create Shipments to Depots*
- *Upload and Generate Randomization Lists*
- *Receive the Unblinded Kit Misallocation Notification*
- *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies*
- *Run the Unblinded Randomization Report*

You can find additional information in the *Add Users Guide* after the RAE upgrade.

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Rules management

- Access data not collected in forms
  Rule developers can now access subject information and other data not collected directly in a forms and include it in the rule processing or as a return value.

Access data not collected in forms

Rule developers can now access subject information and other data not collected directly in a forms and include it in the rule processing or as a return value.

In some scenarios, a custom rule's logic requires you to reference data not collected in a form, such as the subject number and status or site related information. With the introduction of the Subject Object you can now access different attributes for data that is not included in any form.

The Subject Object has the following attributes:

- `SubjectNumber`
- `SubjectStatus`
- `ScreeningDate`
- `ScreenFailureDate`
- `CompletionDate`
- `WithdrawalDate`
- `RandomizationDate`
- `TreatmentArm`
- `CohortName`
- `SiteNumber`
- `SiteName`
- `Country` (of the site)
- `Region` (of the site)

All these attributes are available with their descriptions, using the predictive text feature in the Rule Editor and can be used for rule processing or as a result for a calculated value. This last scenario can be suitable to drive **Show Visit**, **Show Form**, and **Show Question** predefined rules or as a form question base for branching.

> ⚠ **Caution**
>
> Some of these attributes allow access to potentially unblinding information, so use them with caution and with assigned queries to limit access to this information.

Remember that you can lessen the burden on site and sponsor users, and increase overall efficiency by using Clinical One Cloud Service's custom JavaScript rules and query management functionality. Leverage these core features using subject-related data in your custom rules' logic, and gain better control over a subject's visit schedule, country-specific privacy regulations, and many other protocol requirements.

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You can find additional information in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

User experience

- Quickly identify forms that require your attention
  Simple repeating forms, two-section forms (including lab forms) now display improved status icons in a visit.

Quickly identify forms that require your attention

Simple repeating forms, two-section forms (including lab forms) now display improved status icons in a visit.

Whether you're a site or sponsor user, you can better identify the status of a simple repeating form, a two-section form, or a lab form when you look at the **Forms** sidebar or in the repeating form table. With the newly improved form status icons, you can quickly visualize whether your form is complete or if there might be issues with the data included in it.

Here's what's new in the User Interface (UI) depending on the type of form that is included in a visit:

Form status icons and their descriptions

The following form status icon descriptions **apply to all of the above-mentioned form types: simple repeating forms, two-section forms, and lab forms**. This includes forms that contain a Label item.

> **Note**
>
> To accommodate the consistent display of form status icons across all form types, you can now add a new repeating form row or a new two-section form instance by clicking **Add**
>
> next to a form's title within the visit.

Form status icon	Description
	Appears when a form's required questions are completed successfully without any validation errors. • For a simple repeating form, this icon appears when all required questions in the form are completed or when all required questions in a repeating form row are completed. • For a two-section form, this icon appears when all required questions (in both sections) are completed.
	Appears when at least one of the form's required questions are incomplete. • For a simple repeating form, this icon appears when at least one required cell in the repeating form table is left unanswered. • For a two-section form, this icon appears when at least one required question is left unanswered in any of the two-sections.

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Form status icon	Description
	Appears when at least one field in a form contains a validation error.

Details for simple repeating forms

The following notes apply when a form status icon is displayed in a simple repeating form:

- For a **simple repeating form**, each form status icon is displayed both on the **Forms** sidebar and on the **Number #** column next to a repeating form row.
- The icon displayed on the **Forms** sidebar indicates a cumulative status of all started repeating form instances. For example, if a Demography form (designed as a simple repeating form) contains three completed rows and one repeating form row whose data collection was started, but not complete, the **Incomplete form icon** is displayed. You can click the form's title to then navigate to the form and fill-in the empty required fields.
- When a site user hasn't started filling in repeating form yet, the **Forms** sidebar doesn't display any status icons. The **Number #** column next to a repeating form row doesn't display a form status icon either. The same behavior applies when a repeating form's data is cleared.

Details for two-section forms and lab forms

The following notes apply when a form status icon is displayed in a two-section form or a lab form:

- For a **two-section form** (including a lab form), each form status icon is displayed on the **Forms** sidebar, next to the form's title and next to each two-section form instance, as well.
- When a site user hasn't started filling in a two-section form or a lab form yet, the **Forms** sidebar doesn't display any status icons either next to the form's title or next to any of the two-section or lab form instances. The same behavior applies when data is cleared.
- On the **Forms** sidebar, if you notice a form icon that indicates incomplete fields or validation errors, you can expand the list of two-section form instances and click the instance number to navigate directly to it.
- The icon displayed on the **Forms** sidebar indicates a cumulative status of all started two-section form instances. For example, if a form instance of a Hematology form (designed as a two-section form) has any incomplete required fields, the **Incomplete form icon** is displayed next to the original form's title and the form instance number.

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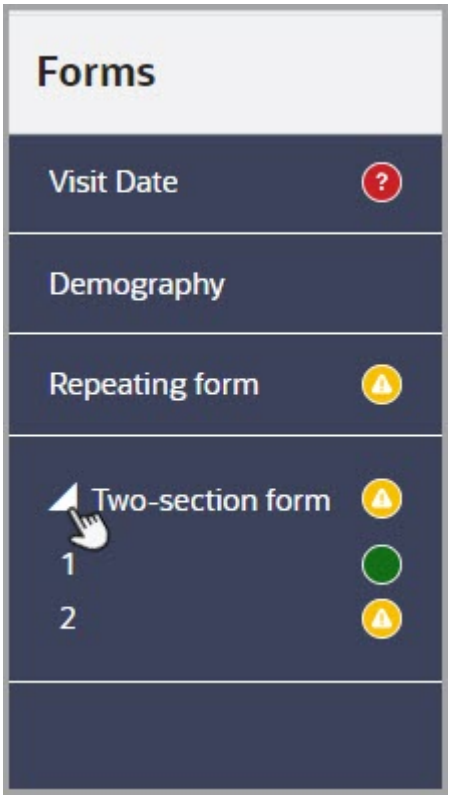
Figure 8-1 How you may see the Forms sidebar



Other enhancements

Improved readability of the Cycle Number text label

To ensure that all users have a comfortable user experience in the application, the following visual changes are introduced on the Subjects page:

- The font size for a visit cycle's number is increased.
- The word "cycle" is appended to the front of the cycle.
- The cycle indicator is left aligned to the separator bar between the cycles of a visit.

Clinical One Digital Gateway User Interface (UI) enhancements

For this release, the following enhancements are introduced in the Clinical One Digital Gateway UI:

- The **Integration Start Date** field is now renamed as **Job Start Date**.
- The **Subject Data for CTMS Report** label is now displayed in the UI to be consistent with other Clinical One Cloud Service report titles.

No functionality changes are introduced with these UI changes. For more information, reach out to your Oracle point of contact.

Additional data points are now included in the User Assignment reports

As a user administrator, these new data points let you easily manage users, as well as review, and audit their data. The User Assignment report report and the User Assignment by Site report report now include the following changes:

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- New columns now include the user's first name and last name to the right of their user name.
- The user's permissions now reflect the overall permission names in the application.
- In the User Assignment report, the site ID assigned to the user appears in the Organization column. For example, you see data populated as: SiteID-OrgName.
- In the User Assignment by Site report, the report's header includes the site ID associated with a user.

Fixed issues

- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and Kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

Users may experience a slower performance intermittently

The application is now updated to address an issue related to distributed caching that was affecting performance during report execution. This issue didn't affect your study's data but it may have caused the application to move slower.

(Issue **36862034**)

Users with view only permissions cannot see form and visit data in newly created visits

Now, any user assigned permissions to view can see form and visit data for newly created visits. Previously, when a user assigned view only permissions attempted to open certain visits, the visit would open to a blank screen and no form for visit data was visible.

Retracted recommended action: After a user with permissions to edit accesses the visit and views the visit data, a user with view only permissions can open the visit and view its data normally.

(Issue **36726515**)

Sponsor and site users are unable to view sites under the Sites & Labs tab

Now, for impacted custom roles, sponsor and site users can see sites on the Sites & Labs tab when they are assigned the *View Sites* permission, as expected.

(Issue **36488514**)

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Chat & Help does not display the hours of operation

Now, after logging in, when you click Chat & Help in the upper right corner of Clinical One Cloud Service, you are presented with the hours of operation. For more information about Chat & Help, see Chat in real time with Oracle Support.

(Issue **36332772**)

Facilities, settings, and user management

The Order Forms button is inactive for a resupply shipment

On the **Shipments** tab, when you select a resupply shipment, you can now view and click the **Order Forms** button successfully. Previously, this button was inactive, preventing you from downloading the Kit Order Form for a resupply shipment. (Issue **36774406**)

You cannot remove a study role after selecting one from the drop-down (former known issue)

Now, when creating a new user or editing an existing one, it is possible to remove a role after selecting it. Previously, you could not remove a role as the default option, Select Study Role, was unavailable after making a selection.

Retracted recommended action: If you need to remove a study role from a user, reverting the drop-down to the default option, Select Study Role on either the Create User or Edit User windows, do the following.

1. Use the tab key to navigate to the mode where you want to remove the study role.
2. Once on the correct cell, click Delete, then click the tab key again to move away from that cell.
3. Do this for each study mode if applicable.
4. Click Save to close the window or Next, if you need to make additional updates on the Sites & Depots tab.

(Issue **34999892**)

Forms, visits, and rules

All visits display under the Previous Visits section

Now, on the Subjects tab, the Previous Visits and Next Visits columns display visits appropriately, whether there is an Adverse Event visit type or not. Previously, all visits were displaying under the Previous Visits section when there was no Adverse Event visit type present in the study design.

(Issue **36292294**)

A user can select a lab even though the triggering condition for the lab form was not met

Now, when a user changes the answer from No to Yes for a question where Yes triggers a dynamic lab form but does not submit the Reason for Change first, they are presented with a validation error and cannot select the lab from the drop-down until they save the Reason for Change.

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Previously, the user was permitted to select a lab even though the triggering condition, which includes submitting the Reason for Change, was not fully satisfied.

(Issue **36524481**)

A query shows as Answered in the Subject Queries report but Open in the user interface

Now, when a user raises a query on an empty question and subsequently adds and immediately removes a comment, the query's status in the user interface and the Subject Queries report display Answered.

(Issue **36477797**)

Cannot verify a blank field on a lab form (former known issue)

Now, when you select an empty field and attempt to verify it, you are no longer presented with a message stating that an error occurred in the system.

Retracted recommended action: If you cannot enter data into the blank field, confirm that the lab form has a local lab selected and that a data flag marks the blank field.

(Issue **33498920**)

Cannot verify blank two-section forms (former known issue)

Now, when you attempt to verify a blank two-section form in an incomplete visit, the verification check boxes are present.

Retracted recommended action: Try completing fields in the Questions Before the Table section and mark at least one question in the Questions in the Table section with a data flag to be able to verify the blank two-section form.

(Issue **33498896**)

Performance is slow when starting a skipped visit

Now, when a user returns to a skipped visit to enter data, they will see an improvement in the time it takes for a skipped visit and its forms to load.

(Issue **35654352**)

Unscheduled visits shown out of order

Now, when a study includes unscheduled visits with visit start dates set between scheduled visits, the unscheduled visits are displayed correctly between the appropriate scheduled visits based on the visit start date instead of displaying scheduled and unscheduled visits grouped based on type.

(Issue **36048993**)

An error occurs on the rule variable when the rule calls the clearChoice( ) helper function

Now, a user no longer encounters the following error (also displayed in the Answer History side panel), resulting in a red box around the parent question.

Error: DCS-030 Item in the request body does not match with existing Data Element Item.

Example: In the following example, the rule target populates only when the rule variable is No.

If the user initially selects Yes, the rule calls the clearChoice( ) helper function to clear the target question, which is blank, resulting in the error.

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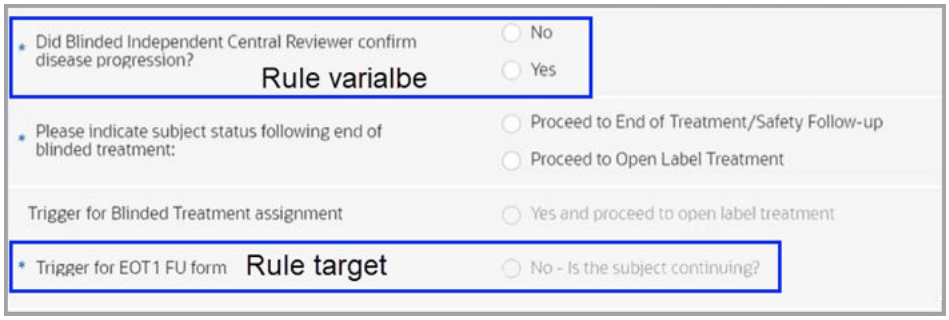

(Issue **36059717**)

Visit hover text does not match the edited Adverse Event visit title

Now, when hovering over the Adverse Event visit tile for a subject, the edited visit title is displayed instead of the previously hard-coded default value, Adverse Event, ensuring the hover text matches the column header's name.

(Issue **36364602**)

Integrations

Form data fails to load in Oracle DMW

Now, for an integration between the Clinical One Cloud Service and Oracle DMW, data for repeating form records loads completely without timing out.

(Issue **36176038**)

Standard reports fail to generate when initiated during an Clinical One Cloud Service upgrade

(Details for bug 35239014) Standard reports such as Subject Visits, Subject Data, and Subject Events now generate successfully when initiated during an Clinical One Cloud Service upgrade.

The reports previously failed during an upgrade because a particular file was updated before the metadata in the database, resulting in incompatible files and report failures. In future upgrades, the file and metadata will be updated together, ensuring the file is always compatible.

> **Note**
>
> The fix for bug 35239014 also resolved bug 35237829 related to CTMS report integration failures.

(Details for bug 35237829) The CTMS report integration initiates a call to the reporting service to generate the Subject Data for CTMS standard report. The integration then places the output file on the Oracle sFTP server for customer consumption. Bug 35239014 caused report failures for reports generated manually in the user interface and when initiated by the CTMS report integration.

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(Issues: Fixing the base bug **35239014** (incompatible file issue) also resolved bug **35237829** (CMTS report integration failure).

The lab integration fails if the study version in the request body does not match the production version

The request body for the lab data intake integration now contains the correct study version, ensuring the job completes successfully.

Previously, the job would fail if a new study version was created and applied to a site while subjects were still active in the visit where the study version change was applied. A study version mismatch between Clinical One Cloud Service and the integration request body caused the integration failure.

(Issue **36695050**)

Oracle Clinical One Analytics

Dynamic forms in baseline visits are not showing as missing forms in the Forms dataset

Now, a form that is dynamically displayed in an associated visit, but not displayed in other associated visits in the same study, is correctly displayed as missing in datasets such as the Forms or Form Items datasets.

(Issue **36453777**)

Study roles in the Queries dataset are not displayed correctly

Now, details for current study roles display correctly in the Queries dataset. Previously, details in some study role columns appeared incorrectly as NULL.

(Issue **36453959**)

Shipments with more than 1000 kits appear as *Deferred* in Oracle Clinical One Analytics reports

Now, a shipment with 1000 kits or more appears as the appropriate state in Oracle Clinical One Analytics reports. Previously, shipments that were created and sent to a site through Clinical One Cloud Service with more than 1000 kits were appearing in a state of *Deferred* in Oracle Clinical One Analytics reports.

(Issue **36457894**)

The Unblinded Kits dataset may not contain data for replaced kits (former known issue)

Now, when you generate a custom report based on the Unblinded Kits dataset, subject details for randomization, visits, and events are included for a replaced, damaged dispensed kit.

(Issue **33543337**)

Null value stored, resulting in data missing in Oracle Clinical One Analytics

Now, complete GUID strings are stored without null values, ensuring data catchup in Oracle Clinical One Analytics picks up all data and completes processing it successfully.

(Issue **36419269** for storing a null value and **36420106** for missing data in Oracle Clinical One Analytics.)

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Randomization and Kits

Need to refresh to see the notification for unmapped treatment arms (former known issue)

Now, when you add a new treatment arm to the first randomization design in a study, a notification appears on the Map Treatment Arms button (in Visits & Events) under the following circumstances.

- You design a study with two randomization designs and map subjects to treatment arms in the second randomization design.
- You add a new treatment arm to the study and associate it only with the first randomization design.

Retracted recommended action: Refresh the page, then the red notification appears.

(Issue **29910314**)

Reports, archives, extracts, and notifications

The Subject Data Extract fails to generate

The Subject Data Extract now generates successfully when generated by a blinded user, allowing blinded data to be extracted for review outside the system.

(Issue **37008259**)

Record of removed and hidden dynamic forms appear in the Subject Data Extract

Now, any record of hidden dynamic forms that were removed does not appear in the Subject Data Extract when it is generated in any format. Previously, a record of dynamic forms that were removed and hidden with no form data showed in the Subject Data Extract.

(Issue **36528076**)

Oracle CRF Submit archive requests fail with no saved data and open queries (former Known Issue)

Now, a Submission PDF, Archival PDF (site and sponsor), and Custom PDF request generate properly. Previously, the requests would fail to generate if a request included a subject with no data, but an open query, saved in any form at any visit.

Retracted recommended action: Use the FailureReport.txt, included with a failed request, to identify the subjects, then lock or freeze them. After a subject is Locked or Frozen, a subject PDF is generated successfully.

(Issue **36275528**)

The Subject Events report displays a different label for kit numbers

Now, the Replaced Kit ID column is renamed to Replaced Kit Number in order to match the data displayed in the Subject Events report for that specific column.

For more information, see the Subject Events Report in the *Reporting Guide*.

(Issue **35864763**)

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Duplicate randomization events displayed in the Subject Events report

Now, in the Subject Events report, the randomization event is displayed a single time for every subject. Previously, the randomization event was displayed multiple times for the same subject, making you think the system randomized a subject multiple times.

(Issue **33545211**)

The Reason audit column in Archives PDFs is blank for transferred subjects

Now, when you select Other as the reason for transfer, the manually entered reason is displayed under the Reason audit column in the Subject Record Transfer History (prth.pdf) file, included with the subject PDFs for transferred subjects. For more information about Archives, see About archives and reports.

(Issue **36113596**)

The User Assignment report contains incorrect organization data

The Organizations column in the User Assignment report correctly displays the organizations (sites and depots) assigned to a user instead of displaying N/A.

Previously, N/A was displayed when the system encountered an unexpected time-out before retrieving all data.

(Issue **35764367**)

Oracle CRF Submit email notifications are not always received (former Known Issue)

Clinical One Cloud Service now sends Oracle CRF Submit email notifications to all eligible users.

> **Note**
>
> Eligible users are defined under each notification and include the following options: Sponsor Users, Site Users, and Default Email.

Previously, some users were not receiving email notifications due to a system limitation on the number of eligible users.

For more information, see Email and in-application notifications.

(Issues **35981904**, related to the Storage limit has exceeded notification, and **36391622**, related to notifications for the Sponsor and Site and the success and failure of requests, were addressed.

In the Rules report, the Visit Name column has a leading space

When generating the Rules report in CSV format, the Visit Name column header no longer contains a leading space.

Retracted recommended action: Manually remove the space in the output file.

(Issue **36710994**)

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The Kit Reconciliation report fails when site names include quotation marks

The Kit Reconciliation report now generates successfully even when site names include quotation marks.

Retracted recommended action: Remove the quotation marks from the site name, then re-run the report.

(Issue **36312970**)

Oracle CRF Submit Archives Custom PDF requests fail when a misallocated kit is not associated with a visit

The Oracle CRF Submit Archives Custom PDF now generates successfully even if a visit is not selected when updating a kit's status to misallocated for a kit dispensed in error.

> **Note**
>
> If you do not select a visit, the Subject History section of the PDF includes details about the misallocated kit.

For more information about RTSM data in archives, see the Submission PDF, Archival PDF (sponsor), Archival PDF (site), and Custom PDF requests.

(Issue **36308776**)

Site users and subject data

Re-verified optional questions aren’t accurately recorded

When you now re-verify any optional questions in a one-section form (flat) or the first section of a two-section form, the verified data is correctly recorded in the application and your study's database. Re-verification of data is correctly recorded even when your study requires source data verification but doesn't include a configured SDV strategy.

This issue didn't affect the way re-verification data was recorded in your study's reports either, whether they are Clinical One Cloud Service reports, data extracts, or Oracle Clinical One Analytics reports and dashboards.

(Issue **36977998**)

Unable to save data for a question group after clearing data

Now, when a user enters data for a question that is part of a question group after clearing data using the Clear option, data is successfully saved.

Retracted recommended action: Refresh the page and continue entering data.

Issue (**35883879**)

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Rest API updates

See the newly added, deprecated, and deleted endpoints of the Clinical One Cloud Service APIs.

Services updates

The following services are updated:

- Data Hub
- Data Integration
- Data Capture
- Designer
- Designer EDC
- Randomization and Supplies
- Query
- Rules
- Rule Designer
- Sites and Depots

Data Hub

Change	Endpoint
New	• POST /v4.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v5.0/studies/{studyId}/{mode}/odm/metadata

Data Integration

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/report/rtsmdataextract

Data Capture

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/properties/{type}/{subjectId}/{id} • POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisitsinfo • PUT /v12.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v13.0/studies/{studyId}/{mode}/visitstatus/subjects • GET /v2.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata • PUT /v3.0/studies/{studyId}/{mode}/dataelements/clear/{scope}
Deleted	• GET /v8.0/studies/{studyId}/{mode}/visitstatus • PUT /v9.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}

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Designer

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/versions/{version}/forms/associateForms • POST /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/previewFormNotification • POST /v17.0/studies/{studyId}/versions/{version}/forms • GET /v17.0/studies/{studyId}/versions/{version}/forms • GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded • GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId} • GET /v17.0/studies/{studyId}/versions/{version}/forms/{formId} • PUT /v17.0/studies/{studyId}/versions/{version}/forms/{formId} • DELETE /v17.0/studies/{studyId}/versions/{version}/forms/{formId} • GET /v17.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms • POST /v2.0/studies/{sourceStudyId}/copy • GET /v2.0/studies/{studyId}/studyversionobjects/formitems • POST /v2.0/studies/{studyId}/updateCopyStudyStatus • POST /v2.0/studies/{studyId}/versions/{version}/branches/{branchid}/copyBranch • GET /v2.0/studies/{studyId}/visits • POST /v2.0/studies/{targetId}/copystudyobjects • POST /v2.0/studies/{targetStudyId}/retryCopyStudy • POST /v3.0/studies/{studyId}/versions/{version}/design/visits/{visitId}/validate/assign/randomization/{randomizationId} • POST /v8.0/studies/{studyId}/versions/{version}/visits • GET /v8.0/studies/{studyId}/versions/{version}/visits • GET /v8.0/studies/{studyId}/versions/{version}/visits/{visitid} • PUT /v8.0/studies/{studyId}/versions/{version}/visits/{visitid} • DELETE /v8.0/studies/{studyId}/versions/{version}/visits/{visitid}
Deleted	• GET /v1.0/studies/{studyId}/integrationreport • GET /v1.0/studies/{studyId}/versions/{versionId}/cohorts • GET /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/formLogo

Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/forms/formitems • GET /v1.0/studies/{studyId}/{mode}/forms/latest

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Randomization and Supplies

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/dndexception • GET /v1.0/studies/{studyId}/{mode}/dndexception • GET /v1.0/studies/{studyId}/{mode}/dndexception/{id} • PUT /v1.0/studies/{studyId}/{mode}/dndexception/{id} • DELETE /v1.0/studies/{studyId}/{mode}/dndexception/{id} • POST /v1.0/studies/{studyId}/{mode}/kits/existingdata • POST /v1.0/studies/{studyId}/{mode}/reports/dndexceptions • GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/visits/{visitId}/status • PUT /v2.0/studies/{studyId}/{mode}/orders/{shipmentId} • GET /v2.0/studies/{studyId}/{mode}/randlistdesigns • POST /v2.0/studies/{studyId}/{mode}/sites/{siteId}/recon/shipments • POST /v2.0/studies/{studyId}/{mode}/{studyVersion}/randlist/generate • POST /v3.0/studies/{studyId}/{mode}/lots/blinded-lots • GET /v3.0/studies/{studyId}/{mode}/lots/blinded-lots • GET /v3.0/studies/{studyId}/{mode}/lots/blinded-lots/{blindedLotId} • PUT /v3.0/studies/{studyId}/{mode}/lots/blinded-lots/{blindedLotId} • GET /v3.0/studies/{studyId}/{mode}/sites/{siteId}/shipments • PUT /v4.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits • PUT /v5.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId} • GET /v6.0/studies/{studyId}/{mode}/shipments
Deleted	• POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisits2s

Query

Change	Endpoint
New	• GET /v3.0/studies/{studyId}/{mode}/queries/queryTable
Deprecated	• GET /v2.0/studies/{studyId}/{mode}/queries/queryTable • POST /v8.0/studies/{studyId}/{mode}/report/{reportName}

Rules

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/rerunhistory/{ruleId}

Rule Designer

> **Note**
>
> Rule Designer endpoints are listed under the Rules category.

Change	Endpoint
Deprecated	• GET /v1.0/rule/studies/{studyId}/{mode}/simple

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Sites and Depots

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/regions/countries/history • GET /v1.0/studies/{studyId}/{mode}/regions/history • GET /v1.0/studies/{studyId}/{mode}/sdfs/allSdf/{sdfType} • GET /v1.0/studies/{studyId}/{mode}/sdfs/allstudyversions/{sdfType} • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/sdfDetails • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/countries • POST /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/validateFields • PUT /v2.0/contacts/deleteContact/{id} • PUT /v2.0/organizations/deleteOrganization/{id}

- Rest API patch updates
  See the updates to the Clinical One Cloud Service APIs for 24.1.1.

Rest API patch updates

See the updates to the Clinical One Cloud Service APIs for 24.1.1.

The following services have been updated:

- Designer EDC
- Query
- Users, Permissions and Roles

Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/forms/labNormalItems • POST /v1.0/studies/{studyId}/visitsforms/formitems • POST /v1.0/studies/{studyId}/visitsforms/strata

Query

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/querymgmt/filteredList • GET /v10.0/studies/{studyId}/{mode}/openQueryDetails • GET /v10.0/studies/{studyId}/{mode}/queryDetails • POST /v10.0/studies/{studyId}/{mode}/report/{reportName}

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Users, Permissions and Roles

Change	Endpoint
New	• POST /v1.0/authstudies/{studyId}/users

Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Impact specific to Oracle DMW

The length of the following columns is increased and this impacts your integrations with Oracle DMW. For more information, reach out to your Oracle point of contact.

The following columns are updated:

Data Hub table	Data Hub column	Current data length	New data length
DH_SITE_DEPOT_ADDRESS	FAX	200	2000
DH_SITE_DEPOT_ADDRESS	PHONE	200	2000
DH_SITE_DEPOT_ADDRESS	EMAIL	1020	2000
DH_SITE_DEPOT_ADDRESS	ADDRESS_POSTALCODE	20	80
DH_SUBJECTS_VISITS	ADDRESS_POSTALCODE	20	80
DH_SUBJECT_FORMITEMS	LAB_NAME	800	2000
DH_SITE_DEPOTS	SDF_NAME	800	2000
DH_SITE_DEPOT_ADDRESS	SDF_NAME	800	2000
DH_SITE_DEPOT_ATTRIBUTES	SDF_NAME	800	2000
DH_SITE_DEPOT_COUNTRIES	SDF_NAME	800	2000
DH_ORS_RND_NUMBERS	SITE_NAME	800	2000
DH_ORS_KIT_TYPES	SITE_NAME	800	2000
DH_SUBJECT_SITE_SUMMARY	SITE_NAME	800	2000
DH_SUBJECTS	SITE_NAME	800	2000
DH_SUBJECT_VISIT_SUMMARY	SITE_NAME	800	2000
DH_QUERY	SITE_NAME	800	2000
DH_SUBJECTS_VISITS	SITE_NAME	800	2000
DH_INVENTORIES	SITE_NAME	800	2000
DH_ORDERS	SITE_NAME	800	2000
DH_SUBJECT_FORMITEMS	SITE_NAME	800	2000

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Data Hub table	Data Hub column	Current data length	New data length
DH_FORMS_ASSOCIATIONS	SITE_NAME	800	2000
DH_SUBJECTS_MISSING_VISITS	SITE_NAME	800	2000
DH_SUBJECT_FORMS	SITE_NAME	800	2000
DH_ORDERS	DEPOT_NAME	800	2000
DH_USER_SITEDEPOT_ACCESS	SITE_DEPOT_NAME	800	2000
DH_SUBJECT_TRANSFERS	FROM_SITE_NAME	800	2000
DH_SUBJECT_TRANSFERS	TO_SITE_NAME	800	2000
DH_SITE_DEPOT_ADDRESS	ADDRESS_COUNTRY	400	16000
All Data extract form tables	SITE	800	2000

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Clinical One Cloud Service and Clinical One Digital Gateway 23.3 (December 2023)

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See the newly added, deprecated, and deleted endpoints of the Clinical One Cloud Service APIs, available upon the Production release.
- Release impact for other applications
  This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.3 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway** application.

Table 9-1 Patch log

Release Number	Release Date	Notes
Release 23.3.1.6	18-April-2024	For this release, we fixed issue **36459618** related to integrations. See Integrations.
Release 23.3.1.5	04-April-2024	For this release, we fixed issues related to forms and visits. For more information, see issues **36373738** and **36430361** in Forms, visits, and rules.
Release 23.3.1.4	30-March-2024	For this release, we fixed issue **36352863** related to the order of questions in a form. See Forms, visits, and rules.
Release 23.3.1.3	22-March-2024	For this release, we fixed several issues related to how subject data is verified in a study: • For issues **36325535** and **36340891**, and **36284515**, see Site users and subject data.

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Table 9-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.3.1.2	08-March-2024	For this release, we fixed several issues related to subject data, lab normal ranges, and Oracle Clinical One Analytics. • For issues **36257210** and **36308286**, see Site users and subject data. • For issue **36260224**, see Sites, labs, depots, settings, and user management. • For issue **36293970**, see Oracle Clinical One Analytics.
Release 23.3.1.1	22-February-2024	For this release, we fixed several issues connected to forms and visits. For more information, see: • Issues **36246646**, **36267457** and **36005744** in Forms, visits, and rules.
Release 23.3.1	10-February-2024	For this release, we fixed several issues connected to forms and visits, subject data collection, as well as reports. For more information, see: • Issues **35726231**, **36070846**, and **36109118** in Forms, visits, and rules; • Issue **35997964** in Sites, labs, depots, settings, and user management; • Issues **35832979** and **36125416** in Reports, archives, extracts, and notifications.
Release 23.3.0.3	05-February-2024	For this release, we fixed two issues related to how subject data is displayed and site events. For more information, see the following: • Issue **36208670** in Site users and subject data; • Issue **36250794** in Sites, labs, depots, settings, and user management. .
Release 23.3.0.2	29-January-2024	For this release, we fixed an issue related to lab forms. For more information, see issue **36221890** in Site users and subject data.

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Table 9-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.3.0.1	16-January-2024	**Note** This fixed issue doesn't impact any customers working with either Clinical One Digital Gateway or Clinical One Cloud Service. For this release, we fixed an issue related to signing data. For more information, see issue **36177246** in Site users and subject data.

What's new

- Data collection
- Data review
- Integrations
- Site management
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management

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- User experience
- Other enhancements

Data collection

- Replace the subject number with the randomization number after randomization
  A new study setting allows the subject number to be replaced by the randomization number after randomization.
- Undo subjects added in error
  If a subject has been added to a study in error, it is now possible to undo this action.

Replace the subject number with the randomization number after randomization

A new study setting allows the subject number to be replaced by the randomization number after randomization.

Before you work with this feature

- To view and configure this new setting for replacing the subject number, a sponsor user must be assigned the new permission called *Manage Subject Number Configuration*.

> **Tip**
>
> To access the Study Settings tab, a user must be assigned the existing *View Study Settings* and *Edit Study Settings* permissions.

Details for sponsor users

- With the appropriate permission, you can find the new setting on the **Study Settings** tab. The setting is called **Replace Subject Number with Randomization Number**.
- This new feature is available in all modes: Testing, Training, and Production and it is mode-specific. This means you can enable the setting in Production mode, where no subjects have been screened or enrolled, even if subjects were already screened or enrolled in Testing or Training mode.
- Subjects are still initially assigned a subject number after being screened or enrolled. After randomization, the subject number is replaced by the randomization number, and the original subject number is referred to as the screening number in the User Interface (UI) and reports.
- The new subject number is propagated throughout the system in the following application areas:
  - The User Interface (UI)
  - All dialog windows
  - Post-randomization notifications
  - All reports that include the subject number
  - The Subject Data Extract
  - Oracle CRF Submit archives and reports
  - Select Clinical One Digital Gateway configured integrations

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Impact on reports and notifications

- The **Subject Data report** includes a new column called **Screening Number**.
- The Subject Number column in the **Subject Events report** has been renamed to **Screening Number**.
- The **Subject Data Extract** includes a new column, called **SCRNID**, to collect the Screening Number.

> **Warning**
>
> As stated above, a new column, SCRNID, has been added to the Subject Data Extract, resulting in a new header. If you have programming based on the column positions in the extract, modifications to your programming may be required.

Already working in a live study?

- This feature is available for existing studies started before 23.3, when no subjects have been screened or enrolled.
- The setting is grayed out if subjects were screened or enrolled in a specific mode.

More information about this feature can be found in the *Sponsor and CRO User Guide*, under Study Settings, after the Release Assessment Environment (RAE) upgrade.

Undo subjects added in error

If a subject has been added to a study in error, it is now possible to undo this action.

Details for site users

Users assigned the *Edit Form Data for Subjects* permission can now remove a subject that has been added in error, so long as no data has been recorded for that subject.

Once the action of adding a subject is undone, their subject number is returned to the pool for reuse. The subject's GUID, however, is not reused.

Impact on reports

The Subject Events report now features an **Add Subject Cancelled** entry if the subject is undone. Moreover, when the subject number of an undone subject is reused, two entries are included for that subject in the following reports:

- ODM-XML Extract
- Subject Data report
- Subject Events report
- Subject Queries report

Data review

- Create queries on the visit date
  It is now possible to set up an automated validation of a visit's date against the visit window! Additionally, a visit's date can be selected to raise manual queries, as well as automated queries, and notifications through custom JavaScript rules.

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Create queries on the visit date

It is now possible to set up an automated validation of a visit's date against the visit window! Additionally, a visit's date can be selected to raise manual queries, as well as automated queries, and notifications through custom JavaScript rules.

Configure alerts for visit dates out of window

Study designers can now configure rules to alert a site user if a visit's date is outside of the visit window, either through a warning or by raising a query. When defining the visit schedule, there is a new field called **Alert if Outside the Visit Window**. This field displays the following options:

- **Off**
- **Warning**
- **Query**

By default, the field is set to **Off**. This means it will not display any kind of alert, and all visits in current live studies will be set to **Off**, as well. Choosing to alert, either through a warning or a query, can help correct data entry errors and collect protocol deviation details to determine if the subject should remain in the study or if it should be included in the investigational product analysis at all.

As soon as this release is complete, you can start configuring these alerts. However, Advanced Study Versioning (ASV) is not supported, which means you need to make the change in a draft study version and move the updated study version to either Testing or Approved, and then apply that study version to the respective sites. Queries and warnings only display for visits added or updated after the Study Version change is applied.

You can find additional information in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Raise manual queries on a visit's date

Previously, Clinical Research Associates (CRAs) and data managers would need to raise queries on the visit date targeting another question within one of the forms associated to the visit, which made it difficult to track and report. With this enhancement, CRAs and Data Managers can now raise queries directly on the visit date field. This helps streamline the data review processes,letting them associate queries to the correct question, document them properly, and generate clean reports with accurate information regarding these visit dates and their queries.

Raise queries on the visit date through custom rules

Besides the visit window validation, there may be other requirements related to visit dates that require custom rules, whether they're scheduled or unscheduled visits. The same way you can now raise manual queries on visit dates, rule developers can now select the visit date as the target for custom rules that raise automated queries and send notifications. The **Add Rule** function is now available when selecting the visit date field. Rules added to the visit date question have the following actions available:

- **Create Query**
- **Create Assigned Query**
- **Send Notification**

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> **Note**
>
> The action option called **Calculate Value** is not available for visit date target rules.

You can find additional details on how to create different types of rules and the available rule helper functions in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

Integrations

- Enhancements to integrations
  This section includes enhancements to integrations configured in the Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

Enhancements to integrations

This section includes enhancements to integrations configured in the Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

Depot-to-depot shipments support for Almac Global Depot Network

Users can now optionally configure depot-to-depot shipments in the Almac integration. The integration will also update these shipments' statuses accordingly.

For more information about depot-to-depot shipments, see About depot-to-depot shipments.

Replacing the subject number with the randomization number is supported in downstream systems

A new study setting allows the subject number to be replaced by the randomization number after randomization.

When the setting is enabled, a new event introduced in Clinical One Cloud Service notifies external systems of a subject number change in a study.

> **Note**
>
> In addition to the new setting being enabled, a configuration update is required to take advantage of this feature. Work with your Oracle Services Consultant to apply the necessary updates.

Supported integrations

- Clinical One Cloud Service to Oracle InForm

More information about this feature can be found in the *Sponsor and CRO User Guide* after the Release Assessment (RAE) upgrade.

Site management

- Manage sites, depots, and labs in one place
  Sponsor and CRO users can now manage organizations (sites, depots, labs) and their contacts at a global level.

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Manage sites, depots, and labs in one place

Sponsor and CRO users can now manage organizations (sites, depots, labs) and their contacts at a global level.

> **Tip**
>
> Did you know that you can now create and manage locally sourced kits at a site? This new feature can be particularly useful now that you can manage organizations and contacts at a global level. For more information, see Manage locally sourced kits.

To further improve your study management capabilities, you can now create and manage sites, labs, or depots, and their contacts for all studies at your organization, all in one place.

> **Note**
>
> Additional information and step-by-step instructions on managing organizations and vendors for multiple studies can be found in the *Sponsor and CRO User Guide* and the *Add Users Guide* after the RAE upgrade.

Before you work with this feature

This new feature can impact all users who work with sites, depots, labs, or administrate a study in general. The following users should be assigned the *Manage Contacts and Organizations* and *View Contacts and Organizations* global roles to be able to manage organizations and their contacts at a global level:

- Global user managers
- Site administrators
- Study managers
- Clinical supply managers

Codelist guidelines when working with this feature

During your environment's upgrade, while the contacts and organizations for your site addresses are populated, the **State/Province/County** and **Prefix** fields are verified using the Clinical One Cloud Service system code lists. If the data in these fields does not match, any contact or organization, State/Province/County and Prefix data is cleared during the upgrade.

> **Note**
>
> These fields are case sensitive; periods (.), and special accents (`) are ignored.

After the migration, if your study has an integration that uploads the **State/Province/County** and **Prefix** fields into Clinical One Cloud Service, the data is verified against the Clinical One Cloud Service code lists prior to them being imported into the Clinical One Cloud Service. If the data in these fields does not match, the data points are cleared in Clinical One Cloud Service only. This does not cause the full integration to fail.

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Sponsor users can be notified when the State/Province/County data is cleared via notification. To receive the notification, the user must be assigned the *State Set to Null Notification* permission. This informs the user that the **State/Province/County** field has been cleared during integration. The notification includes the following information to help determine the mismatch, so that it can be resolved in the source system:

- Study Name
- Site Name
- Site ID
- Site Mode

For more information, reach out to your Oracle point of contact.

Updates to the existing site and depot workflows

If you're a site manager creating sites or labs, or a clinical supply manager setting up depots, here's what you should know about the workflow you used to follow to set up these organizations:

- All sites, depots, and labs are created at the global level only. Their addresses and their associations with specific contacts are maintained only at the global level. You can still add a site, depot, or lab to a specific study and this action can be performed at the study level only after that site, depot, or lab was configured at the global level.
- On the Sites & Labs tab, you can now click **Create Site** to add an existing site created at the global level to a study. On the Add Site dialog, you can then enter or modify information, such as the Site ID, Status, Mode, and permissions you'd like to give the site users. You can also associate existing addresses created at the global level with your site and select different shipment addresses by kit type. The same applies for depots.
- On the Sites & Labs tab, when you click **View Labs**, you can now click **Add Lab**. On the Add Lab dialog you can then search for a lab created at the global level to add it to your study. You can also further assign a lab to a site at the study level.

Details about contacts

When it comes to managing contacts, here's what's new for you:

- On the Global Settings page, a new tab called **Contacts** is introduced.
- On the Contacts tab, you can create new contacts, edit or retire them, and filter through them, as well as transfer study sites.
- You can filter contacts by study mode, their status, country, state, specialty, or search for a specific contact's name.
- For every contact that you create, you must specify any required information and their addresses. A contact can have multiple types of addresses, such as a primary address, a billing address, a shipping address, or an alternate address.
- Once you create a contact on the Organizations tab, you can associate that contact with an institution. For example, you may associate the contact of a Principal Investigator with the selected institution.
- You can associate the same contact with multiple institutions at your organization.

Details about organizations

When it comes to managing organizations and contacts, here's what's new for you:

- On the Global Settings page, a new tab called **Organizations** is introduced.

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- On the Organizations tab, you can create, edit, delete, or retire any organization, as well as filter through the organizations that are associated with the organization you work at.
- Your options for creating an organization include creating an institution (such as a hospital) or a vendor (such as a lab or a depot facility).
- For every organization that you create, you must specify any required information, as well as their addresses. An organization can have multiple types of addresses, such as a primary address, a billing address, a shipping address, or an alternate address.
- For an institution, you can also create departments to better organize the hierarchy and workflows at that specific organization.
- Upon creating an institution, you can associate a contact with that institution, and then you assign that institution to a study and a specific study mode at your organization. This effectively creates a site that becomes available in the studies that you associated that site with. For example, if you create Hospital A and associate it with Contact B, and assign it to Study-123 in Production mode, Hospital A will show up on the Sites & Labs tab, in Study-123.

Details about setting up a master address

You can now reduce the amount of places you update a primary address by creating that address once and using it throughout your studies, letting you manage a recurring address in one place, as opposed to updating it in numerous contacts or organizations. Here's what's new when it comes to setting up a primary address:

- Smart search identifies new addresses, enabling you to quickly add or update addresses.
- Creating or modifying a master address updates the address across all associated contacts and organizations.
- The first address entered in the system becomes the default primary address.
- The checkbox option allows you to copy the primary address into other address fields, such as Billing or Shipping.
- At least one address is required and must be selected as the main primary address.

Already working in a live study?

If you're currently working in a live study that has sites, depots, or labs setup, you must know that Oracle will handle the migration of all of your organizations and vendors at the global level. The transition will be seamless, ensuring that your studies are not compromised throughout their study conduct period.

This new feature is not available in the Release Assessment Environment (RAE), but you can reach out to your Oracle point of contact for more specific information, as well as to request a separate testing environment.

Randomization and trial supply management

- Control depot users' access
  Sponsor users can now restrict access for depot users and control what they can view in the application on a study-to-study basis.
- Manage locally sourced kits
  When defining inventory settings, sponsor users can now include locally sourced kits and allow site users to manage their dispensation.

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- Pool kits easily across studies
  Global users who are assigned the appropriate roles and permissions can now define and manage pooled kits across studies at their organization.

Control depot users' access

Sponsor users can now restrict access for depot users and control what they can view in the application on a study-to-study basis.

Before you work with this feature

As a user administrator or any other sponsor user, you must be aware of the following changes introduced for permissions and study roles:

- *Blinded Depot User* is a new permission that lets the user access the new **Depot Inventory** tab and provides access to view the kit numbers, but doesn't see the descriptions for all blinded and Unblinded Pharmacist kits.

  > ⚠ **Caution**
  >
  > Use with caution. The *Blinded Depot User* permission grants access to view the Sequence Number, which could potentially unblind the study for blinded site users and blinded sponsor users.

- *Blinded Depot User* is also introduced as a new template study role. The study role contains several existing permissions compiled to give the adequate access to a depot user who must be blinded in a study.
- To unblind the *Blinded Depot User* study role, add the permission *Create Shipments to Depots* that exposes all kit descriptions to the blinded depot user.
- The existing *Clinical Supply Manager* study role template is modified to include the new *Blinded Depot User* permission.
- The following permissions are no longer unblinding:
  - *Receive Notification of Depot Shipment*
  - *Release Shipments from Quarantine*
  - *Receive New Shipments at the Depot*
  - *Receive and Reconcile Shipments at the Depot*

You can find additional information on the *Add Users Guide* after the Release Assessment environment (RAE) upgrade.

Details for blinded depot users

If you're a depot user who is assigned the *Blinded Depot User* permission or study role, here's what's new for you:

- To view supplies at a specific site or all sites, request permission from your user administrator.
- On the Study Supplies page, you can view a new tab called **Depot Inventory**.
- The **Depot Inventory** tab displays data on a study's blinded inventory and contains columns, such as: Kit Number, Sequence Number, Block Number, Kit Description, Status, Expiration Date, and Units per Kit.

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- On the new tab, you can filter blinded kits by depot, status, blinded lot, shipment ID, and quarantine ID. Also, you can search for kits by kit or sequence number.
- You can update the status of kits in your depot's inventory to **Available**, **Dispensed**, or **Quarantined**.
- The word *blinded* now appears in the search bar or for filters to indicate that some treatment descriptions may be unavailable to the blinded depot user.
- As a blinded depot user, you cannot modify the inventory received at a site, as per contract, except for releasing kits from quarantine, if you have the appropriate permissions. You also cannot view the full description of kits, as well as upload or generate kit lists.

You can find additional information on the *Depot User Guide*, after the Release Assessment environment (RAE) upgrade.

Details for user administrators and sponsor users

As a sponsor user, here are some new things you can do to control a depot user's access:

- You can let each depot user only view shipments for their assigned depots.
- As a clinical supply manager, you can remove the location from the kits when they are assigned to the depot in error. For example, if you didn't receive the kit to the site, you can change it back to the depot.
- If you want to give a blinded depot user viewing access to the Site Inventory tab, you must assign one or more sites in the study to the depot user. By default, a blinded depot user doesn't have access to the Site Inventory or the Study Inventory tab.
- If you want to give a blinded depot user access to view Unblinded Pharmacist kits, assign them with the *View Unblinded Pharmacist Kits* permission.

You can find additional information on the *Sponsor and CRO User Guide*, after the Release Assessment environment (RAE) upgrade.

Impact on reports

The following reports will reflect depot user activity:

- Kit Chain of Custody (Blinded) report
- Shipment Order Summary report
- Kit Inventory (Blinded) report
- Kit Reconciliation report

You can find additional information about these reports on the *Reporting Guide* after the RAE upgrade.

Manage locally sourced kits

When defining inventory settings, sponsor users can now include locally sourced kits and allow site users to manage their dispensation.

You can now configure locally sourced kits for your studies to accommodate their many needs, such as:

- Sites may need different kit types to be sent to different locations due to storage purposes.
- The protocol utilizes multiple kit types distributed by different depots.
- A drug is approved in a specific geographical area, but not in another.

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Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- On the Supply Settings tab, a new section called **Locally Sourced Kit Settings** is now displayed. In here, you can add a kit and define its details so it can be locally sourced.

> **Note**
>
> The kit type must be set to Unblinded at the time it is created in order for it to be available to be locally sourced.

- Any kit type within a specific titration event can be selected to be added as locally sourced. Once a kit has been added and saved as locally sourced, the kit type cannot be edited.
- Multiple countries can be selected and added to either **Locally Sourced Countries** or **Sourced by Site Countries**.

> **Note**
>
> A country can only be added to either **Locally Sourced Countries** or **Sourced by Site Countries**, but not added to both.

- All locally sourced countries must be removed in order to disable or delete a locally sourced kit.

More information and step-by-step instructions on configuring locally sourced kits can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

When it comes to your workflow, here's what you should know:

- Information on locally sourced kits is provided in the dispensation details and Subject History.
- The **Subject Dispensation notification** includes details on locally sourced kits for users assigned one or all of the following permissions:
  - *Receive the Dispensation Notification*
  - *Receive the Dispensation with Dosing Instructions Notification*
  - *Receive the Unblinded Dispensation Notification*

More information on this notification can be found in the *Notifications and Permissions Guide* after the RAE upgrade.

Impact on reports

Updates to the following reports can be found in the *Reporting Guide* after the RAE upgrade:

- Kit Dispensation report
- Shipment Order Summary report
- Shipment order form
- Study Design report

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- Subject Dispensation report
- Subject Visits (Blinded) report
- Subject Visits (Unblinded) report
- Titration Summary (Blinded) report
- Titration Summary (Unblinded) report

Already working in a live study?

As soon as the upgrade for this release is complete, you can begin locally sourcing kits in existing studies.

Pool kits easily across studies

Global users who are assigned the appropriate roles and permissions can now define and manage pooled kits across studies at their organization.

As opposed to defining kit types for a single study only, pooling kits lets you strategically distribute the investigational product across different studies. In turn, you can now create powerful supply strategies that can significantly reduce drug overages and preserve supplies for all study patients.

> **Note**
>
> You can find more information in the following user guides, after the Release Assessment (RAE) upgrade:
>
> - *Add Users Guide*
> - *Sponsor and CRO User Guide*
> - *Study Designer User Guide*

Before you work with this new feature

As a global user manager or a user administrator, you should know that your workflow hasn't changed. However, there some new roles and permissions that you need to be aware of. The following new global roles and permissions are new or modified:

New role or permission	Description
Create and Edit Library Kits for Pooled Supplies	This is a global role. You can assign this role to a library user or a study designer so that they can create and edit a kit while it has a status of Draft in a library study.
Approve Library Kits for Pooled Supplies	This is a global role. You can assign this role to a library user or a study designer so that they can approve a kit in a library study.
Delete Library Kits	This is a global role. You can assign this role to a library user or a study designer so that they can delete kits in a library study.

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New role or permission	Description
Create Manual Shipments (Unblinded)	This is an existing permission that is updated to become unblinded. This means that whoever is assigned this permission can now view pooled kits to include them in a shipment request. **Warning** This update partially unblinds a depot user if they are granted this permission. You are not restricted or prevented from assigning a user with this permission as this change doesn't present the risk of compromising your study's integrity.

Details for library managers and study designers

If you're a library manager, here's what's new for you:

- On the Library page, you can now see a new tab called **Kit Types**.
- With the right role, you can now create or edit kit types in a library study, and import them into a Production study.
- When defining a kit type as a library object, you can specify several details for it, such as the pooling ID, a description, as well as information about its storage requirements and the units per kit.
- In your study's library, on the Kit Types tab, you can also change the status of a kit to any of the available statuses: **Draft**, **Approved**, **Published**, and **Archived**.
- On the Kit Types tab, you can monitor the entire history of a kit type in a library study.

If you're a study designer, here's what's new for you:

- In a study's design, on the Kits tab, you now have a new button called **Import Kit Type** that takes you to the study's library where you can choose which kits to import.
- Upon selecting a kit to import, you can define its usual details that you specify when you create a kit type in your Production study.

Details for clinical supply managers and depot users

Whether you're a clinical supply manager or a depot user, here's what's new for you:

- When creating shipments, you now have to specify the manufacturing lot ID for a pooled kit type. For example, if you want to create a shipment that contains multiple types of kits, and one of those kits is pooled, you need to select a manufacturing lot ID for that specific pooled kit type. When a shipment that has both pooled and non-pooled kits is created, the system generates separate shipment order - one for pooled kits and one for non-pooled kits.

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- On the Shipments tab, you can see the specific category of a shipment in the new Category column. This column indicates whether the shipment is pooled or not.
- The system doesn't generate a kit order form for a shipment that contains pooled kits until the shipment is returned (and it has an **In Transit** status).
- When it comes to kit lists for pooled kits, you cannot deactivate or upload a kit list when that kit list contains pooled kits. Pooled kits are dynamically uploaded to the database as they are submitted in the integration file from the depot.

Details for site users

As a site user, there are no workflow changes for you. However, you should know that anytime you register a pooled shipment at your site, the receipt will contain the kit numbers, as usual. The lot numbers and the kits' sequence numbers are displayed only if you have unblinded access to the study.

Details for integration managers

If you're an integration manager and the study you're working with is integrated with another supply system, here's what you need to know:

- A pooled manual shipment can be raised through this integration by specifying the kit type and the kit count in the integration template. Pooled shipments can also be generated automatically as part of a study's resupply strategy.
- You or another user cannot add or remove kits from a pooled shipment.
- A pooled shipment's date is sent to the supply system as part of the integration. Another user cannot modify that pooled shipment's date in the User Inteface (UI).
- A pooled shipment that is sent from one depot to another is handled outside of the system. For an Clinical One Cloud Service user, this means that they cannot modify the shipment in Clinical One Cloud Service.

Reporting, archives and analytics

- Analyze your patients' data with the Subject Data Analysis dashboard
  Sponsor users can now gather more insights into a patient's journey through different stages in a clinical study.
- New Blinded Kits dataset in Oracle Clinical One Analytics
  Blinded users can now work with the new Blinded Kits dataset in Oracle Clinical One Analytics.
- Create pixel-perfect reports using BI Publisher
  Oracle Clinical One Analytics users can now create pixel-perfect reports in BI Publisher and schedule them to be run and emailed.
- Enhancements to Oracle CRF Submit archives and reports

Analyze your patients' data with the Subject Data Analysis dashboard

Sponsor users can now gather more insights into a patient's journey through different stages in a clinical study.

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> **Tip**
>
> Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study or just starting to work with analytics, reach out to your Oracle point of contact to learn more about the Subject Data Analysis dashboard.

Analyzing your patients' data throughout a study has never been easier. With the Subject Data Analysis dashboard template, available in Oracle Clinical One Analytics, you can now oversee relevant parameters for patients during different stages in a clinical study. This dashboard assists you in making sound medical decisions, improving your subjects' safety, and improving the quality of your study's data.

Remember this template is available to you so that you don't have to create a dashboard from scratch and rather customize it to meet your needs. All you have to do is download the template, re-import it, adjust filters and tweak the data. For more information, see Customize templates.

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can view data in a corresponding dashboard. To work with the Subject Data Analysis dashboard, you must have access to the following datasets :

- The Subject Form Items dataset
- The Subject dataset

Details for sponsor users

In Oracle Clinical One Analytics, the Subject Data Analysis dashboard leverages the existing functionality by combining data elements from multiple existing datasets. The main features of this dashboard consist of displaying the demographics of a subject, the events schedule, the severity of each adverse event and the concomitant medication, as well as lab data and other vitals of a subject. With this combination of key features, you can use the Subject Data Analysis dashboard in a variety of use cases:

- To identify a subject's crucial data such as ethnicity, age, gender, and much more.
- To monitor the progress of a patient on their study journey.
- To detect the occurrence of adverse events, their duration, and the concomitant medication that was administered during the course of the treatment.
- To get an overview of the lab test results during a subject's medication period.

You can find more information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

New Blinded Kits dataset in Oracle Clinical One Analytics

Blinded users can now work with the new Blinded Kits dataset in Oracle Clinical One Analytics.

Particularly useful to clinical supply managers, the Blinded Kits dataset allows users to create blinded custom reports based on kit-related data collected within Clinical One Cloud Service. This way, sponsor users with appropriate permissions can track shipments, lots, and kit statuses within their studies without unblinding risk.

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Details for user administrators and global user managers

A new permission, *Run the Blinded Kits Dataset*, has been added to grant access to the Blinded Kits dataset. As a user administrator or global user manager, you can assign this permission to any sponsor user who must have the ability to work with this dataset in Oracle Clinical One Analytics. This new permission is included, by default, in the following predefined template study roles:

- Clinical Supply Manager
- View Only for Blinded Support Users
- Study Manager

Details for clinical supply managers and other sponsor users

The Blinded Kits dataset contains additional study metadata about, sites, depots, and kits. Not only does this allow you to control your supply system better, but it also provides the opportunity to answer numerous questions related to supply elements within your studies while remaining blinded. For example, you can build blinded custom reports and visualizations to get insights on kit inventory statuses, shipments, kit dispensation, lots, and so much more.

Remember that to properly visualize data when working with any dataset, you must include at least one element from the folder listed as required. When working with the Blinded Kits dataset, include data elements from the Kits (required) folder on your custom reports and start analyzing your study's supply system data.

You can find additional information regarding the Blinded Kits dataset, and its data elements, in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Create pixel-perfect reports using BI Publisher

Oracle Clinical One Analytics users can now create pixel-perfect reports in BI Publisher and schedule them to be run and emailed.

Oracle BI Publisher is a reporting product from Oracle that lets you create and manage highly formatted reports, also known as pixel-perfect reports. Starting with this release, you can access BI Publisher from the Oracle Clinical One Analytics application.

The pixel-perfect reports you create through BI Publisher can use any of the existing datasets as data source. The same permissions that let you access specific datasets in Oracle Clinical One Analytics, which are assigned in Clinical One Cloud Service, control your access to each dataset in BI Publisher. Additionally, for each report you can specify parameters to filter data, select different layouts, select an output type from a wide list of available options, and many actions to manage the view and share of your reports. Some of these actions include:

- Export
- Share via link
- Send via email
- Schedule a job to run and distribute the report
- Manage report jobs

You can find additional information about pixel-perfect reports and BI Publisher in the *Analytics User Guide* after the Release Assessment (RAE) upgrade.

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Enhancements to Oracle CRF Submit archives and reports

Subject PDFs now include Visit Date query details

Now, custom and manual queries can be created to check that the date entered for the **Visit Date** fits within the specified visit window defined for a study.

Visit Date query details are included in the subject PDF **eCRF Audit Trail History** section of Submission, Archival, and Custom archive requests.

Replacing the subject number with the randomization number is supported in subject PDFs and reports

Now, users can configure studies to replace the subject number with the randomization number after randomization. When configured, the randomization number is visible anywhere the subject number was displayed in the study.

The **Subject No:** field in the subject PDF header and the **Subject ID** column in the **Download Log** report display the original subject number assigned after screening or the updated subject number assigned after randomization, depending on when the PDF or the report is generated.

> **Note**
>
> The **Download Log** contains a history of all downloads and may include both values if subject PDFs were generated before and after randomization.

More information about this enhancement can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Form associations for two-section forms are now supported in subject PDFs

In a previous release, we introduced the ability to link between the sections of a two-section form (flat and repeating) and other form types.

Such associations, the removal of these associations, and all audit history details are now included in the subject PDFs.

More information about Linking forms can be found in the *Site User Guide*.

Email and in-application notifications are now available

Email and in-application notifications can be configured to notify sponsor and site users about the status of PDF and report requests and to inform sponsor users about site-level PDF request, download, and confirmation activities.

This feature, available in Testing and Production modes only, is turned off by default. To enable the feature and manage notifications, the *Manage Archives Settings* permission must be assigned to access the new **Archives Settings** tab available under Study Settings.

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Table 9-2 Notification name, details, and required permissions

Notification name	Notification details	Required permissions to receive the notification
Request available for download	Site and sponsor users receive this notification when a request has been completed successfully and is available for download.	• *Run Archival PDFs for your site(s) (Site)* • *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*
Request failure	Site and sponsor users receive this notification when a request has failed to complete successfully.	• *Run Archival PDFs for your site(s) (Site)* • *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*
Request submitted by site user	Sponsor users receive this notification when a site user has generated a new request.	• *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*
Request shared with site downloaded	Sponsor users receive this notification when a request shared with a site has been downloaded by that site.	• *Run and download Site Confirmation and Download Log audit reports*
Request confirmed by site	Sponsor users receive this notification when a request shared with a site has been confirmed by the site after they have downloaded and reviewed its contents.	• *Run and download Site Confirmation and Download Log audit reports*
Storage limit has exceeded	Sponsor users receive this notification when the storage limit has reached 75% capacity.	• N/A: Sponsor users with access to Oracle CRF Submit receive this notification.

More information about this enhancement can be found in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- The clearChoice( ) helper function now clears data
- Manage all custom rules in one place
  A new Rule Management page is available for rule designers to see and manage all custom rules in a study.

The clearChoice( ) helper function now clears data

The clearChoice helper function has been enhanced to clear the answers from multiple-choice questions like check boxes and drop-downs. Previously, the function removed the answers, converting them to null values, which is not a true clear.

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> **Note**
>
> When data is cleared, the answer is removed, and the questions status is reverted to that of an unanswered question.

For more information, see clearChoice (Multiple-choice questions) in the *Rules Developer Guide* and Understanding data clearing in the *Site User Guide*.

Manage all custom rules in one place

A new Rule Management page is available for rule designers to see and manage all custom rules in a study.

Rule designers with rule management related permissions can now access the new **Rule Management** page. You can still see existing rules by navigating directly to the visit and form where the rule exists in either Production, Testing or Training modes. However, this new page allows you to see and easily manage all custom rules within a study, for all modes, in one single place.

The rules in the Rule Management page are classified into two different tabs: **Design & Testing** and **Production & Training**. On the Design & Testing tab you can see all rules in any status (*Draft*, *UAT*, *Approved*, *Published* and *Invalid*), while only the published rules are listed under Production & Training. Each rule is listed along with the following details:

- Rule name and description
- Target form
- Target question
- Rule state (Only for Design & Testing)
- Whether the rule is enabled or disabled for a given mode
- Whether, when published, the rule runs on all data or future data only (Only for the Design & Testing)
- Last modified or last published date and user

Aside from viewing your rules, this page also provides you with the options to:

- Enable or disable a rule for a specific mode, either individually or in bulk.
- While in testing, change a rule to run either on all data or future data only when it gets published.

  > **Note**
  >
  > This change will be applied as part of a study version tile move from Testing to Approved containers. This does not impact rules that are published with the slider (as a change of rule state).

- Find a given rule on the other tab to manage it for a different mode.
- Open a rule in the Rule editor to view it in read only mode.

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> **Note**
>
> As of now, to edit a rule or create a new one you still need to access the rule editor from the study in Testing mode. These abilities are going to be added to the Rule Management page as part of a future release.

The new Rule Management page provides a complete overview of all custom rules within your study letting you streamline processes related to rule management. You can find additional information in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

User experience

- Provide feedback on Clinical One Cloud Service
  Provide feedback regarding Clinical One Cloud Service within the application.

Provide feedback on Clinical One Cloud Service

Provide feedback regarding Clinical One Cloud Service within the application.

Users can now provide their feedback on Clinical One Cloud Service within the application through a user satisfaction survey. Completing the user satisfaction survey allows you to promote new system functionality and reflect on the ability to follow guided learning. By collecting this feedback, Oracle is able to identify areas of improvement and enhance user satisfaction.

Survey configuration and management is available in the Oracle Guided Learning console. For more information, contact your Oracle Guided Learning administrator.

Other enhancements

Transfer active contacts and organizations between studies

Sponsor users can now transfer contacts and organizations (such as institutions, labs, or depots) with an **Active** status between studies without retiring them.

Previously, organizations and contacts had to be retired before users could transfer them to other studies.

Perform a visit edit to reflect its latest status update

> **Note**
>
> While the behavior described in the section below is not an enhancement, we recommend you follow these guidelines if a visit's status in your study is not updated appropriately after the upgrade to the 23.3 release.

Prior to the 23.3 upgrade, if you created a form that contained hidden and classified questions, and then proceeded to assign that form to a visit in your live study version, you may have noticed that the visit's status remained as **Complete** after the 23.3 upgrade.

As a site user, when you navigate to that visit and the hidden and classified questions remain unanswered in the newly added form, the status of that visit should automatically update to **Incomplete**. However, this doesn't happen until you edit a field in the visit or the form. We

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recommend you perform an edit that doesn't affect your subject's data to accurately reflect the status of that visit.

Fixed issues

- All users
- Code lists
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data

All users

Subject Number scrolls off the screen when viewing previous visits

Now, the first three columns, the subject avatar, Subject, and Logs, are static and no longer disappear when scrolling through a subject's previous visits.

Retracted workaround: None. (Issue **35001431**)

Code lists

Consecutive validation messages for required Custom Code list fields are not read by the screen reader (former known issue)

Now, if you forget to complete multiple mandatory fields when creating a custom code list (on the Code List tab), your screen reader successfully reads all validation messages, ensuring you can complete the creation of the custom code list.

Retracted workaround: None. (Issue **34647715**)

Forms, visits, and rules

Visits containing a large volume of data take too much time to load

Now, when you click to view visits that have a large volume of data captured, the page takes an adequate amount of time to load.

Retracted workaround: None. (Issue **36373738**)

Radio button selections do not appear after saving a form

Now, selections made for radio buttons are shown after saving a form. Previously, at intermittent times, when you selected a radio button option and saved a form that contained a dynamic question, the value of the selection would not appear for that radio button option.

Retracted workaround: None. (Issue **36430361**)

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Questions in a form may appear unordered

Now, when you update one or multiple questions in any form type through Advanced Study Versioning (ASV), the order of the questions is preserved when you start a subject visit with an older version of the form in a live study version. (Issue **36352863**)

All queries are closed in all instances for both repeating and two-section forms

Now, only impacted queries on cleared dynamic questions are closed for the instances on repeating and two-section forms. Previously, any time a dynamic question was cleared, all queries were closed for that question.

Retracted Workaround: None. (Issue **36005744**)

The Complete option is not available for subjects when all visits are optional

Now, the **Complete** option, which appears under the Manage Subjects dropdown, on the Subjects page, is available when a study has been designed with all visits as optional and no **Earliest Visit to Complete Study** has been configured. In this case, only the Screening visit would need to be completed to progress the subject to study completion.

This also covers the following use cases:

- When a dynamic optional visit was triggered, even if no data was entered and the visit was not started or incomplete.
- When a dynamic optional visit was triggered in error.

This fix supports scenarios not covered in issue 36007300.

Retracted Workaround: None. (Issue **36246646**)

The Complete option is not available for subjects with incomplete or in progress optional visits

Now, the **Complete** option is available to manage a subject when having an optional visit started, with a status of either Incomplete or In Progress.

This fix supports a scenario not covered in issue 36007300.

Retracted Workaround: None. (Issue **36267457**)

Exit questions do not trigger the expected visits for branches with multiple visits

Now, selecting **Yes** for a branch visit exit question, thus opting to continue on the same branch, triggers the appropriate follow-up visit. Previously, in the context of a branch with multiple visits, three dashes (---) would be displayed in the visit train, preventing the subject from progressing on its current branch.

Retracted workaround: None. (Issue **35726231**)

Unexpected number of optional visits appears when trigger question is answered

Now, in the context of a dynamic visit design, the correct number of optional visits appears when a trigger question is answered. Previously, all optional visits would appear in the visit train once the trigger question was answered.

Retracted workaround: None. (Issue **36070846**)

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Visits are not displayed in the correct order when multiple tiers are present

Now, visits are ordered logically whenever the study design features three or more tiers, each with multiple branches. Given the same study design, visits would previously be ordered incorrectly.

Retracted workaround: None. (Issue **36109118**)

The Complete option is not available under Manage Subjects

Now, the **Complete** option, which appears under the Manage Subjects dropdown, on the Subjects page, is available when all visits left for a subject are optional, as long as all required visits are complete including the one set as the **Earliest Visit to Complete Study**, if defined.

In this scenario, only the required visits would need to be completed to progress the subject to study completion.

Retracted workaround: None. (Issue **36007300**)

A user can’t update a dynamic-visit trigger question

Now, a user can successfully update the answer to a question that triggers a dynamic visit after clearing all the data entered in the dynamic visit. Previously, a trigger question could not be updated, even after clearing the data.

Retracted workaround: None. (Issue **35717145**)

Creating a new draft study version fails after importing from a library study

Now, creating a new draft study version that includes importing from a library study no longer fails if the library study is deleted after import.

Retracted workaround: None. (Issue **35940490**)

Kits added to an unscheduled visit for a copied library study are not visible in the study (former known issue)

Now, kits added to unscheduled visits in a copied library study that includes randomization design are visible in the study after saving its details.

Retracted workaround: None. (Issue **35712173**)

Queries can be created on a deleted repeating form instance (former known issue)

Queries for the following use cases can no longer be created on a deleted repeating form instance:

- When using a direct API call. The back-end API call now checks for the deleted form state before creating a query.
- When two users have the same repeating form instance open in their browsers. If User 1 deletes the form instance while it's still available in the browser of User 2, User 2 can no longer create a query via the User Interface (UI).

Retracted workaround: On the Queries sidebar, you no longer have to close queries if opened on a deleted row. (Issue **35604053**)

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Dynamic visits are not displayed correctly when a decision visit is unskipped

Now, when you skip a decision visit and proceed past the dynamic visits it controls, then unskip the visit and answer the decision form, you can complete the dynamic visit without the requirement to complete the preceding dynamic visits.

For example, after un-skipping the decision visit and answering the item on the decision form to trigger dynamic Visit 4, you no longer need to complete the preceding visits: Visit 1, Visit 2, and Visit 3 first.

Retracted workaround: None. (Issue **35921814**)

A rule associated with the Visit Date does not run when the system automatically populates the Visit Date

Now, rules run successfully when the Visit Date is populated automatically by the system.

Retracted workaround: None. (Issue **35909061**)

Hidden and required questions are not considered when calculating a visit's status (former known issue)

Now, hidden and required questions are considered when determining whether a visit is complete. Previously, they were not.

Impact on already completed visits: After the upgrade to 23.3, if existing completed visits are opened or edited and contain at least one hidden, required question that is not complete, the visit status remains **Incomplete** until those questions are completed.

Retracted workaround: None. (Issue **35857474**)

Duplicate rows are displayed when viewing associated forms

Now, the system only lets one user at a time create or update a row association for a repeating form, avoiding the possibility of duplicate associations. Previously, duplicate associations could be made if two users created associations for a subject during the same log in session.

Retracted workaround: None. (Issue **35756400**)

The partialDateDiff Rules helper function incorrectly considers UNK as 00

Now, when UNK is entered for hours or minutes as part of a date-time item, the Rules helper function no longer considers that as 00 when comparing date values.

Previously, using the example below, the helper function (at the database level) considered UNK:UNK as 00:00 in the comparison logic, which resulted in an incorrect comparison.

- Date1: 2-Jun-2023 UNK:UNK
- Date2: 2-Jan-2023 00:01

Retracted workaround: None. (Issue **35904823**)

A lab form shows Completed even though all tests have not been entered

Now, view-only users no longer see a green icon indicating a Completed form when data entry on the lab form is incomplete. This issue did not impact users with data entry permission

Retracted workaround: None. (Issue **35835251**)

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Integrations

Updates made through integration with Data Capture service are showing successful response but value is not updated

Now, when an update to a data element is sent through an integration with the Data Capture service, using REST APIs, changes are properly validated and identified. This results in an actual value update.

Retracted workaround: None. (Issue **36459618**)

Oracle Clinical One Analytics

Rows deleted from a two-section form are marked as not deleted in (DMW) Clinical data extract tables if you update the flat section of the form

Now, rows deleted in the repeating section of a two-section form retain the status DELETED = Y (Yes) in Oracle Clinical One Analytics data extract tables after editing a question in the flat section of the form.

Previously, the status of the deleted repeating rows was updated to DELETED = N (No), adopting the status of the item edited in the flat section of the form. (Issue **36293970**)

> **Note**
>
> The scope of impact and fix for this bug (36293970) is limited to Clinical data extracts, which are used exclusively in the DMW integration and are not available/accessible in Oracle Clinical One Analytics.

Study data elements are not loading after using drag-and-drop

Now, the page loads successfully after using drag-and-drop to move study data elements such as STUDY_ID_NAME and STUDY_TITLE in the **Kits and Randomization Design Dataset**.

Retracted workaround: None. (Issue **35854892**)

Admin API calls are not producing a result

Now, Admin API calls no longer fail to produce a result. This issue was caused by an Oracle internal change to the View Only for Unblinded Support Users (template) study role that has been corrected.

Retracted workaround: None. (Issue **35937653**)

The Unblinded visits REST API v6.0 requires excessive time to execute

Now, due to improved pagination, v6.0 of the Unblinded visits REST API generates in an acceptable amount of time.

Retracted workaround: None. (Issue **35775900**)

SCHEDULED_FROM_EVENT_NAME incorrectly displays the visit title refname

Now, the SCHEDULED_FROM_EVENT_NAME correctly displays the visit title, and a new data element displays the visit title refname. Previously, the visit title refname was displayed under SCHEDULED_FROM_EVENT_NAME.

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Existing records in all applicable datasets where the SCHEDULED_FROM_EVENT_NAME column is present have been corrected; this includes the related DMW-loaded extracts DHVW_RAND_KITS_DESIGN_DATASET_V, DHVW_SUBJECT_VISITS_V, and DHVW_UNBLD_KITS_DATASET_V.

A new data element, SCHEDULED_FROM_EVENT_REFNAME, was added to the Event folder for the following Analytics datasets to address this issue going forward.

> **Note**
>
> For more information about the new data element, see Dataset descriptions.

- Blinded Kits dataset
- Blinded Subject Event dataset
- Kits and Randomization Design dataset
- Queries dataset
- Study Codelist dataset
- Study Design dataset
- Subject Form Items dataset
- Unblinded Kits dataset
- Unblinded Subject Event dataset

Retracted workaround: None. (Issue **35017937**)

Unable to view hidden items when data classification is applied

Now, hidden items with data classification applied can be viewed under ITEM_NAME in Oracle Clinical One Analytics datasets. Previously, a system-imposed character limit impacted what was displayed.

Retracted workaround: None. (Issue **36017180**)

Reports, archives, extracts, and notifications

User Assignment report takes a long time to generate

Now, the User Assignment Report generates within a reasonable time frame, as a result of performance improvements.

Retracted workaround: None. (Issue **35832979**)

Subject Data Extract fails to generate

Now, the Subject Data Extract generates as expected, following performance improvements.

Retracted workaround: None. (Issue **36125416**)

An Oracle CRF Submit Custom request, Advanced Setting is not configurable

Now, the Oracle CRF Submit Advanced Setting, **Include Study Name in the Subject File Name**, for Custom PDF requests, which defaults to Yes, can be changed to No.

Retracted workaround: None. (Issue **35758876**)

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The Subject Data extract contains the incorrect site for an item edited after subject transfer (former known issue)

Now, if an item on the flat section of a two-section form is updated after a subject is transferred, the Subject Data extract includes the new site name for the updated item and not the previous site name.

Retracted workaround: None. (Issue **35904395)**

The Subject Data Extract (SAS) report fails if data values contain leading zeros

Now, the Subject Data Extract (SAS) report is generated successfully even when data values contain leading zeros. For example, if the Heart Rate captured on the Vital Signs form is 078.

Retracted workaround: None. (Issue **35606065**)

Form item options starting with < (less than) are not in a Blank Form PDF request

Now, form item options that start with < are present in the output files of an Oracle CRF Submit Blank Form PDF request.

Retracted workaround: None. (Issue **35905179**)

Oracle CRF Submit Custom PDF header limits display to 11 items

Now, Oracle CRF Submit Custom PDF requests can accommodate all 12 possible header items.

Retracted workaround: None. (Issue **35869771**)

The query count in the Subject Queries report does not match the user interface

Now, the query count in the Subject Queries report matches the query count in the Clinical One Cloud Service user interface. Previously, the report included duplicate entries for some queries; other queries were missing, which caused the discrepancy.

Retracted workaround: None. (Issue **35976595**)

The Study Design report contains an incorrect Last Modified date

Now, updating kits in treatment arms does not result in an incorrect **Last Modified** date being displayed for kits in other treatment arms in the kit dispensation portion of the Study Design report.

Retracted workaround: None. (Issue **35760784**)

Sites, labs, depots, settings, and user management

The Effective Date for a lab normal range reduces by one day when a range update is saved

Now, the Effective Date, defined when you configure a lab normal range, is no longer reduced by one day after saving updates to the lab normal range. Previously, the system applied a conversion to the date based on the user's time zone, and in some cases, resulted in a reduction of one day. (Issue **36260224**)

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Error encountered when trying to access the Source Data Verification tab

Now, users assigned to the *Rule Designer (template)* study role no longer encounter an error accessing the Source Data Verification tab on the Settings page.

Retracted workaround: None. (Issue **35997964**)

Processing data related to sites may take longer than expected

Processing and sending data related to site events for Oracle Clinical One Analytics no longer takes more time than expected. This issue was caused by the absence of a specific parameter that would return all data for all sites in a study, instead of data for a specific site in the study.

Retracted workaround: None. (Issue **36250794**)

Text entry when creating sites and depots for Chinese language studies caused randomization to fail (former known issue)

Now, when you create a site or depot for a Chinese language study, you are presented with a predefined list for the State/Province/County field, and text entry is no longer permitted. Previously, text entry allowed special characters to be entered; for example, 北京 could be entered for Beijing, resulting in failed randomization.

Retracted workaround: None (Issue **34765926**)

The tabs on the Global Settings page do not load or refresh as expected (former known issue)

Now, when you are on the Global Settings page, the settings displayed align with the tab selected.

Retracted workaround: Select the Users tab, then select the other tab that you want to access. (Issue **34638369**)

The Add Subject button is still visible despite system configuration

When a site has been selected from the Site filter, and the user clicks **Add Subject**, the system presents a message to the user informing them that they can no longer add subjects.

Now, when the filters on the subject listings page are set to All, users are also presented with the same message: You can no longer manually add subjects to this site. Previously, no message was displayed when the filters on the subject listings page were set to All and **Add Subject** was clicked.

Retracted workaround: None. (Issue **34742872**)

Site users and subject data

A repeating row or instance unexpectedly becomes unsigned or unverified

Now, when you clear a result only that instance of the form is unverified or unsigned. The SDV and **Signed** status of other repeating instances is not impacted. (Issue **36325535**)

A visit's status is incorrectly displayed as Unverified

Now, when you verify a visit that was previously unverified, and you refresh, close, and re-open that visit, its status is still displayed as **Verified**, as expected.

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After the upgrade of release 23.3.1.3 is complete, we recommend you open any visits impacted by this issue. You will notice that their status is correctly updated as **Verified**. We do not recommend refreshing the **Subjects** page to ensure that your verified visits display the expected status.

> **Note**
>
> The existing Audit History for any impacted visits will display a new record indicating that the visit was verified appropriately. No other new changes will be displayed in a visit's audit history.

(Issue **36340891**)

A deleted row reappears when a user conducts Source Data Verification (SDV), Signs, Locks or Freezes at the visit level

Now, a row deleted from a repeating form, or the repeating section of a two-section form does not reappear when a user conducts visit-level Source Data Verification (SDV), Signing, Locking or Freezing. The deleted row previously appeared when the following actions occurred:

1. A user entered data in at least two questions in an instance, leaving at least one other question unanswered.
2. A user then cleared at least one question (using the clear functionality).
3. A user then deleted the row.
4. Visit level SDV, **Sign**, **Freeze** or **Lock** is performed.

After these steps, the deleted row is present in the UI. (Issue **36284515**)

Data for choice questions is not displayed for a visit

Now, the data for choice questions (drop-down, check box, and radio button) displays in a visit when you change the filter selection (within the visit) from **All reviews** to **Ready to Verify**. (Issue **36257210**)

Users in different time zones see different time data for the same date/time question

Now, the value entered for the time component of a date/time question is displayed to all users as entered, regardless of the viewing user's computer time zone setting.

Previously, the system converted the time value based on the time zone setting of the user viewing the data. (Issue **36308286**)

Visit schedule and data may not correspond to a selected subject

When you access a subject's visit, then access a second subject's visit, and return to the **Subjects** page, the expected visit schedule, as well as their associated and collected data is displayed in the application. Previously, you may have encountered an issue where you would see the projected visit schedule and form data associated with a different subject than the one you previously selected.

If you experienced this, know that this was an issue only affecting the User Interface (UI) and it didn't affect your study's data. (Issue **36208670**)

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Partial dates prevent data from being collected in a lab form

If a subject's date of birth is configured as a Date/ Time question allowing partial dates, this no longer prevents a site user from properly collecting data in a lab form for lab units and ranges. Previously, when a subject's date of birth allowed the collection of partial dates (such as YYYY), the lab form wasn't loading and the application displayed a message stating that demographic data was required before filling in a subject's lab normals. (Issue **36221890**)

Username and password fields are not displayed in the Sign Data window

In the Production environment, when you you attempt to sign data in your study, the Sign Data window displays the **Username** and **Password** fields, as expected. Previously, the window displayed an error message that didn't provide any helpful information and prevented you from successfully signing data. (Issue **36177246**)

Users cannot view or add form-level comments in a repeating form (former known issue)

Now, users can view and add form-level comments in a repeating form after clicking the hamburger icon at the form level, followed by clicking **View Comments** or **Add a comment**.

Retracted workaround: Open one of the records in the repeating form table, then click the hamburger icon at the form or item level to view or add comments. Issue (**35682899**)

Users with the Japanese language selected are unable to enter dates

Now, Japanese language users can enter dates, for example, Informed consent date and Date of Birth, using the calendar to select a date for an item. Previously, users were presented with the error, The month you selected is out of scope, please select a value from 1 to 12.

Retracted workaround: None. (Issue **35475774**)

Rest API updates

See the newly added, deprecated, and deleted endpoints of the Clinical One Cloud Service APIs, available upon the Production release.

Permissions

- The *ec-designer-edc-svc* permission has been added to access some APIs of the Designer category.

Services updates

The following service is added:

- Designer EDC

The following services are updated:

- Codelist
- Data Action
- Data Hub
- Data Integration
- Data Capture
- Designer

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- File Upload
- Notifications
- Library
- Randomization and Supplies
- Query
- Rule Designer
- Sites and Depots

Designer EDC

> **Note**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/formSummaryInfo

Codelist

Change	Endpoint
Deleted	• DELETE /v2.0/codelist/code/{codeId}

Data Action

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/validate/dataelements
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks • GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements

Data Hub

Change	Endpoint
New	• POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits • POST /v2.0/tenant/{tenantId}/studies/{studyId}/codelists • POST /v3.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v3.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

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Data Integration

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/formStatus • GET /v2.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v2.0/studies/{studyId}/{mode}/subjects/history/all • GET /v2.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Data Capture

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/subjects/screeningnumber • PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/randomizationnumber/{randNumber} • GET /v1.0/studies/{studyId}/{mode}/svf • PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/undoSubject • POST /v11.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v3.0/studies/{studyId}/{mode}/subjects/migratesubject • POST /v4.0/studies/{studyId}/{mode}/dataelements/multiple • GET /v4.0/studies/{studyId}/{mode}/subjects • GET /v8.0/studies/{studyId}/{mode}/visitstatus • GET /v9.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • PUT /v9.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
Deprecated	• PUT /v1.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/visit/verify/history • GET /v1/studies/{studyId}/{mode}/subjects/history/all • GET /v1/studies/{studyId}/{mode}/subjects/history/{subjectId} • POST /v1/studies/{studyId}/{mode}/subjects/migratesubject • POST /v1/studies/{studyId}/{mode}/subjects/visitschedule • GET /v1/studies/{studyId}/{mode}/visitstatus/dateRange/{subjectId} • POST /v10.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v2.0/studies/{studyId}/{mode}/dataelements/verify • GET /v2.0/studies/{studyId}/{mode}/subjects/history/all • POST /v2.0/studies/{studyId}/{mode}/subjects/visitschedule • POST /v3.0/studies/{studyId}/{mode}/dataelements/freeze • GET /v3.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId} • GET /v3.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v4.0/studies/{studyId}/{mode}/subjects/history/all • GET /v4.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v5.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v6.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • POST /v7.0/studies/{studyId}/{mode}/dataelements • GET /v7.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v7.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • PUT /v7.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId} • PUT /v8.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v8.0/studies/{studyId}/{mode}/visitstatus/subjects • PUT /v8.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId} • GET /v9.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v9.0/studies/{studyId}/{mode}/dataelements/{dataElementId}

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Designer

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/formLogo • GET /v5.0/studies/{studyId}/kits • POST /v7.0/studies/{studyId}/versions/{version}/kits • GET /v7.0/studies/{studyId}/versions/{version}/kits • GET /v7.0/studies/{studyId}/versions/{version}/kits/{kitId} • POST /v9.0/studies/{studyId}/versions/{version}/kits • GET /v9.0/studies/{studyId}/versions/{version}/kits • GET /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • PUT /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • DELETE /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • GET /v9.0/studies/{studyId}/versions/{version}/visits
Re-instated	• POST /v1.0/report/{reportName} • POST /v2.0/report/{reportName}

File Upload

Change	Endpoint
Deleted	• POST /v3.0/storage/{bucketName}/{objectName}

Notifications

Change	Endpoint
Deprecated	• POST /v1.0/studies/{studyId}/{mode}/notificationlog • GET /v1.0/studies/{studyId}/{mode}/notificationlog • POST /v2.0/studies/{studyId}/{mode}/notificationlog • POST /v3.0/studies/{studyId}/{mode}/notificationlog

Library

Change	Endpoint
New	• POST /v1.0/libraryObjects/kits • GET /v1.0/libraryObjects/kits • POST /v1.0/libraryObjects/kits/bulk/{status} • GET /v1.0/libraryObjects/kits/pagination • GET /v1.0/libraryObjects/kits/{libraryKitId} • PUT /v1.0/libraryObjects/kits/{libraryKitId} • DELETE /v1.0/libraryObjects/kits/{libraryKitId} • GET /v1.0/libraryObjects/kits/{libraryKitId}/history

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Randomization and Supplies

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • PUT /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • GET /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits/{inventoryId}/historyById • POST /v1.0/studies/{studyId}/{mode}/locally-sourced-kits • GET /v1.0/studies/{studyId}/{mode}/locally-sourced-kits • GET /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • PUT /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • DELETE /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • POST /v1.0/studies/{studyId}/{mode}/orders/{shipmentNumber}/assignkits • GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/details • GET /v1.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/locally-sourced-kits • POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisits2s • POST /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots • PUT /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • GET /v3.0/studies/{studyId}/{mode}/kitlists • GET /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • POST /v3.0/studies/{studyId}/{mode}/resupply/manual • GET /v3.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits • GET /v5.0/studies/{studyId}/{mode}/shipments • GET /v7.0/studies/{studyId}/{mode}/orders • GET /v7.0/studies/{studyId}/{mode}/orders/{shipmentId}

Query

Change	Endpoint
New	• PUT /v9.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate
Deprecated	• PUT /v2.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate

Rule Designer

> **Note**
>
> Rule Designer endpoints are listed under the Rules category.

Change	Endpoint
New	• POST /v1.0/rulemgt/studies/{studyId}/{mode}/filteredlist • PUT /v1.0/rulemgt/studies/{studyId}/{mode}/{publishRun} • GET /v1.0/rulemgt/studies/{studyId}/{ruleId}/rulehistory • GET /v2.0/rule/studies/{studyId}/{mode}/simple • POST /v6.0/studies/{studyId}/{mode}/report/{reportName}

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Sites and Depots

Change	Endpoint
New	• GET /v1.0/addresses • POST /v1.0/contacts • GET /v1.0/contacts • DELETE /v1.0/contacts/contact/{contactId} • PUT /v1.0/contacts/deleteContact/{id} • POST /v1.0/contacts/validateFields • GET /v1.0/contacts/{contactId} • PUT /v1.0/contacts/{contactId} • PUT /v1.0/entitymanagement/entities/{entityType}/{srcEntityId}/manage • PUT /v1.0/entitymanagement/entities/{entityType}/{srcEntityId}/manage/all • GET /v1.0/entitymanagement/studyentities/{entityType}/{tenantEntityId}/details • GET /v1.0/entitymanagement/tenantentities/{entityType}/{tenantEntityId}/details • POST /v1.0/facilities/{InstitutionId} • GET /v1.0/facilities/{InstitutionId} • PUT /v1.0/facilities/{InstitutionId} • POST /v1.0/organizations • GET /v1.0/organizations • PUT /v1.0/organizations/deleteOrganization/{id} • POST /v1.0/organizations/validateFields • GET /v1.0/organizations/{id} • PUT /v1.0/organizations/{id} • DELETE /v1.0/organizations/{id} • POST /v1.0/sdfs/migration • GET /v1.0/sdfs/migration/{tenantId}/status • POST /v1.0/studies/{studyId}/{mode}/report/{reportName} • GET /v1.0/studies/{studyId}/{mode}/sdfs/depot/{pathAttr} • POST /v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties • PUT /v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties • POST /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties • PUT /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propName} • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType} • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{kitTypeId}/shipToAddress • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId} • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId} • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId}

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Change	Endpoint
	• GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/kitSettings/{kitTypeId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/locallySourced • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/sdfRegion/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/status • DELETE /v1.0/tenantsite/associations/{associationId} • GET /v1.0/tenantsite/associations/{associationId}/addresses • POST /v1.0/tenantsite/associations/{associationId}/studySites • GET /v1.0/tenantsite/associations/{associationId}/studySites • GET /v1.0/tenantsite/{associationType}/associations • POST /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • GET /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • PUT /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • POST /v2.0/studies/{studyId}/{mode}/labs • GET /v2.0/studies/{studyId}/{mode}/labs • POST /v2.0/studies/{studyId}/{mode}/labs/siteslabs • PUT /v2.0/studies/{studyId}/{mode}/labs/{studyLabId} • DELETE /v2.0/studies/{studyId}/{mode}/siteslabs • POST /v3.0/studies/{studyId}/{mode}/report/{reportName}
Deprecated	• POST /v1.0/studies/{studyId}/{mode}/labs • PUT /v1.0/studies/{studyId}/{mode}/labs/{id} • DELETE /v1.0/studies/{studyId}/{mode}/labs/{id} • POST /v1.0/studies/{studyId}/{mode}/siteslabs • DELETE /v1.0/studies/{studyId}/{mode}/siteslabs • POST /v1/studies/{studyId}/{mode}/sdfs • DELETE /v1/studies/{studyId}/{mode}/sdfs/deleteDepotEmail • POST /v1/studies/{studyId}/{mode}/sdfs/sdf • PUT /v1/studies/{studyId}/{mode}/sdfs/sdf/{sdfId} • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId} • POST /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address/{addressId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address/{addressId} • POST /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId}

Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

- Instructional text items are not currently supported in downstream applications, such as Oracle DMW, Clinical One Digital Gateway, or Oracle Clinical One Analytics. For more information about instructional text, see Add instructional text.
- Drug reconciliation forms are not currently supported in downstream applications, such as Oracle DMW, Clinical One Digital Gateway, or Oracle Clinical One Analytics. For more information on this type of forms, see Drug Reconciliation forms.

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10

Clinical One Cloud Service and Clinical One Digital Gateway 23.2 (September 2023)

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs, available upon the Production release.
- Release impact for other applications
  This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.2 release.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway** application.

Table 10-1 Patch log

Release Number	Release Date	Notes
Release 23.2.1	30-October-2023	For this release, we fixed six issues related to forms, visits, rules, reports, and notifications. For more information, see: • Issues **35560725**, **35692719**, **35726231**, **35401876** in Forms, visits, and rules. • Issues **35781902** and **35826804** in Reports, archives, extracts, and notifications. Enhancements related to Oracle Central Coding and Oracle Clinical One Analytics have also be introduced in this release. For more information, see: • Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects • Enhancements to Oracle Clinical One Analytics

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Table 10-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.2.1.1	22-November-2023	For this release, we fixed some issues related to data collection and reporting. For more information, see: • Issues **35852581**, **35963321**, **35917673**, and **35917721** in Site users and subject data. • Issue **35972590** in Reports, archives, extracts, and notifications. • Issue **35994707** in Oracle Clinical One Analytics. • Issue **35940121** in Facilities, settings, and user management.

What's new

- Data collection
- Data review
- Integrations
- Reporting, archives, and analytics
- Rules management
- Study design
- User experience
- Other enhancements

Data collection

- Enhanced way of clearing dynamic questions and forms
  Site users can now easily clear dynamically-displayed questions, forms, repeating sections in a two-section form, and form associations included in the same visit with fewer manual steps.
- Lock a subject
  Sponsor users can lock a subject to prevent any user from making further changes to that subject.

Enhanced way of clearing dynamic questions and forms

Site users can now easily clear dynamically-displayed questions, forms, repeating sections in a two-section form, and form associations included in the same visit with fewer manual steps.

If you complete a dynamically-displayed question (child question) in error and then need to update the determining question (parent question), you can do this in a much easier way. Previously, you had to first manually remove the data from all of the dynamically-displayed questions to update the answer of the determining question. Now, the user experience is easier and faster - once you attempt to clear a determining question, the system indicates

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which of its dynamically-displayed elements are automatically cleared and which ones you'll have to manually clear.

> **Note**
>
> This enhancement applies to any type of dynamic question, dynamic form, dynamic section in a two-section form, and form associations included in the same visit as their determining question, except for dynamically-displayed questions that are frozen, locked, read-only, or hidden, as they need to be manually cleared. Clearing form associations only removes the link between the forms, the data already collected in the linked forms will not be impacted.

> **Caution**
>
> While this enhancement applies to forms, dynamic sections in a two-section form, and form associations, too, for the sake of clarity and brevity the enhancements below are described referring to dynamic questions. Every behavior described below applies to all of the above-mentioned elements, as well.

Whether you want to update or clear a determining question, here's what you need to know:

- Whenever you attempt to update a determining question's answer, a new dialog is displayed informing you that you're attempting to update data that would result in the clearing or hiding of certain questions in your form in the same visit. The dialog lists the impacted questions or forms. This dialog is displayed only if the dynamically-displayed questions were previously answered. If there is no answer associated with them, you are prompted directly to enter a reason for this change.
- If there are any dynamically-displayed questions that are locked, frozen, hidden, or read-only associated with the determining question that you're trying to update, all of these questions that are not hidden to you are also displayed in the dialog.
- If you want to clear answers for dynamically-displayed questions, besides being prompted to enter a reason for this change, the same dialog appears indicating that data will be cleared for these questions.
- If the questions you are attempting to clear or update are also associated with future visits, the dialog indicates that you have to manually clear dynamically-displayed questions before updating the determining question.
- If there are multiple layers of dynamically-displayed questions (for example, a child question can act as the determining parent question for other dynamic questions), then you must manually clear any "grandchildren" questions. For example, if you attempt to clear the answer for parent question A, the system could clear the answer to child question B. But if child question B has other dynamic questions determined by its answer (questions C and D), then you must first clear the answers for the granchildren questions (questions C and D). Only after that, will the dialog display the dynamically-displayed questions that are directly impacted by the given determining question (parent).
- If you attempt to clear any dynamically-displayed questions that were previously signed or verified, those questions become unsigned and unverified.
- All dynamically-displayed questions that are cleared are displayed, in the Answer & Visit History, with a status of **Cleared-Dynamic hidden**.

More information on this enhancement can be found in the *Site User Guide* after the Release Assessment Environment (RAE) upgrade.

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Lock a subject

Sponsor users can lock a subject to prevent any user from making further changes to that subject.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can lock an entire subject to prevent users from adding new or updating existing data for that subject, including:

- New visits and events (Scheduled or unscheduled)
- Signing
- Verifying
- Freezing
- Unfreezing
- Screening
- Randomization
- Transfer
- Withdrawal
- Completion
- Dispensation
- Changing a subject's number
- Data entering or API loading data
- Running programmable rules

Users assigned the *Lock Subject Data Entered at a Site* permission can also unlock a subject.

Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- Subject locking is available in Testing, Training, and Production mode.
- On the Subjects page, under the View filter, you can now select **Locked** or **Unlocked** to view any locked or unlocked visits for subjects.
- On the Subjects page, a lock icon ( ) appears next to the subject, indicating that it is locked, along with a *Subject Locked* status in the Subject History side panel.

> **Note**
>
> While subject locking is in progress, the *Subject Locked* status will not be reflected in the subject's history until the lock action has completed.

- When unlocked, an icon ( ) appears next to the subject, along with a status of *Subject Unlocked* in the subject's history.
- Locking all subjects at a site does *not* prevent additional subjects from being added. On the Sites page, the **Add Subjects** option must be set to Off to disallow users from adding additional subjects.

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- A subject can be locked even if there are incomplete visits or open queries for that subject.
- When a subject is locked and any data is unlocked at the visit level, the subject's status will update to *Subject Unlocked*.
- If all data is locked at the visit level, the subject is locked at the casebook level.
- When a subject is locked, the subject's existing data becomes read-only.
- Existing data remains signed, verified, and frozen as it was prior to the subject lock.

More information and step-by-step instructions on subject locking can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

Site users can view the statuses for locked and unlocked subjects, so long as they have the corresponding permissions to see that element.

- A lock icon ( ) appears next to a subject, along with a status of *Subject Locked* in the Subject History, indicating the subject has been locked by a sponsor user.
- An unlocked icon ( ) appears next to a subject, along with a status of *Subject Unlocked* in the Subject History, indicating the subject has been unlocked by a sponsor user.

Impact on reports

Updates to the Subject Events Report can be found in the *Reporting Guide* after the RAE upgrade.

Already working in a live study?

At the time of the RAE upgrade, if all visits are locked, you will still need to explicitly lock the subject in order for the subject to be considered locked. It will also be possible to lock or unlock a subject that was entered in a study prior to this upgrade.

Additional information on subject locking can be found in the *Sponsor and CRO User Guide* after the RAE upgrade.

Related Topics

- Lock a form or visit
- Unlock a form or visit
- Lock a query
- Unlock a query

Data review

- Auto-update of support template roles for existing studies
  Starting with this release, the View Only for Unblinded Support Users (template) role is updated automatically with new permissions.

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Auto-update of support template roles for existing studies

Starting with this release, the View Only for Unblinded Support Users (template) role is updated automatically with new permissions.

With the introduction of this enhancement, support users who are assigned the View Only for Unblinded Support Users (template) role are automatically updated with any new permission introduced for a given release. Previously, new permissions for new features had to be manually assigned to the support users and only then could they have access to the new functionality to assist customers in existing studies that take advantage of any new feature.

Details for support users

The View Only for Unblinded Support Users (template) role will update only during Oracle Life Sciences Clinical One Cloud Service upgrades. With this release, the View Only for Unblinded Support Users (template) role receives the following permissions:

- Permissions related to Analytics View classified data
  - View Classified Subject Data Only
- Permissions related to re-running rules
  - *Re-run rules*
- All the permissions of the ODM
  - Execute ODM Clinical Data API with Hidden Data
  - Execute ODM Clinical Data API without Hidden Data
  - Execute ODM Metadata API
  - Execute ODM Administrative Data API
- Extract role Permission to run Archives by site
  - Run the Archival PDF for your site

Also, we removed the permission to *Edit classified subject data*.

Already working on a live study?

Users with the *View Only for Unblinded Support users (template)* role will have their permissions updated on live studies, as soon as the Release Assessment Environment (RAE) upgrade completes, and subsequently with every new permission on future releases.

For more details, see View only for Unblinded Support Users.

Integrations

This section includes enhancements to integrations configured in the Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

- Oracle Siebel CTMS (report) now supports the ability to map multiple form items
- Screen fail enhancements
- Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects
  Under the Study Settings tab, you can prevent Clinical One Cloud Service from sending verbatim terms entered by users to Oracle Central Coding for New or Screen Failed subjects.

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Oracle Siebel CTMS (report) now supports the ability to map multiple form items

You can now map multiple form items, for example, Date of Birth (partial) and Date of Birth (full) to a common element in the configuration file.

> **Note**
>
> This enhancement only applies to the Oracle Siebel CTMS (report) and not the standard report available in the user interface, Subject Data for CTMS report.

Screen fail enhancements

Study completion and withdrawal events for screen failed subjects can now integrate with downstream systems

Integrating the study completion and withdrawal events for screen failed subjects with downstream systems is now possible. Previously, this was only possible for screened subjects.

> **Note**
>
> This enhancement is applicable for those studies where subject completion and withdrawal are supported for screen failed subjects. This is controlled by the study setting **Screen Failed Subjects**. For more information, see Specify study, enrollment, and visit settings

User-entered screen fail visit dates now integrate with downstream systems

Screen fail visit dates entered manually in Oracle Life Sciences Clinical One Cloud Service studies now integrate with downstream systems. Previously, only the system-generated screen fail date was integrated.

What do you need to do to take advantage of these enhancements

An integration template update is required to take advantage of these enhancements. Work with your Oracle point of contact to make the necessary updates.

Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects

Under the Study Settings tab, you can prevent Clinical One Cloud Service from sending verbatim terms entered by users to Oracle Central Coding for New or Screen Failed subjects.

A new study setting, **Code data for new and screen failed subjects**, has been added to the Study Settings tab to control the flow of verbatim terms to Oracle Central Coding for subjects with a status of *New* or *Screen Failed*.

Details for sponsor users

When it comes to your workflow, here's what you should know:

- No new permissions are required to access the setting.

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- The **Code data for new and screen failed subjects** is set to **Yes** by default to maintain the current system functionality of sending verbatim terms for all subjects.
- This setting can be changed at any time.
  - Changing the setting to **No** has no impact on verbatim terms already sent to Oracle Central Coding, and new verbatim terms are sent once the subject status is changed to *Enrolled* or *Active*.
  - Changing the setting back to **Yes** results in verbatim terms, entered before and after changing the setting to be sent to Oracle Central Coding.
- There is no impact to reports.

For more information, see Specify study, visit, limit, and cohort settings in the *Sponsor and CRO User Guide*.

Reporting, archives, and analytics

- Enhancements to Oracle Clinical One Analytics
- Enhancements to Oracle CRF Submit archives and reports
- Enhancements to Randomization and Trial Supply Management reports
  Improvements have been made to some of the reports related to Randomization and Trial Supply Management (RTSM).
- Diversity & Inclusion dashboard in Oracle Clinical One Analytics
  The Diversity & Inclusion dashboard is now available in Oracle Clinical One Analytics allowing you to visualize the diversity on the subject population of a clinical study. This dashboard can provide an insight of the trial objectivity to test the safety and efficacy of a drug formulation.
- New Study Codelist datasets
  You can now work with the Study Codelists dataset in Oracle Clinical One Analytics to create reports to identify the current global and study-level code lists, as well as the historical changes to the code lists configuration.

Enhancements to Oracle Clinical One Analytics

Support for data classification security

With the support for the data classification security, all questions in a form that you can view in Clinical One Cloud Service are now visible to you in Oracle Clinical One Analytics, as well. Your view is determined by any data classifications that are applied to those questions and your permissions to view them. Before this enhancement, all questions that had any data classifications applied to them were hidden to all users in Oracle Clinical One Analytics, regardless of their permissions.

The data classification security is only applicable for the Subject Form Items dataset and the Queries dataset.

Oracle Analytics Server (OAS) upgrade

Oracle Clinical One Analytics Data Visualizer is getting an OAS upgrade from 5.9 to 6.4. Although the current functionality remains basically the same, there are some minor changes in appearance of the Data Visualizer user interface (UI). These changes shouldn't affect the way you currently work with Oracle Clinical One Analytics. However, you can refer to the *Analytics User Guide* for step by step help on different tasks or reach out to your Oracle point of contact for more information on Oracle Clinical One Analytics training and mentoring.

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This upgrade is not impacting any of your saved reports, projects and data.

New data elements for query and verification reporting

With the new data elements added to multiple datasets in Oracle Clinical One Analytics, data managers can now create enhanced reports about query and verification. These changes include:

- A boolean flag for items containing queries, irrespective of the status, in the Subject Form Items dataset.
- A boolean flag for events requiring verification in the Blinded and Unblinded Subject Event dataset.
- Current user role data in the audit and reference folders.

> **Tip**
>
> **Never heard of a boolean flag?** A boolean flag is a True or False value to identify an object as having a particular characteristic or not.

Additional kit identifiers

The Unblinded Kits dataset now has two additional kit identifiers, to allow data managers to monitor kits in a closer manner. The two new data elements are available in the Kit folder and, because this data is unavailable from the Clinical One Cloud Service user interface, these are populated through integration.

You can find additional information about the new added fields in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Enhancements to Oracle CRF Submit archives and reports

Study withdrawal and completion data for screen fail subjects is now included in subject PDFs

If the study setting, **Screen Failed Subjects**, is set to either **Allow Withdrawal** or **Allow Completion**, a site user can complete a withdrawal or completion visit for a screen-failed subject. The data captured in the visit is now included in the subject PDFs.

> **Note**
>
> For more information about this setting, see Specify study, enrollment, and visit settings.

Sponsor users can now share the Kit Chain of Custody (Blinded) report with sites

Both sponsor and site users are required to archive the **Kit Chain of Custody (Blinded)** report, but site users are only sometimes granted access to this report. For more information about this report, see the Kit Chain of Custody (Blinded) report.

Sponsor users can now generate and share the **Kit Chain of Custody (Blinded)** report. The (new) site shareable report is under the Archives tab. The (existing) non-shareable report is under the Reports tab.

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> **Note**
>
> The permission, *Run the Blinded Chain of Custody Report* is required to generate the shareable report.

Although the settings for each report are different, the output is the same, as the output is generated from the same database tables and includes the following for each kit.

- Creation of the kit
- Assignment to a lot
- Assignment to a depot
- Shipped to a site
- Dispensation to a subject
- Destruction of a kit

Site users can only download this report. The report appears under the **Download Archives** side panel after being successfully generated by the sponsor and it only contains information for the site that you're assigned to.

> **Note**
>
> Site user download and confirmation actions are tracked in the Download Log report and the Site Confirmation report.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

PDF headers now include the Locked form status for non-repeating and repeating forms for locked subjects

As a part of the 22.3 release, we announced that the **Locked** status is included in the PDF header when forms are locked at the visit and form level.

For this release, the subject PDF header, specifically the Form Status row, now displays the **Locked** status for all forms in all visits when a subject is locked. The status appears in the output files generated for Submission, Archival, and Custom PDF requests.

Subject PDF behavior when a dynamic question is edited after data entry has already occurred

Suppose a site user incorrectly answers a determining (parent) question, such as a question that determines the treatment arm for a subject, and enters data in any dynamically generated element, such as a form question. The determining (parent) question can be edited by the user to remedy the situation. For more information about this feature, see Clearing dynamic questions and forms.

If the determining (parent) question is edited, the system asks the user to confirm if the data entered incorrectly on the dynamically generated elements should be cleared. If yes, the data except for data on frozen, locked, read-only, and hidden forms and questions is cleared.

If this occurs, subject PDFs capture information in the following ways.

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- The cleared questions display as empty cells in the subject PDF, and the Reason for Change, selected when the dynamic question was updated, is displayed in the question audit trail.
- Form statuses, for example, **Complete**, **Signed**, and **Verified**, update accordingly when the dynamic question is edited. The statuses are accurately reflected in the subject PDF.
- A signature is invalidated if clear data is applied to already signed data. If this happens, the subject PDF includes the signature invalidation audit for the form.
- If the value cleared is a variable in a calculation, the calculation runs again upon saving. The calculated value is updated based on the logic of the calculation rule. The subject PDF reflects the correct data displayed in the question and the calculated value.
- Open queries (auto and manual) are closed with the Reason for Change, *Item Cleared*, captured for each query.
- Form disassociation details are captured in the subject PDF audit history if form associations are removed.
- If a dynamic visit containing multiple forms is triggered, and the visit is canceled with no data entered into the dynamic visit, the Date of Visit form status is updated to **Not Started**, and the remaining added forms do not appear in the subject PDF.
- If a dynamic visit containing multiple forms is triggered with data entered for the dynamic visit, and the entered date is cleared, the visit is canceled, and all forms have a status of **Incomplete**, with the exception of the Date of Visit form.

Enhancements to Randomization and Trial Supply Management reports

Improvements have been made to some of the reports related to Randomization and Trial Supply Management (RTSM).

Certain edge cases are also addressed through this update, primarily in the context of replacement kits.

Details for clinical supply managers

The following improvements have been brought to reports:

Report	Enhancements
Shipment Order Summary report	• A new **Received By** column has been added. • Users can now schedule the report.
Kit Dispensation report	In addition to .html and .pdf, this report is now available in CSV format.
• Subject Events Report • Kit Chain of Custody (Blinded) report • Kit Chain of Custody (Unblinded) report	• These reports have been updated to include kit replacement data, in order for sponsor users to be able to determine which kits have been replaced in a study. • This includes new columns for dispensation dates, replacement kit numbers, as well as reasons for replacement.

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Report	Enhancements
• Subject Visits (Blinded) report • Subject Visits (Unblinded) report	• These reports now include kit replacement data, in order for sponsor users to be able to determine which kits have been replaced in a study. • This includes new columns for dispensation dates, replacement kit numbers, and reasons for replacement. • Users can now filter on projected window dates. **Tip** as a sponsor user, use this new feature to preview potential upcoming kit dispensations within a particular window of time.
Kit Inventory (Blinded) report	New **Blinded Lot ID** and **Blinded Lot Expiry Date** columns have been added for better supply management.
Kit Inventory (Unblinded) report	New **Manufacturing Lot Expiry Date**, **Blinded Lot ID**, and **Blinded Lot Expiry Date** columns have been added for better supply management.
Study Design report	• The following column names from the **Signature Configuration** section have been updated: – **Required Forms** to **Required Form(s)** – **Required Visits** to **Required Visit(s)** – **Effective Scope** to **Required on Selected Visits** – **Target Date** to **Target** • The visit summary of the report has been updated to display the visit branch, in order for users to differentiate between visits when these are named identically.
Study Enrollment report	• This report has been updated to feature the following site enrollment audit data categories: – Screening Limit – Randomization Limit – Last Modified – Last Modified By • A new **Site ID** column has been added. • The name of the **Site** column has been updated to **Site Name**. • This report can now be exported in CSV format, part of which each report section will have its own sheet.

Diversity & Inclusion dashboard in Oracle Clinical One Analytics

The Diversity & Inclusion dashboard is now available in Oracle Clinical One Analytics allowing you to visualize the diversity on the subject population of a clinical study. This dashboard can provide an insight of the trial objectivity to test the safety and efficacy of a drug formulation.

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> **Tip**
>
> Whether you are working in a live study (and already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle point of contact for more information on Oracle Clinical One Analytics training and mentoring.

With the introduction of the new Diversity & Inclusion dashboard template in Oracle Clinical One Analytics, you can get a holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to a customizable and interactive dashboard. This contains reports and visualizations that can help improve your decision-making on subject screening and randomization, to increase diversity within the group of study participants. With a more diverse group of participants, you are more likely to objectively test the safety and accuracy of the drug formulation for everyone.

Since they are templates, you do not have to create dashboards from scratch, but you can customize them to meet your needs. All you have to do is download the template and re-import it to tweak the data in and adjust filters, making sure that you are viewing data relevant to your work. For more information see Customize templates.

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. To work with the Diversity & Inclusion dashboard, you must have access to the Subject Items Dataset.

Access to a dataset is given based on the permission that you must be assigned in Clinical One Cloud Service. To access the Subject Form Items dataset, and so this new dashboard, make sure you are assigned with the *Run the Subject Form Items Dataset* permission. For more information on these permissions, see About your access to Clinical One Analytics.

Details for data managers

With the new Diversity & Inclusion dashboard, data managers can monitor subjects' diversity by age, gender and demographics across studies and sites. Even though this dashboard is intended to assist data managers with their duties, the Diversity & Inclusion dashboard is available to any user with the appropriate permissions. This customizable dashboard offers you complex data on the clinical study population diversity, organized within the following interactive reports:

- Diversity & Inclusion Overview
- Diversity By Sites
- Diversity by Age Group
- Patient Demographics

The reports and visualizations grouped in this dashboard can help data managers to analyze the study population and subject distribution across sites and studies. With this, the study team can identify a possible need of randomization design and limits update, as well as screening requirement adjustments.

You can find additional information regarding dashboards in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

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New Study Codelist datasets

You can now work with the Study Codelists dataset in Oracle Clinical One Analytics to create reports to identify the current global and study-level code lists, as well as the historical changes to the code lists configuration.

Codelist managers and other sponsor users can now use the Study Codelists dataset to analyze and visualize customized codelist at either global or study level, as well as current code configurations and changes made over time. With this dataset you can:

- Reference all code lists available for an organization and their details, such as: title, description, type (system or custom), localization, as well as codes, values and labels.
- View all available code list items in multi-select questions, instead of just selected choices.
- Reference the study codelist dictionary when reviewing clinical data extracts.
- Review updates made to a code list at the study level.
- Review updates made to code configuration at the global level.

The Study Codelists dataset is available to any user assigned the new *Run the Analytics Study Codelist Dataset* permission. Global level codelists data is available to global users assigned with the *Code List Manager* or the *Oracle Admin* roles. If you are a sponsor user who needs to work with this dataset, make sure you reach out to your user administrator or Oracle point of contact to get the appropriate permission.

You can find additional information regarding these datasets and their permissions in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- Predictive text in the Rule editor
  Rule developers can now reduce coding efforts using predictive text in the rule editor.

Predictive text in the Rule editor

Rule developers can now reduce coding efforts using predictive text in the rule editor.

Oracle provides rule helper functions to facilitate the creation of custom rules. A new predictive text feature is available to help rule developers work with the existing helper functions, as well as suggest variable names and some standard JavaScript syntax. As you type in your expression, this feature provides a list of suggestions, including helper functions along with a brief description, which gets narrowed as you type to include only relevant functions matching the entered text. You can then go through the list and select a helper function to add to your expression. The added functions include the correct syntax with placeholders for you to complete the required parameters.

Using the predictive text to review and enter helper functions, variables and standard syntax can help you reduce your coding efforts. By letting you have all the rule helper functions at hand, along with their purpose and correct syntax, you can get an overview of how you can simplify your rule logic with the available helper functions and make sure you use them correctly.

You can find additional information about custom rules and rule helper functions in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

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Study design

- Enhancements to library studies
  Library users can now make their work more collaborative and much faster with a new set of enhancements implemented for library studies.
- Template role names include new unblinding label
  Role names have been updated to reflect the alert of unblinding potential for particular template user roles.

Enhancements to library studies

Library users can now make their work more collaborative and much faster with a new set of enhancements implemented for library studies.

As a user administrator or global user manager, you must be aware that a user must be assigned the existing permission *View Study Design* to ue this new feature.

Whether you're a study designer or a library user, here's what's new for you:

- On the Home page, you have a new option to copy a study into your library. This will help you kickstart your library study design much faster. Conversely, you can copy an entire library study into Production, as well. Upon selecting to copy a study, the Copy Study dialog appears. In there, you will see the options to select whether you're copying the study for Production or for a library.
- If copying a study fails, you will see a warning on the Home page, next to the study that couldn't be copied.. Additionally, all copied studies (whether live or library studies) will indicate the user name of the user who performed the action.
- In your library, in the **Used in Studies** section, you can view how your library objects are used in Production or other library studies.
- You can now better collaborate with fellow library users or designers when working a library study. With the new comments feature, you can leave each other comments, organize everything by threads, as well as sort through comments, search through them, or resolve them.
- You can leave or reply to comments in both Study Design and Testing mode, and you also get an email notification whenever you are tagged in a specific comment.

More information on these new library enhancements can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Template role names include new unblinding label

Role names have been updated to reflect the alert of unblinding potential for particular template user roles.

To alert user managers to the potential of particular study roles for unblinding data, the following template study role names have been updated:

- Clinical Supply Manager - Unblinded (Template)
- Pharmacy User - Unblinded (Template)
- Statistician - Unblinded (Template)

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> **Note**
>
> This name change doesn't impact the permissions included in these study role templates. Moreover, users who are assigned custom study roles are not impacted by this change at all.

Impact on reports

The new template role names will be reflected in all user management reports:

- Global study roles report
- Study roles report by study
- User assigned across studies
- User assignment
- User assignment by site
- User upload error
- User upload template

Already working in a live study?

If you have been assigned any of the roles mentioned above and are currently working in a live study, the name of your role will also be updated.

User experience

- Enhanced Chat & Help experience
  The Chat & Help screen has been enhanced to provide a better and simplified user experience.

Enhanced Chat & Help experience

The Chat & Help screen has been enhanced to provide a better and simplified user experience.

On the Clinical One Cloud Service home page, when you click **Chat & Help** you now get a simplified dialog with the following options to help you get the assistance that you need:

Option	Description
Urgent Issue?	Opens the Oracle Life Sciences Support Cloud portal where you can submit a Service Request (SR).
Chat with Customer Support	Opens a new chat window and adds you to the queue to engage with a support agent in real time.
Call Technical Support	Opens the Life Sciences Support page where you can find out the details about where to call depending on your location.
Check the Knowledge Base	Opens FAQs and other documentation from the Oracle Life Sciences Support Cloud Knowledge Base.

When you click **Chat with Customer Support** and fill in the details, a chat window opens. The screen indicates your number in the queue and an estimated time of response. In the chat

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window, when connection is established, you can start your conversation with a support agent and get realtime assistance.

For more information on how to use this feature, see Chat in real time with Oracle Support.

Other enhancements

Form associations are now reflected in ODM-XML extracts

Association between forms is now reflected in ODM-XML extracts. Within the extract, form associations are presented as sets of transactions, conforming to the CDISC standard.

To reflect form associations, the new **`KeySet`** and **`annotation`** elements are added to the clinical data and metadata responses.

For a detailed breakdown of all the newly-added attributes, see the ODM-XML reference documented as part of the *API Guide*

A study's dashboard now displays all subjects

On the Home page, the total number of a study's subjects is now displayed on a study's dashboard, regardless of site status.

Previously, the dashboard would only count subjects at active sites.

Fixed issues

- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

HAR files are no longer needed for issue resolution

Oracle Support no longer requires customers to provide HAR files for Service Request (SR) analysis. They now have tools to gather the information previously provided in a HAR file.

Retracted workaround: The steps defined in KnowledgeBase Article 3011 are no longer needed.

Issue: 35856377

System slowness/freezing after clicking the Subject History or Queries right side panels

Now, you no longer encounter system slowness or freezing after clicking the **Subject History** or **Queries** right side panel for subjects with more than thirty (30) visits that contain multiple queries.

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Retracted workaround: None. (Issue **35684076**)

The Select Language drop-down on the What's New window does not work

Now, the Select Language drop-down on the What's New window allows users to select a language (English, Chinese, or Japanese) upon initial log in.

Retracted workaround: None. (Issue **35385066**)

An error occurs after filtering sites and viewing queries under the Queries side panel

Now, you no longer encounter an error after filtering subjects by site on the Subjects page, followed by clicking View on the Queries side panel.

Retracted workaround: None. (Issue **35387816**)

A site's status changes without user action (former known issue)

Now, if you retire an active site, then navigate through the tabs (the Sites tab, the Depots tab, the General tab), the site's status no longer fluctuates between Active and Retired.

Retracted workaround: None. (Issue **33874708**)

Facilities, settings, and user management

Users with the View Only for Unblinded Support Users cannot view the Users tab

Now, any user who is assigned the *View Only for Unblinded Support Users* study role can properly view data on the Users tab without requiring other specific permissions, other study roles, or global roles to be assigned to them. (Issue **35940121**)

The edit depot countries window does not display the full list of associated countries

Now, when editing a depot, the Countries window displays the complete list of associated countries under the <depot name> Depot Countries table (on the right side).

Retracted workaround: Click the Primary Countries tab to confirm which countries are checked off. Or hover over Supply Countries on the Depot tab to view the complete list. (Issue **35504845**)

Users assigned the *Edit Form Data for Subjects* permission can also skip and unskip visits (former known issue)

Now, users assigned to a role that includes the permission *Edit Form Data for Subjects* cannot skip/unskip visits.

Retracted workaround: None. (Issue **35204854**)

Clinical Supply Manager with proper permissions receives an error when creating a depot

Now, you only need the permissions, *Create and Manage Depots*, and *View Depots* to successfully create depots. The permission, *Create and Manage Sites* is no longer required to achieve this.

Retracted workaround: None. (Issue **34206639**)

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Forms, visits, and rules

A Subject's visit data of event type Visit_Inserted is not reaching Data hub

Now, Visit_Inserted records for new visits applied to a study via advanced study versioning (ASV) are inserted into the DC_VISITS_INFO table in Data Hub, making the data available in Oracle Clinical One Analytics.

Retracted workaround: None. (Issue **35560725**)

Subject PDFs generated under the Archives tab include incorrect usernames

Now, when multiple users sign forms in a single visit, subject PDFs generated under the Archives tab show the username associated with the signing action. Previously, the username of one signatory showed for all form signatures.

Retracted workaround: None. (Issue **35692719**)

The next logical visit does not appear after answering a branch visit exit question

Now, when the rule execution occurs only for the current visit and does not impact the previously calculated or answered target questions in the previous visits, no issues are observed, and the next logical visit appears as expected. Previously, when branch exit questions were answered in a certain way, the next logical visit did not appear in the visit train. Instead, the Next Visits column was populated with three (3) dashes (---).

Retracted workaround: None. (Issue **35726231**)

Error encountered when multiple rules try to update the same form or visit

Now, errors no longer occur when multiple rules attempt to update the same form or visit simultaneously.

Retracted workaround: None. (Issue **35401876**)

A visit remains IN PROGRESS after clearing all form data, limiting the ability to skip the visit

Now, a visit no longer remains in the status of IN PROGRESS after clearing all data in the visit, allowing the visit to be skipped. Previously, the visit would be stuck at IN PROGRESS after clearing all form data, limiting the ability to skip the visit.

Retracted workaround: PL SQL script execution to version end the active data element record with a null value and version end the currently active IN PROGRESS visit status. This results in a new record introduced in the visit status table with a status of NEW. (Issue **35541809**)

The Visit Date field for a new visit displays the date of the previously completed visit

Now, the **Visit Date** field for a new visit is blank after clicking a previously completed visit, followed by returning to the new visit. Previously, the date from the previously completed visit was displayed in the Visit Date field for the new visit.

Retracted workaround: None. (Issue **35741399**)

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Clicking Start Visit multiple times for a skipped visit can result in system slowness (former known issue)

Now, after clicking **Start Visit** (for a skipped visit), the system blocks the ability to click Start Visit again. Previously, the system allowed Start Visit to be clicked multiple times, impacting study performance.

Retracted workaround: None. (Issue **35654270**)

An auto-assigned query is not appearing in a Screen Fail visit after being generated

Now, auto-assigned queries are visible in a Screen Fail visit. Previously, the auto-assigned query would generate successfully, but it was not visible in the visit, as queries could not be assigned to a Screen Fail visit.

Retracted workaround: None. (Issue **35333522**)

A source data verified (SDV) visit gets unverified after a read-only item is populated by a rule in another visit

Now, a source data verified visit (ex. Visit_1) is no longer unverified when a new read-only item (not eligible for verification) is populated by a rule generated in another visit (ex. Visit_2).

Retracted workaround: None. (Issue **35266051**)

Rules fail to populate multiple items when the visit date is a variable in the rule

Now, when Visit Date is referenced as a variable in a rule, rule target items are populated correctly when the Visit Date is entered or updated.

Retracted workaround: To avoid screen-blocking issues related to this bug, mark your rules as 'unblocking' in the rule-design dialog. This allows a user to proceed to enter data without getting blocked. The rule executes in the background, and the user must reopen/refresh the visit to see the rule execution results. (Issue **34526808**)

No action takes place when clicking Save or Save and Close after completing a form association (former known issue)

Now, you are automatically taken back to the **All Subjects** page when clicking **Save** or **Save and Close** after completing a form association.

Retracted workaround: After saving, click into the white space of the visit to return to the All Subjects page. (Issue **35139761**)

Users can delete a Library study even when it includes forms and associated visits (former known issue)

A Library study can be deleted if its design objects have not yet been imported into another study. If library objects have been imported into another study, end-users are now presented with a message stating why the study cannot be deleted.

Retracted workaround: None. (Issue **35283510**)

An automated query is not being displayed for an age field (former known issue)

Now, when the target field of an automated query is an age (read-only) field, the query is displayed automatically without the need to refresh the browser.

Retracted workaround: Use the time and date (date of birth) question as the target field of the automated query rule. (Issue **31895089**)

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A predefined label included in a rule does not work (former known issue)

Now, for a tabular form, rules work as expected when you define a rule that includes the tabular form's predefined labels as variables.

Retracted workaround: Use an OR clause in the rule expression that includes the item value string and index. For example, if the first record in the predefined block is "Glucose", the rule expression would be: if (var1 == "Glucose" || var1 == 0) (Issue **31979445**)

Dynamically displayed forms do not behave as expected in an Adverse Event (former known issue)

Now, a dynamic child form in the Adverse Event visit is not hidden based on the answer to the determining question in another scheduled visit.

Retracted workaround: None. (Issue **34287388**)

The delete form confirmation window remains after clicking Delete for a two-section form (former known issue)

Now, when deleting a two-section form, the delete form confirmation window no longer remains open after clicking Delete.

Retracted workaround: Manually close the window, then refresh your browser. (Issue **35293584**)

The validation rule error message does not change when a rule is copied

Now, the error message associated with a copied validation rule changes correctly based on the type of validation rule selected and no longer displays the error message associated with the original validation rule.

For example, if you create a validation rule, Select at Least, then copy that rule and change the type to Select at Most, the correct error message is displayed for the second rule instead of the error message associated with the initial validation rule.

Retracted workaround: None. (Issue **35552799**)

The Share Form drop-down does not include all expected users

Now, when you double-click a form (in the test container) and select Preview, then Share, all relevant users are available in the Share Form drop-down. Previously, a fifteen (15) user maximum was enforced.

Retracted workaround: None. (Issue **35528467**)

Error encountered after entering data in a two-section form and clicking Save (former known issue)

The error no longer occurs if you have different values stored for the Label and Value in a codelist.

Retracted workaround: Create a new form and assign the corrected codelist to the label question. (Issue **35508707**)

A deleted row on a repeating form is visible after verification

Now, if you clear an item on a repeating form and then delete that row, the row does not appear after verifying the visit.

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Retracted Workaround: None. (Issue **35487676**)

Rule execution fails when trying to write to a question on a form in a skipped visit (former known issue)

Rule execution no longer occurs when the rule target items are in a skipped visit. The rule runs as expected on all other visits.

Retracted workaround: None. (Issue **35386395**)

Queries closed automatically after clearing a visit date are not reflected on the screen (former known issue)

Now, when you clear a visit date, queries automatically closed on a form in that visit show as closed on the screen without requiring a screen refresh

Retracted workaround: Refresh your browser's page to see the updates on your screen. (Issue **35143313**)

Auto-queries are applied when the rule logic controlling the query is not met

Now, auto-queries are no longer applied incorrectly on associated form items when the query rule logic controlling the query is not met. Previously, the system misinterpreted the dateTimeValueUTC as null for date/time items resulting in the query being applied.

Retracted workaround: None. (Issue **35338504**)

Repeating Label form status shows Incomplete, but the visit status shows Completed

Now, the system considers label form items, Label (Repeating table only), as data when calculating the visit status for lab forms.

Retracted workaround: None. (Issue **35281506**)

Clinical ODM API call returns different record counts when no toTimestamp parameter is passed

Now, when no toTimestamp is specified in the output ODM, the toTimestamp is set to the maximum value (the most current DHTimeStamp transaction) of all available levels (visit, subject, form, item, and query).

Retracted workaround: None. (Issue **35260813**)

Queries display as Opened on the Query side panel but are not present on the form

Now, queries created in an unscheduled visit are visible on the associated form and the Query side panel.

Retracted workaround: Action the queries from the Queries tab. (Issue **35111514**)

Visit status is stuck at In Progress when it should be Complete

Now, if you have a visit containing, for example, a lab form and a standard form and save the data entered on each simultaneously, the visit status is changed to Complete.

Retracted workaround: None. (Issue **35554827**)

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Kit dispensed for an In Progress visit

Now, kits are no longer dispensed for an In Progress visit. Previously, this occurred when form data for multiple forms was saved simultaneously (see bug 35554827), resulting in a completed visit being stuck at an in-progress status.

Retracted workaround: None. (Issue **32975691**)

A screening visit may remain incomplete (former known issue)

Now, a screening visit no longer remains incomplete after dispensing kits or randomizing a subject.

Retracted workaround: None. (Issue **34314545**)

Using an API to hide a dynamic dispensation visit marks the visit status as New instead of Incomplete

Now, when using an API to clear all data in a dynamic dispensation visit, including changing the determining question and hiding the visit, the user is presented with the following dialog related to the determining question; *You cannot change this answer at this time. Some visits are available based on the data in this answer. To update the answer, you must clear any data that is included in those related visits*. This results in the status of the visit being set to Incomplete.

Retracted workaround: None. (Issue **35201062**)

Question hint text for an item in the flat portion of a two-section form persists after navigating away from the item

Now, the question hint text associated with an item in the flat portion of a two-section form, displayed under the Question Hint text in the right-side panel, is no longer displayed after moving to the repeating section of the same form.

Retracted workaround: None. (Issue **34275441**)

The unlock icon is not orange for a required in-progress visit

Now, the unlock icon displays in orange for a required in-progress visit making it easy for users to distinguish between the locked and unlocked icons.

Retracted workaround: None. (Issue **34722585**)

Dynamic form in a future visit – Visit reordering occurring

Now, multiple updates to a determining question which results in a change to the visit status, for example, Complete to Incomplete for future completed visits, no longer results in visits appearing out of order or repeatedly changing positions in the visit train.

Previously, for example, entering No for the Childbearing Potential determining question, then changing to Yes, then back to No would result in inconsistent visit order in the visit train.

Retracted workaround: None. (Issue **35388908**)

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Integrations

The InForm to Argus Safety integration fails when special characters are present

Now, the integration supports special characters in the narrative for the InForm to Argus integration.

Retracted workaround: None. (Issue **35518789**)

Oracle Clinical One Analytics

Data is not loading properly in the CRA and Data Manager dashboards

Now, when you access the CRA dashboard or the Data Manager dashboard, data is properly displayed in the Missing Forms Report and in the Missing Visits Report, without the information taking a long time to display. (Issue **35994707**)

The VALUE field in the Analytics Queries dataset is populated with the latest value

The VALUE field, which stores the raw value for a form question where a query is opened, answered, closed, or deleted, is now populated correctly based on the audit history in the Queries dataset.

Retracted workaround: None. (Issue: **35363371**)

The tile names in the CRA Dashboard in Clinical One Analytics are not visible when display settings are set to Recommended (former known issue)

Now, when you view the CRA Dashboard with the recommended display settings configured, you can see the tile names in the dashboard.

Recommended settings:

- **Scale**: 150% (Recommended)
- **Display resolution**: 1920 x 1080 (Recommended)

Retracted workaround: Switch the display settings to the following to view all tile names in the dashboard.

- **Scale**: 100%
- **Display resolution**: 1920 x 1080 (Recommended)

(Issue **34830326**)

Randomization and kits

A misallocated kit is not reflected in the Subject History, Visit History, or Kit History

Now, if the removal of the old visit association and assignment of the new visit association for a misallocated kit occur simultaneously, the misallocated kit is reflected correctly in the system under the Subject History, Visit History (on the Subjects page), and Kit History (on the Supplies page).

Retracted workaround: None. Issue (**35755272**)

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Reports, archives, extracts, and notifications

The Subject Queries report doesn't properly display audit-related data

Now, when you generate the Subject Queries report with the **Include Audit Trail** set to **Yes**, you'll notice that the expected and relevant data is displayed in the following columns:

- Query State
- Query Comment
- Value
- Unit of Measure
- Last Updated On Site
- Last Modified By
- Last Modified Date

Previously, these columns were populated with a value of N/A. Moreover, the columns would only display data when the **Include Audit Trail** setting was set to **No** and this issue could only be reproduced for some subjects. (Issue **35972590**)

The Site Status Change Alert email notification fails with a system error

Now, the Site Status Change Alert email notification is sent successfully. Previously, the email notification failed to send with the error, `userList Size exceeds max length: 4000`.

Retracted workaround: None. (Issue **35781902**)

The SDV Configuration column in the Study Design Dataset does not populate correctly

Now, the SDV Configuration column in the Study Design Dataset in Oracle Clinical One Analytics accurately reflects what is recorded in the system when generated.

Retracted workaround: None. (Issue **35826804**)

Cannot generate the Subject Queries report for large studies

Now, you can generate the Subject Queries report successfully when the setting **Include Audit Data** is set to Yes.

Retracted workaround: None. (Issue **35571602**)

Kit Dispensation report does not display visit branches for the Visit Title filter (former known issue)

Now, visit branches, defined in a study, are displayed in the **Visit Title** drop-down on the Settings side panel when running the Kit Dispensation report. The permission, *Run the Kit Dispensation Report* is required to generate this report.

Retracted workaround: Use All (default option) for the Visit Title filter when running the report. (Issue **32411770**)

Form status (signature details) displays incorrectly in CRF Submit Submission PDF archive (former known issue)

Now, if both form and visit level signatures are configured and a user signs at the visit and subject level (not at the form level), then edits an item on a form in the signed visit, the Form

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Status (signature details) in the Submission PDF header displays *Ready to Sign* instead of *Ready to Sign, Unsigned*.

In this scenario, the Form Status should not include Unsigned as the form was never signed.

Retracted workaround: None. (Issue **35272192**)

The Study Enrollment standard report includes incorrect Screened Subjects count

The Country Enrollment tab in the Study Enrollment standard report now displays the correct number under the Screened Subjects column. This column includes the number of subjects with a state of screened at the time the report was run. Previously, screen-failed subjects that were never screened were counted as screened and counted in the report.

Retracted workaround: None. (Issue **35332850**)

Training Completion date discrepancy between HS Learn and the Clinical One Training report

Now, the training completion date for training assigned in UMT matches when comparing HS Learn and the Clinical One Training report. Previously, the completion date in the Clinical One Training report showed the training completion date one hour earlier than the date in HS Learn.

Retracted workaround: None. (Issue **35369914**)

The Clinical One Training report fails when it includes email addresses containing a single quotation mark

Now, the Clinical One Training report generates successfully when it includes users with a single quotation mark in their email addresses. A check has been implemented to check and escape when a single quotation mark is present in an email address.

Retracted workaround: None. (Issue **35469774**)

Date values in the Subject Data Extract are swapped (former known issue)

Now, the Entered Date and Last Changed Date values are no longer switched in the Subject Data Extract output and appear under the appropriate columns.

Retracted workaround: None. (Issue **35506296**)

The Notifications icon on the home page does not turn blue, indicating unread notifications (former known issue)

Now, the notifications icon on the Home page, Studies list, turns blue when new notifications are available.

Retracted workaround: Hover over the Notification icon; it displays the number of unread notifications. Click the notification icon to view them. (Issue **35355647**)

The Annotated Case Report Forms & Study Design report (in PDF) fails when a SAS Variable includes an invalid XML character

Now, additional validation during study design does not allow invalid XML characters to be entered in a SAS Variable. This removes the possibility of downstream impact when generating these reports in PDF format.

Retracted workaround: Generate the reports in HTML format or remove the invalid XML character (Issue **35120652**)

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The Study Design report does not properly display code list data (former known issue)

Now, if a code list's name is identical to the questions reference code, the code list name, code values, descriptions, and codes are displayed consistently in the List of Values column in the Study Design report.

Retracted workaround: To properly display code list details in the Study Design report, change the code list's name or the question's reference code; they should not match. Otherwise, code list data will not be displayed as you would expect. (Issue **34751953**)

The Annotated Case Report Forms and Study Design reports contain no Forms section

Now, the correct visit details are included in the Forms section of the Annotated Case Report Forms and Study Design reports after a new study version has been applied using Advanced Study Versioning (ASV).

Retracted workaround: None. (Issue **35386033**)

The Study Roles report (by study) does not include the study name

Now, when filtering by all studies, the Study Roles report (by Study) includes the study name in the blue banner above the report table and not the studies GUID value.

Retracted workaround: None. (Issue **35455370**)

The Study Design Delta report results in an error when generated for approved study versions

Now, the Study Design Delta report, used by study designers to identify study design configuration differences and verify changes between study versions before moving to Production, no longer results in errors and displays the changes between the chosen study versions.

Retracted workaround: None. (Issue **35484673**)

Cyclic visits have the same Projected Visit Date in the Subject Visits (Unblinded) report affecting the predictive resupply

Now, the Projected Visit Date (for cyclic visits) in the Subject Visits (Unblinded) report includes the correct dates. This ensures there is no impact to the resupply algorithm, which uses the Projected Visit Date in the Subject Visits (Unblinded) report for drug projection for predictive resupply. For more information, see the Subject Visits (Blinded) report.

Retracted workaround: None. (Issue **35598456**)

Site users and subject data

Loading subject data takes more time than expected

Now, when you access subject visits associated with a large site, the forms and their collected data load properly and without exceeding the expected loading time. (Issue **35852581**)

Incorrect message appears on the Forms left side panel

Now, when you access a subject's visit, all forms are displayed without delay on the Forms left side panel, and the message *No items to display* is no longer presented to the user. (Issue **35963321**)

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Large-sized repeating forms and two-section forms take longer to load

Now, when you access a subject's visit containing form tables with dozens of rows (in a simple repeating form) or instances (in a two-section form), it no longer takes an extended period of time for the page to load. (Issue **35917673**)

Large-sized repeating forms and two-section forms with queries take longer to load

Now, when you access a subject's visit containing form tables with dozens of instances (in a two-section form), rows (in a simple repeating form), and queries, it no longer takes an extended period of time for the page to load. (Issue **35917721**)

Subjects show as completed in the APIs but not in the user interface (UI)

Now, on the subject list page, the complete and withdraw options appear in the Manage Subjects drop-down after a subject completes the earliest required visit allowing a subject to complete the study.

Retracted workaround: None. (Issue **34787534**)

Incorrect results on the Subjects screen when filtering with a country with multiple sites

Now, when filtering subjects using a country that includes multiple sites, the correct subject list is displayed even when one of the sites is retired and has no subjects.

Retracted workaround: Filter with an individual site, then filter using United States for Country and All sites to show the correct subjects. (Issue **34728469**)

On the Data Capture page visit train, the focus is on another visit instead of the selected visit

Now, the focus is on the selected visit and not other visits in the visit train on the Data Capture page. Users no longer need to scroll to the first visit to confirm that the correct visit is selected.

Retracted workaround: None. (Issue **34605036**)

Subject tags disappear in the user interface after being added

Now, subject tags defined in your study design no longer disappear in the user interface after creation. This bug only impacted the user interface. The Study Design report accurately reflected the subject tags even when they were not visible in the user interface after creation.

Retracted workaround: None. (Issue **35463949**)

Subject status is not updated from Screened to Enrolled

Now, the subject state changes from Screened to Enrolled after completion of the first non-dispensation visit, even if there is a dynamic form included in the design.

Retracted workaround: Use the Save and Close or Return to All Subjects buttons to properly complete the process. (Issue **35561229**)

Rest API updates

See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs, available upon the Production release.

The following service has been added:

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- Comment

The following services have been updated:

- Codelist
- Data Action
- Data Hub
- Data Capture
- Designer
- Library
- Query
- Randomization and Supplies
- Reporting
- Sites and Depots
- Users, Permissions, and Roles

Comment

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/comments • POST /v1.0/studies/{studyId}/comments/markAsRead • POST /v1.0/studies/{studyId}/comments/markAsUnRead • POST /v1.0/studies/{studyId}/comments/objects • POST /v1.0/studies/{studyId}/comments/objects/unreadCount • GET /v1.0/studies/{studyId}/comments/objects/{objectId} • GET /v1.0/studies/{studyId}/comments/objects/{objectId}/unreadCount • PUT /v1.0/studies/{studyId}/comments/{commentId} • DELETE /v1.0/studies/{studyId}/comments/{commentId}

Codelist

Change	Endpoint
New	• GET /v1.0/history/codes • GET /v1.0/history/codevalues • GET /v1.0/history/groups

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Data Action

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/dataelements/freeze • GET /v1.0/studies/{studyId}/{mode}/dataelements/sdv • POST /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/lock/allvisit • POST /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/validate/multiplevisits • GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/lock • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/unlock • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/unlockvisits • PUT/v1.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/validate/multipleitems • GET /v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks

Data Hub

Change	Endpoint
New	• POST /v1.0/tenant/{tenantId}/codelists • POST /v1.0/tenant/{tenantId}/studies/{studyId}/codelists • POST /v2.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v2.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • GET /v4.0/studies/{studyId}/{mode}/odm/metadata • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

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Data Capture

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/{mode}/subjects/count • GET /v1.0/studies/{studyId}/{mode}/dataelements/{dataelementId}/{opeartionType}/childItems • PUT /v1/studies/{studyId}/{mode}/subjects/{subjectId}/undoSubject • PUT /v11.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v12.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v2.0/studies/{studyId}/{mode}/visitstatus/multiple • POST /v3.0/studies/{studyId}/{mode}/subjects/visitschedule • POST /v4.0/studies/{studyId}/{mode}/subjects/randomizeordispense • POST /v4.0/studies/{studyId}/{mode}/subjects/visitschedule • PUT /v6.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}/clearruleerror/{message}
Deprecated	• GET /v1/studies/{studyId}/{mode}/dataelements/sdv • POST /v2.0/studies/{studyId}/{mode}/dataelements/freeze • PUT /v2.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/asynch/report/{reportName} • POST /v1/studies/{studyId}/{mode}/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/reports/{reportName} • POST /v2.0/studies/{studyId}/{mode}/report/{reportName} • POST /v3.0/studies/{studyId}/{mode}/report/{reportName} • POST /v4.0/studies/{studyId}/{mode}/report/{reportName}

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Designer

Change	Endpoint
New	• GET /v1.0/studies/{studyId}/versions/{versionId}/cohorts • GET /v2.0/studies/library/{libraryId}/studyType/{studyType}/studyUses • GET /v2.0/studies/{studyId}/approved/choiceoptions • GET /v2.0/studies/{studyId}/approved/objectids • POST /v2.0/studies/{studyId}/forms/formitems • GET /v2.0/studies/{studyId}/forms/{formId}/formitems • GET /v2.0/studies/{studyId}/forms/{formId}/itemhistory • GET /v2.0/studies/{studyId}/objectids • GET /v2.0/studies/{studyId}/randomizationfactors • GET /v2.0/studies/{studyId}/versions/{version}/forms/numericItems • GET /v2.0/studies/{studyId}/visitsforms • GET /v2.0/studies/{studyId}/{mode}/forms • POST /v3.0/studies/{studyId}/lockObjectDetails • GET /v3.0/studies/{studyId}/{mode}/forms • POST /v4.0/studies/{studyId}/allForms/coding • GET /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • POST /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • PUT /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • DELETE /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • POST /v5.0/studies/{studyId}/allForms • GET /v6.0/studies/{studyId}/studyversionobjects • GET /v7.0/studies/{studyId}/versions/{version}/arms/{armId}/dispensings • GET /v7.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo • GET /v8.0/studies/{studyId}/studyDesign • POST /v8.0/studies/{studyId}/studyDesign/paginated • POST /v8.0/studies/{studyId}/versions/{version}/kits • GET /v8.0/studies/{studyId}/versions/{version}/kits • GET /v8.0/studies/{studyId}/versions/{version}/kits/{kitId} • DELETE /v8.0/studies/{studyId}/versions/{version}/kits/{kitId} • GET /v8.0/studies/{studyId}/versions/{version}/visits/{visitid}/dispensings • GET /v8.0/studies/{studyId}/versions/{version}/visitschedules • POST /v9.0/studies/{studyId}/design • POST /v9.0/studies/{studyId}/studyDesign • GET /v9.0/studies/{studyId}/versions/{version}/design • POST /v9.0/studies/{studyId}/versions/{version}/visits • GET /v9.0/studies/{studyId}/versions/{version}/visits/{visitid} • PUT /v9.0/studies/{studyId}/versions/{version}/visits/{visitid} • DELETE /v9.0/studies/{studyId}/versions/{version}/visits/{visitid}
Deprecated	• POST /v1.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • PUT /v1.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • DELETE /v1.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • POST/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • PUT /v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • DELETE /v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule

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Library

Change	Endpoint
New	• GET /v1.0/libraryHistory/{libraryId} • POST /v1.0/libraryObjects/studies/{studyId}/versions/{studyVersion}/revertCopyObjects • POST /v2.0/libraryObjects • GET /v2.0/libraryObjects • DELETE /v2.0/libraryObjects • POST /v2.0/libraryObjects/bulk • GET /v2.0/libraryObjects/pagination • POST /v2.0/libraryObjects/studies/{studyId}/versions/{studyVersion}/{copyObjectMethod}/copyObjects • POST /v2.0/libraryObjects/updateStudyVersion • PUT /v2.0/libraryUses • GET /v2.0/libraryUses/library/{libraryId}/studyType/{studyType} • GET /v2.0/libraryUses/studies/{studyId}/versions/{studyVersion} • GET /v2.0/libraryUses/study/{studyId}/studyType/{studyType}
Deprecated	• GET /v1.0/libraryObjects/{libraryId}

Query

Change	Endpoint
New	• PUT /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/bulkCloseDelete

Randomization and Supplies

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/reports/locallysourcedkits • GET /v15.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v16.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v2.0/studies/{studyId}/{mode}/reports/unblinded-visit-schedule • POST /v3.0/studies/{studyId}/{mode}/reports/kits/blindedInventory • POST /v3.0/studies/{studyId}/{mode}/reports/kits/blindedchainofcustody • POST /v3.0/studies/{studyId}/{mode}/reports/kits/unblindedInventory • POST /v4.0/studies/{studyId}/{mode}/reports/order-summary • POST /v4.0/studies/{studyId}/{mode}/reports/subjects • GET /v4.0/studies/{studyId}/{mode}/shipments • POST /v5.0/studies/{studyId}/{mode}/reports/order-summary • GET /v6.0/studies/{studyId}/{mode}/orders • GET /v6.0/studies/{studyId}/{mode}/orders/{shipmentId} • POST /v7.0/studies/{studyId}/{mode}/reports/kits/chainofcustody

Reporting

Change	Endpoint
New	• POST /v2.0/scheduled/reports

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Change	Endpoint
Deprecated	• GET/v1.0/reportmetadata/downloadList • GET /v1.0/reportmetadata/reportId/{id} • GET /v1.0/reports/download • POST /v1.0/reports/page • GET /v1.0/studies/{studyId}/{mode}/reportmetadata/reportId/{id} • POST /v1.0/studies/{studyId}/{mode}/reports • DELETE /v1.0/studies/{studyId}/{mode}/reports • GET /v1.0/studies/{studyId}/{mode}/reports/download • POST /v2.0/reports/page • GET /v2.0/studies/{studyId}/{mode}/reports/download

Sites and Depots

Change	Endpoint
New	• GET /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals • PUT /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals • GET /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals/lookup • GET /v5.0/studies/{studyId}/{mode}/sdfcountry

Users, Permissions and Roles

Change	Endpoint
New	• GET /v1.0/userinfo/bulk • GET/v2.0/userinfo/bulk

Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Oracle Life Sciences Data Management Workbench (DMW)

- The new fields related to queries and Source Data Verification (SDV) introduced in Oracle Clinical One Analytics will be made available in Oracle DMW in a future release.
  For more information on these new fields, see Enhancements to Oracle Clinical One Analytics.

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Clinical One Cloud Service and Clinical One Digital Gateway 23.1 (April 2023)

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs for 23.1, available upon the Production release.
- Release impact for other applications
  This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.1 release.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway application**.

Table 11-1 Patch log

Release Number	Release Date	Notes
Release 23.1.4	11 August 2023	For this release, we fixed an issue pertaining to visits. For more information, see issue **35620027** in Forms, visits, and rules.
Release 23.1.3	17 July 2023	For this release, we fixed three issues related to forms, visits and Subject Queries report. See issues: • **35554738**, **35454836** in Forms, visits, and rules Also, we documented enhancements to the Data Intake integration. For more information see, Data Intake integration enhancements.

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Table 11-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.1.2	21 June 2023	For this release, we fixed 13 issues related to visits, rules, training, performance, Inform subject import to Clinical One, notifications, forms, and reports. For more information see: • Issues **35429014**, **35400909**, **35383291**, **35382903**, **35393191**, **34896490** in Forms, visits, and rules. • Issue **35362448** in Sites, labs, depots, settings, and user management. • Issues **34159843**, **35369692**, **35356232**, **35299270**, and **35143048** in Reports, archives, extracts, and notifications. • Issue **35430907** in Site users and subject data. Also, an update was made in Oracle Central Coding that benefits Clinical One Cloud Service studies. For more information, see Oracle Central Coding now supports a subject number change
Release 23.1.1.1	28-May-2023	For this release, we fixed one issue related to the Subject Data Extract. For more information, see Issue **35396396** in Reports, archives, extracts, and notifications.

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Table 11-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.1.1	16-May-2023	For this release, we fixed six issues related to study design, sites, reports, Analytics, and visit branches. For more information see: • Issues **35310223**, **35309668**, and **35285490** in Sites, labs, depots, settings, and user management. • Issue **35279146** in Reports, archives, extracts, and notifications. • Issue **35281545** in Oracle Clinical One Analytics. • Issue **35274867** in Forms, visits, and rules. We also documented enhancements to Signature Configurations and the Unblinded Subject Events dataset. For more information, see Other enhancements.

What's new

- Data collection
- Data review
- Integrations
- Randomization and trial supply management
- Reporting, archives, and analytics
- Rules management
- Study design
- Other enhancements

Data collection

- Manage screen failure subjects
  Sponsor users can now set configurations that allow subjects who have failed screening to complete or withdraw from the study.

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Manage screen failure subjects

Sponsor users can now set configurations that allow subjects who have failed screening to complete or withdraw from the study.

Details for sponsor users

Under the Study Settings tab, the new **Screen Failed Subjects** configuration provides you with multiple options to enhance your screen failed subject management:

- By selecting **Allow Screen Fail before Screening**, subjects can be manually screen failed if they have not yet been screened.
- By selecting **Allow Withdrawal**, on the Subjects page, the **Withdraw** option becomes available for screen failed subjects.
- By selecting **Allow Completion**, on the Subjects page, the **Complete** option becomes available for subjects who have failed screening.

> **Note**
>
> The **Allow Withdrawal** and **Allow Completion** settings are deselected by default for existing studies.

- By selecting **Yes** for the **Allow Withdrawal for Subjects before Enrollment** configuration, the ability to withdraw subjects before they've been enrolled in a study becomes available.
- Screen failed visits can now be included in a subject's visit schedule.

More details on configuring these settings can be found in Specify study enrollment and visit settings after the Release Assessment Environment upgrade.

Details for site users

When it comes to your workflow, here is what's new for you:

- If your study's settings have been configured to allow for screen failed subjects to withdraw from the study, the **Withdraw** option is enabled in the **Manage Subjects** drop-down, and withdrawal event forms become available to record additional data.
- If your study's settings have been configured to allow for subjects who have failed screening to complete the study, the **Complete** option is enabled in the **Manage Subjects** drop-down, and completion even form become available to record additional data.
- **Withdraw** and or **Complete** are not available in the **Manage Subjects** drop-down if they are not selected in the study settings.

Step-by-step instructions on managing screen failed subjects can be found in the *Site User Guide* after the Release Assessment Environment upgrade.

Impacts on reports

The Study Design report and Subject Events report have been enhanced to include details on screen failed subjects.

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Data review

- Sign off at the form and visit level with custom affidavits
  As a sponsor or CRO, you can now define Signature Configurations at the form and visit level, and program the system to remind users about signing data at all levels.

Sign off at the form and visit level with custom affidavits

As a sponsor or CRO, you can now define Signature Configurations at the form and visit level, and program the system to remind users about signing data at all levels.

Before you work with this feature

For the 23.1.1 patch release, we've introduced a minor enhancement for this new feature. For more information, see the Other enhancements.

The following users can sign off at the form and visit level and manage custom affidavits:

- Users assigned the *Approve and Sign Subject Data* permission can sign at the casebook level and their signature is applied to all questions available to them based on their permissions. This permission also allows users to sign data that has been assigned to them in a signature configuration.
- Users assigned the *Approve and Sign Assigned Data Only* permission are only able to sign data that has been assigned for their role at the form or visit level in a signature configuration.
- Users assigned the *Receive the Pending Signatures Notification* permission will receive email notifications informing them when a signature, for a site they are assigned to, has reached the defined target date or become overdue.

> **Note**
>
> The **Signature Requests** notification is only sent once the **Send Reminder Through Email** setting is configured to **Yes**.

- Sponsor users assigned the *Manage Signature Settings* permission have the ability to create and edit signature configurations.

More details on notifications and permissions for this feature can be found in the *Notifications and Permissions Guide* and the *Add Users Guide* after the Release Assessment Environment upgrade.

Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- Signature configurations at the form and visit level are disabled until the **Display signature elements for site staff and sponsors** setting is configured to **Yes** in the Study Settings.

> **Note**
>
> Signature configurations for casebook level signatures are still available when this setting is configured to **No**.

- The signature option is available in all study modes.

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- If you are required to sign off at more than one level, signatures applied at a lower level fulfill those at a higher level only for that specific form or visit. For example, a signature at a form level fulfills visit or subject level requirements.

  > **Note**
  >
  > Signatures at a higher level do not fulfill those at a lower level, therefore, a signature at the subject level will not fulfill a form level requirement, requiring separate signatures.
  > This only applies if the user signing is responsible for signing at the higher level, as well.

- The first value in the Affidavit's codelist will be used for subject level signatures if more than one affidavit is included in the codelist.
- Be aware that if a new visit is named the same as a deleted visit, both appear as options in the Signature Configuration.
- Signature icons and requirements for impacted visits are updated for a subject once data is entered into a question or form, when the given question or form is added or modified through Advanced Study Versioning (ASV).

Details for site users

When it comes to your workflow, here's what you should know:

- The **Ready to Sign** filter now includes incomplete forms and visits with signature requirements.
- In order to confirm data accuracy, the forms under the following signature configuration types require a re-signature after previously signed if they are deleted, hidden, or no longer require signing:
  - Subject level
  - Two-section form
  - Visit level

You can find additional information in the *Site User Guide* after the Release Assessment Environment upgrade.

Impact on reports

The following reports have been updated for this feature:

- Study Design report
- Subject Data report
- Subject Events report

More information on these report impacts can be found in the *Reporting Guide* after the Release Assessment Environment upgrade.

Integrations

- Better shipment management for the Almac integration
  This feature allows a user to pick which depots to integrate to Almac in their study.

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- Oracle Central Coding now supports a subject number change in an Clinical One Cloud Service study
- Data Intake integration enhancements

Better shipment management for the Almac integration

This feature allows a user to pick which depots to integrate to Almac in their study.

Integration managers can now configure an integration with Almac Global Depot Network to exclude orders from depots that are not managed by Almac Global Depot Network.

Previously, it was expected for Clinical One Digital Gateway to handle shipment orders for all depots in a study, including the ones that were not specified for an Almac integration.

Oracle Central Coding now supports a subject number change in an Clinical One Cloud Service study

Starting with Oracle Central Coding 7.0.1.0, a subject number change made in Clinical One Cloud Service displays correctly in the Oracle Central Coding user interface, reports, and extracts.

> **Note**
>
> Oracle Central Coding 7.0.1.0 is scheduled for release by the end of June 2023. You will need to upgrade to take advantage of this functionality.

Previously, the updated subject number was not reflected in the Oracle Central Coding user interface. The integration still functions because a unique ID (one that does not change when the subject number is changed) is included in the exchange of information between the systems. This fix ensures that the correct subject number is displayed in the Oracle Central Coding user interface, reports, and extracts.

Data Intake integration enhancements

The Data Intake integration no longer requires the site ID to be included in the data file

The Clinical One Digital Gateway Data Intake integration, used to load generic data such as subject and questionnaire data into an Clinical One Cloud Service study, no longer requires site ID to be included in the data file.

Site id can now be derived from the site portion of the subject number, for example, 01-001, where the site id is 01. Previously, site ID was a required value in the data file.

For more information about the Data Intake integration, see Labs & general subject data intake.

The Data Intake integration now supports the date format dd-MM-yyyy (22-02-2023)

The Clinical One Digital Gateway Data Intake integration now supports importing dates in the dd-MM-yyyy format into Oracle Life Sciences Clinical One Cloud Service studies. This includes visit date and regular date fields, such as a sample collection date.

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Randomization and trial supply management

- Tracking numbers for temperature excursions
  You can now provide tracking numbers for kits that have experienced a temperature excursion to improve your tracking and visibility for supply chain issues in a study.

Tracking numbers for temperature excursions

You can now provide tracking numbers for kits that have experienced a temperature excursion to improve your tracking and visibility for supply chain issues in a study.

Details for sponsor users

When it comes to your workflow, here's what's new for you:

- You can now define the Temperature Excursion Starting Number on the Supply Settings tab when **Yes** is selected for the Allow Temperature Excursions setting.
- Temperature excursion starting numbers can be configured with a starting value of one (1) digit up to eight (8) digits that sequentially increment by 1. For example, 001, 002, 003, 004, and so on.

> **Note**
>
> The starting number cannot begin with 0.

- All kits that are quarantined together receive the same tracking number.
- Users assigned the *Receive the Quarantined Depot Shipment Notification* permission receive the new Study Inventory Quarantined notification. This notification alerts users when available kits at a site or depot are marked as Quarantined.
- Users assigned the *Receive Notification of Shipments* permission receive the new Pending Shipment notification when a shipment has not been received at a site within the number of days defined in the supply settings.

Updates to the following reports have been made to reflect the new tracking number feature:

- Kit Chain of Custody (Blinded) report
- Kit Inventory (Unblinded) report
- Study Design report

Details for site users

Be aware that temperature excursion tracking numbers are displayed under the Kit History side-panel on the Site Inventory page only for kits marked as Quarantined.

> **Note**
>
> If a temperature excursion tracking number is assigned to a kit, it always remains with that kit and can be filtered by Temperature Excursion Number regardless of the kit status.

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Reporting, archives, and analytics

- Enhancements to the Subject Data Extract
  The Subject Data Extract no longer includes deleted, cleared, and undone visit data, while the format of date fields has been unified.
- Enhancements to ODM-XML clinical data extracts
  To ensure appropriate data granularity, enhancements have been added to the ODM-XML clinical data extract.
- Enhancements to Oracle CRF Submit archives and reports
- RTSM Dashboard in Oracle Clinical One Analytics
  The Randomization and Trial Supply Management (RTSM) dashboard is now available in Oracle Clinical One Analytics allowing you to visualize key information related to randomization and supply management.

Enhancements to the Subject Data Extract

The Subject Data Extract no longer includes deleted, cleared, and undone visit data, while the format of date fields has been unified.

Deleted or blank forms will no longer be included in the report

The Subject Data Extract now includes only the current version of data collected at sites. As such, the **DELETED** column has been removed, while any other deleted, cleared, or undone visit data will no longer be included in the report.

Unified date formats

All dates are now exported in the YYYYMMDD format in the report, in accordance with ISO 8601.

Enhanced Subject Data Extract notification emails

The Subject Data Extract notification email will now indicate the site where the data originated, as well as the file type the report was generated in (CSV, CPORT, XPORT, or SAS7BDAT).

Enhancements to ODM-XML clinical data extracts

To ensure appropriate data granularity, enhancements have been added to the ODM-XML clinical data extract.

> **Note**
>
> for these enhancements to take effect, please ensure you are using the latest version of the clinical and metadata APIs. For more information, see the REST API for Clinical One Platform guide.

New data fields

To make it easier to track the source of data contained in a lab form, **Lab Id** and **Lab name** have been added to the ODM-XML clinical data extract. These fields only populate whenever the data for the repeating part of a lab form has been entered or updated.

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For queries submitted as part of a study, the new **assignedRole** field indicates the role of the user which needs to close that particular query. Moreover, the new **QueryType** field identifies the source of a query, while the new **QueryRaised** co extension indicates how the query was generated.

Improvements made to existing fields

ODM metadata now correctly identifies repeating forms and sections.

A new co extension, **QuestionGroup**, has also been added, which helps identify whether a question group is present.

Data availability and formatting

Users can now extract metadata from Testing study versions which have afterward been moved to Approved or have been Archived; previosuly, Testing metadata would not have been available in this scenario. The data contained in a study prior to production is marked accordingly within the report.

Measurement units now display properly for both calculated and normal values.

Enhancements to Oracle CRF Submit archives and reports

Form & Visit level Signatures and Affidavits (from code lists) are now supported

Starting with 23.1, signatures can now be configured at the form and visit level. Subject PDFs include the signatures and indicate the type of signature applied, Form, Visit, or Subject. The affidavit text is displayed according to the signature configuration, using the code list value as of the signature date.

Previously, subject PDFs included the signature history at the form level when all items on a form or the subject casebook were signed. The associated affidavit text was displayed using the code list value as of the signature date.

You can find more information about signing at the visit and form level in the *Site User Guide*, and details about signature configuration can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment upgrade.

The As of Date in the Request Settings PDF now displays in a users time zone

In the request settings PDF, the **As of Date** now displays the date/time based on the time zone settings of the user who generates the request. Previously, the Request Settings PDF displayed GMT by default.

Electronic Trial Master File (eTMF) transfers are now supported

Oracle CRF Submit output files for Archival PDF (sponsor and site), and Custom PDF archive requests can now be delivered to the Oracle sFTP server. These files can be programmatically transferred to your eTMF storage system or downloaded manually in the Clinical One Cloud Service user interface.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment upgrade.

RTSM Dashboard in Oracle Clinical One Analytics

The Randomization and Trial Supply Management (RTSM) dashboard is now available in Oracle Clinical One Analytics allowing you to visualize key information related to randomization and supply management.

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> **Tip**
>
> Whether you are working in a live study (and already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle point of contact for more information on Oracle Clinical One Analytics training and mentoring.

With the introduction of the new RTSM dashboard template in Oracle Clinical One Analytics, you can get a holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to a customizable, interactive dashboard containing reports and visualizations that can help improve your decision-making on randomization and supply management processes.

Since they are templates, you do not have to create dashboards from scratch, but you can customize it to meet your needs. All you have to do is download the template and re-import it to tweak the data in and adjust filters, and this way make sure you are viewing data relevant to your work. For more information see Customize templates.

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. To work with the RTSM dashboard, you must have access to the following datasets:

- Unblinded Kits dataset
- Subject dataset

Access to a dataset is given based on a permission that you must be assigned in Clinical One Cloud Service. For more information on these permissions, see Descriptions of permissions in Clinical One.

Details for clinical supply managers

With the new RTSM dashboard, Clinical Supply Managers (CSM) can monitor randomization and supply details across studies and sites. Even though this dashboard is intended to assist CSMs with their duties, the RTSM dashboard is available to any user with the appropriate permissions. This customizable dashboard offers you complex data on randomization and supply management, organized within the following interactive reports:

- Overall Summaries
- Subject Details
- Subjects Enrolment Summary
- Site Status
- Unblinded Randomization
- Site Overall and Monthly
- Site Overall (Shipment)
- Unblinded Shipment History
- Site Inventory
- Unblinded Visit Summary
- Unblinded Clinical Supplies Return

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- Unblinded Site and Depot Kit Status
- Unblinded Depot Inventory

The reports and visualizations grouped in this dashboard can help CSMs to analyze the study inventory and treatment arm distribution across the study. With this, the study team can identify a possible need of randomization design and limits update, as well as supply management adjustments.

You can find additional information regarding dashboards in the *Analytics User Guide* after the Release Assessment Environment upgrade.

Rules management

- Enhancements to rule helper functions

Enhancements to rule helper functions

Access data from forms in other visits using `getValues()`

You are now able to create variables referencing items that do not exist within the same visit as the rule target. Previously, you could reference all of the visits where the rule target form exist. Now, when defining rule variables, you have a new option in the visit selection drop-down that allows you to declare variables for *Any Visit*. This allows referencing data collected in any other form at different visits, regardless if the target rule form is present or not.

By using `getValues()` you can fetch these values and use them in comparisons and other logical operations with data in the current form. For example, you can get the sample collection date from a previous visit and compare it with the infusion date in the current form, to make sure the sample collection date is prior to the infusion date. This example considers that sample collection date question exists within a form present in a first visit but not present in a second visit in which infusion is performed.

Refer to values in different table rows

A new helper function now allows you to fetch the immediate previous not-null value from previous rows in repeating forms and repeating sections on two-section forms. The introduction of `getPrevRepeatValue()` facilitates logical operations between values in different rows, whether it is the same or a different question, while reducing programming efforts. For example, you can get the end date of a dose on the immediate previous row and compare it with the start date of a dose in the current row.

You can find additional details about this new helper function in the *Rules Developer Guide* after the Release Assessment Environment upgrade.

Reuse variables passed into helper functions

Previously, when using repeating forms and two-section forms helper functions, you needed to create a second variable for the same question if it also needed to be referenced elsewhere in the expression. Now, the following helper functions have been enhanced to allow the reuse of variables (all item types are supported):

- Repeating forms helper functions:
  - FindMinInRepeatingForms()
  - FindMaxInRepeatingForms()
  - FindMatchingRepeatingForm()

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  - FindMatchingRepeatingFormWithinRange()
  - FindDuplicateRepeatingForm()
  - FindDuplicateRepeatingFormWithinRange()
  - FindRFInstance()
  - ListRFInstances()
  - getRFValues()
  - FindMinDateInRFs()
  - FindMaxDateInRFs()
  - GetMatchingRepeatingFormsCount()
- Two-section forms helper functions:
  - FindMatching2SForm()
  - list2SInstances()
  - findDuplicate2SForm()
  - getCurrent2STableInstance()
  - get2SValues()
  - findMinDateIn2SForm()
  - findMaxDateIn2SForm()
  - find2SFormInstance()
  - getMatching2SFormsCount()
  - findMinIn2SForms()
  - findMaxIn2SForms()
  - findDuplicate2SFormWithinRange()
  - findMatching2SFormWithinRange()

Enhancement to use helper functions with codelists

When working with code lists in choice questions, you can now specify whether to get the code or the label value. To do this, you can use the `getArrayFromChoice()` and `getStringFromChoice()` helper functions, which now have a new optional parameter that allows you to define which value to return.

You can find additional information on these and other Helper function reference in the *Rules Developer Guide* after the Release Assessment Environment upgrade.

Study design

- Create your very own library study
  Users at a sponsor organization or Clinical Research Organization (CRO) can now create their own library study and include objects in these libraries to be used in live studies.
- Preview forms in Draft mode
  Study designers can now preview a form's design while in Draft mode, to address any issues and make necessary adjustments before moving a study version to Testing.

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Create your very own library study

Users at a sponsor organization or Clinical Research Organization (CRO) can now create their own library study and include objects in these libraries to be used in live studies.

By creating your own library study, you can not only reduce the time for study building, but you can also better manage standards for study metadata and improve the consistency of design throughout all studies at your organization. With every object created and tested within the context of a library, users can then add these objects to a live study ensuring that their protocol is up to the organization's standards.

Before you work with this feature

This new feature can impact global users, as well as study designers. As a global user manager, you can assign the following new global roles to users so they can view and manage library studies:

- Change Library Objects Status
- Manage Library Objects
- View Library Objects

Details for library users

Here's what's new for you:

> **Note**
>
> For this release, you can only include forms as objects in your library.

- Now, when you navigate to the Library page, you land on the Library Studies page where you can create and manage all of your library studies.
- On the Library Studies page, you can click **View Library**. This takes you to the organization's library where you can navigate between the **Code List** tab and the **Forms** tab. The new **Forms** tab contains all of the forms from your library studies. The **Code List** tab has no functional changes and it will still display all of your organization's custom and system default code lists.
- On the Library Studies page, you can click **Create Library Study**, fill in the fields of the Create Library Study dialog and create a new library study in your library.
- On the Library Studies page, a library study is displayed similarly to how a study is displayed on a Home page. A library study can be versioned and moved through all four different containers: Draft, Testing, Approved, and Archived.
- By clicking a library study in the Draft container, you can navigate to the Forms tab within a library study. You can then choose between creating a brand new form or importing an existing form from another live study or another library study at your organization.
- An object in a library can have various statuses. By default, when you import or create a new object, its status is set to **Draft**. Other statuses that an object can have are **Testing**, **Rejected**, **Approved**, **Published**, or **Archived**.
- After you create an object in a library study, you can test it, approve it, and then publish that object in your library study. Only after you test, approve, and publish an object within your library study, can you add it to a live study and further test it in that updated study version.

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- You can choose to version an object that was already published so that your library contains multiple iterations of the same object. For example, you can choose to create two or three different versions of the same Demographics form. All of the different versions can be used across live studies at your organization.
- Irrespective of its status, you can always edit an object's attributes, such as its description and associated tags.
- Along the top of the Library page, you have several options to make navigation of library objects easier: you can filter objects by status or tag, you can expand or collapse all objects to view or hide their details, or you can search for a specific library object.
- On the right side of the Library page, upon selecting an object, you can view its history on the Object History side panel.

Reporting updates

Objects created in library studies will be displayed in reports and datasets in Oracle Clinical One Analytics for a future release.

Impact on integrations

You cannot set up integrations for library studies.

Impact on custom JavaScript rules

As a rule designer and tester, you must know that you can create custom rules in a library study, as well. The workflow for creating, testing, approving, and ultimately publishing a custom rule in a library study is the same as the workflow that you follow for a live study.

When you add an object with custom rules to a live study, keep in mind that all custom rules are imported in the live study with a status of **Invalid**. You will then have to test, approve, and publish the copied rules to ensure that they run correctly in your updated live study version.

Already working in a live study?

As soon as the release upgrade is complete, you can begin creating library studies and adding objects to them. You can add forms to your new library study from any other study whether it is newly created or already live.

You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Preview forms in Draft mode

Study designers can now preview a form's design while in Draft mode, to address any issues and make necessary adjustments before moving a study version to Testing.

With this new feature, study designers can preview forms during design. Beside your own ability to preview a form, you can share preview links to other users in your study team to get feedback before releasing the study version for Testing. This allows users to quickly address any issues that may arise during data collection and make the necessary adjustments while the study design is still available in Draft mode.

Before you work with this feature

To either preview forms or share preview links, you must have at least one of the following permissions for the given study:

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> **Note**
>
> Users with a preview link can forward the preview form invite; however, only authorized users can access the form preview.

- *Design Forms*
- *Design Randomization*
- *Design SDV Properties on Forms*
- *Design Supplies and Dispensation*
- *Design Visits and Events*
- *Move a Study Design to Testing or Production*
- *Run the Study Design Report*
- *Run the Study Rules Report*
- *Upload and Generate Inventory Lists*
- *Upload and Generate Randomization Lists*
- *View Study Design*

Details for study designers and other sponsor users

This feature is available for one and two-section forms, as well as lab forms. Previewed forms display as they would within a visit in a live study. Additionally, users can enter mock data to also preview dynamic questions and dynamic sections. Repeating rows get displayed on their tabular form and, by clicking on any data entry field, the data entry view can be expanded. In the case of lab forms, the preview gets rendered successfully; however, lab normal ranges are not validated.

When accessing through a preview link, if the form design is no longer in Draft mode but still exists within the given study version (whether in Testing or Production), users get to see the latest version of the form. If the requested form is not available for preview, users get notified if the requested form doesn't exist, if it has been deleted, or if you are not authorized to access it.

You can find additional information on the *Study Designer User Guide* after the Release Assessment Environment upgrade.

Other enhancements

Hide or enable user interface elements for signature configurations

Sponsor users can now allow for signature configuration elements to appear in the user interface.

Signature elements on the Study and Subject homepages are hidden by default for existing studies. In the Study Settings, selecting **Yes** for the **Display signature elements for site staff and sponsors** option enables the Signature widget (

) to display in Production mode, while the Signature Request side panel appears in all modes.

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> **Note**
>
> It is not possible to go back and select **No** for the **Display signature elements for site staff and sponsors** option once **Yes** has been selected and saved for the corresponding mode.

New fields in the Unblinded Subject Events dataset

New fields have been added to the Kit and Subject folders of the Unblinded Subject Events dataset in Oracle Clinical One Analytics. The new fields provide information about titration, treatment arm, and unblinding details, allowing users to report subjects and events alongside these data points.

Additional information can be found in the *Analytics User Guide*.

Fixed issues

- All users
- Integrations
- Oracle Clinical One Analytics
- Facilities, settings, and user management
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data

Forms, visits, and rules

Visit cycle is skipped incorrectly
Now, cycle visits that have been skipped and unskipped, resulting in a status of **New** or **In Progress**, are included in the logic used to calculate subsequent visits.

Retracted workaround: None. Issue (**35620027**).

Lab forms in cyclic visits populate incorrectly with lab normals
Now, if working in a study that uses cyclic visits, the lab normals appear only when the Sample Collection Date is set after the Effective Date. Previously, the lab forms populated incorrectly with lab normals if the Sample Collection Date (or visit date) was set before the Effective Date (the date from which the lab normal range became effective at the laboratory).

Issue (**35554738)**

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Error when adding a custom rule in a lab form

Rules developers: Now, when creating a custom rule referencing fields in the first section of a lab form, that rule returns the correct values when running. Previously, when you created a custom rule that referenced a question such as the Sample Collection Date or the question on Fasting (both located in the first section of a lab form), the system would return an Internal Server Error.

Issue (**35454836**).

For more information, see Create and manage custom rules

Cycle visits show the same date

Site users: The scheduled future cycle visits now show different dates. Previously, the same date showed for all future cycle visits in a week. This prompted unrequested shipments for site dispensation.

Issue (**35383291**).

Error encountered submitting a lab form when UNK is entered as a time component
(Former Known Issue)
Site users: Now, selecting UNK for a time component with a partial date shows as expected. Previously, site users encountered an unexpected error after submitting a lab form that included a date item that allowed for partial date entry, and selected UNK for the time component.

Retracted workaround: You no longer have to collect the data first, and then complete the partial date/time question with UNK afterward.

Issue: (**35382903**)

Re-running a custom calculation value rule results in an error'

Rule designers: Re-running a calculated value rules in a live study now work seamlessly with data re-populating the targeted fields, as expected. Previously, when you re-ran a rule in a live study, you would receive an email that an error has occurred, and data would not be updated in the rule's targeted fields.

Issue (**35393191**)

Error when editing visit schedule in Draft mode

Study designers: Now, when you specify a visit's window, you can save your changes as expected. Previously, when editing and saving the changes in any of the Visit Window fields, an "Update Scheduled Failed" error message would appear. The targeted field would remain unchanged.

Issue (**34896490**)

Radio buttons cannot be updated when links are present

Site users: Now, you can modify the answers to a question with radio buttons even when the form containing that question is linked to other forms in a study. Previously, you were unable to modify to answer of a question that was included in a linked form, even though that question did not determine the linking. For example, when you attempted to modify the answer to a question unrelated to a linked form, an error message appeared that stated: "The answer to this question impacts other related questions on this form. You must clear any answers or links to the related questions, as well as answer or update related queries before you can change this answer".

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Workaround: Remove the form link and clear the dynamic questions to allow the system to change the option for the radio control.

Issue (**35429014**)

The cycle visit branch shows incorrect order

Study designers: Now, the future cycle visits you create are displayed in a subject's schedule with their specified dates. Previously, all future cycle visits were displayed with the same date throughout a week. This prompted unrequested shipments for site dispensation.

Issue (**35400909**).

Subject switches to the wrong branch when configured on form criteria

Study Designers: Currently, the visit branches that you configure using form criteria work as expected. Previously, at times, visits in a branch were not displayed for you as expected when they were configured on form criteria.

For example, if a subject answers a question such as "*Do you want to continue with the same treatment?*" with "*No*," they will be moved to the appropriate visit branch that you configured.

(Issue **35274867**)

Integrations

ODM Metadata API v2.0 failing due to classnotfound exception

Now, the call is successful when using the ODM Metadata API version 2. Previously, the call would fail due to the absence of a specific class file.

Retracted workaround: None. (Issue **35217778**)

Oracle Clinical One Analytics

Two active records showing for the same form in the Subject Forms dataset

The Subject Forms dataset now shows a single record for each form where the site has been renamed. Previously, entering the data in one of the forms, renaming the site and subsequently entering data in a second form would lead to the Subject Forms dataset to feature two records for each form, one in a **Completed** status and another in a **Scheduled** status.

(Issue **35281545**)

Reports, archives, extracts, and notifications

Error in generating a Kit Reconciliation report in a CSV format

Users can now generate a Kit Reconciliation report in CSV format. Previously, users with the permission to 'Run the Kit Reconciliation report in a CSV format' were unable to successfully generate a Kit Reconciliation Report in CSV format if they are not assigned to the appropriate depot, as a user.

Issue (**35369692**)

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Site users receive pending shipment notifications originating from another site (former Known Issue)

Site users: Shipment notifications from sites now activate only when selected. Previously, we reported that site users receive pending shipment notifications originating from a site other than their own. Users should only receive these notifications for the sites they are assigned to.

Retracted workaround: None

Issue (**35356232**)

The User Assignment and User Assignment by site reports do not generate for specific studies and tenants

Site users: Now, generating User Assignment and User Assignment by Site reports work as expected. Previously, specific studies at your organization experienced errors and delays when attempting to generate either the User Assignment or User Assignment by Site report.

Issue (**35299270**)

The Subject Data Extract has columns in the incorrect order

Data managers and statisticians: Now, the Subject Data Extract displays form-related data in the appropriate order without any duplicate data. Previously, the extract displayed data in an unexpected way, with duplicate data being present. This issue is now fixed after introducing a new parameter in the logic of the extract called *baseStudy Version*. This field ensures that any forms you add in between study versions are properly displayed in the extract.

Issue (**35143048**)

Subject Queries report cannot generate for complex studies when the Audit Trail is on

Now, generating the Subject Queries report for complex studies works as expected. Previously, when users generated the Subject Queries report for complex studies, the action would fail when the option for the Audit Trail was on. Some users received an error message with "Date couldn't be parsed successfully', some would not receive any notification of the incomplete task.

Issue (**34159843**)

The Subject Data Extract is missing data from lab forms

Data managers and statisticians: Now, in the Subject Data Extract, you can see all of the data that was collected in a lab form, including the data collected through questions in the flat section (Questions Before the Table). For example, data collected for the Sample Collection Date and the Fasting questions are included in the extract, as expected. Previously, any data that was collected for questions in the flat section of a lab form was not included in the Subject Data Extract.

> **Note**
>
> The previously unexpected behavior was observed when a site user collected data in the flat section as well as selecting a lab to associate with the lab form.

(Issue **35396396**)

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Study Design report generates without forms

Sponsor users: Now, all forms associated with the visits of a study version display appropriately in the Study Design report when run in the .pdf format. Previously, the .pdf file generated by running the Study Design report did not include all visits and their respective forms as expected. This issue occurred in all modes of a study: Draft, Testing, Training, and Production.

(Issue **35279146**)

Data related to form associations might be missing from the Subject Data Extract

Data managers and statisticians: Now, the data related to form associations in the Subject Data Extract within the Form Associations Dataset is appropriately displayed. Previously, you may have encountered the following issues:

- Values displayed for REPEATNUMBER or RREPEATNUMBER and SREPEATNUMBER were reversed.
- Values for SREPEATID or RSREPEATID might have been missing from the dataset.

Going forward, the following values are displayed:

- The two-section form number is displayed for SREPEATNUMBER or RSREPEATNUMBER.
- The two-section form repeating section row numbers are displayed for REPEATNUMBER or RREPEATNUMBER.
- For a two-section form where a repeating section row is linked, the UUID is displayed for SREPEATID.

Retracted workaround: None. (Issue: **35156289**)

Sites, labs, depots, settings, and user management

General slow performance of the Release Assessment Environment (RAE)
Now, any studies you might have in an Assessment Environment (RAE) will work as expected. Previously, some pages would not load, such as the login page, the General tab, a study's settings, or a subject's visit pages. As a user, you had to clean your cache or refresh the page to see an improvement in the environment's performance.

Issue (**35362448**)

Records for randomization lists are not loading in the Randomizations tab

Study designers: When accessing a study version in Production, users can now view the list of randomizations accordingly on the Randomizations tab. Previously, the list of randomizations would only load the first item, making it impossible to select a different randomization.

(Issue **35310223**)

Normal ranges are not loading for lab forms

Site users: Lab normal ranges now populate as expected when selecting a lab to associate with a lab form. Previously, lab normal ranges would not populate during a visit, even when a lab was associated to a lab form.

(Issue **35309668**)

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Study version title cannot be changed using Rename

Study designers: You can now rename study versions in the Edit Study panel. Previously, you could not interact with the name of the study version even when selecting Rename.

(Issue **35285490**)

Site users and subject data

Subject number sequences are inconsistent in a study

Study managers: Now, when you add subjects from InForm in your study and add subjects through Oracle Clinical One Platform, too, the sequence numbers of your subjects are displayed as you configure them. For example, if all subjects added through Oracle InForm follow the numbering pattern starting with 0001, the subjects you then add through Clinical One will follow the new numbering pattern you configured (starting with 9001). Previously, after making this change in the subject number sequence, you may have noticed that any subsequent subjects you added through Oracle Clinical One Platform used the old subject number format and not the new one you specified, instead.

Issue (**35430907**)

A closed query automatically reopens without a data change

Site users: Now, a query closed manually remains closed even after navigating to the next visit, entering the visit date, then returning to the visit where the query was closed. Previously, when the user navigated back to the previous visit, the query status Re-opened was displayed.

Retracted workaround: Create a report to identify the impacted queries and manually close them before a site user can answer them. Issue (**35062639**)

Site users are unable to save a form associated with a new study version after clearing and reentering data

Site users: Now, you can save a form associated with a new study version after clearing data entered in the previous version, then entering data for the new version. Previously, you would encounter an error when trying to save the form..

Retracted workaround: None. (Issue **35155305**)

Reason for undoing a screen failure is displayed for a randomization visit (former known issue)

Site users: Now, when you undo screen fail for a subject, followed by randomization, the reason captured for the randomization visit displays correctly.

Previously, undo screen failure followed by randomization resulted in the reason for undo screen failure showing for the randomization visit. This also affected how data was displayed in Oracle Clinical One Analytics datasets.

Retracted workaround: None. (Issue **34491558**)

Unable to skip an optional visit after clearing the visit date

Site users: With the appropriate permissions, you can now skip an optional visit after clearing the visit date. Previously, you were presented with the following message after clearing the visit date: You cannot skip the <visit_name> visit.

Retracted workaround: None. (Issue **35170613**)

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Rest API updates

See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs for 23.1, available upon the Production release.

The following new service has been added:

- Library

The following services have been updated:

- Data Action
- Data Hub
- Data Capture
- Designer
- Notifications
- Query
- Randomization and Supplies
- Rules
- Rule Designer
- Users, Permissions and Roles

Library

Change	Method	Endpoint
New	GET	/v1.0/libraryUses/studies/{studyId}/versions/{studyVersion}

Data Action

Change	Method	Endpoint
New	PUT	/v1.0/studies/{studyId}/{mode}/unsign-unverifyforitem
	POST	/v2.0/studies/{studyId}/{mode}/cleardatacheck/{scope}

Data Hub

Change	Method	Endpoint
New	GET	/v3.0/studies/{studyId}/{mode}/odm/metadata

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Change	Method	Endpoint
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries
	GET	/v5.0/studies/{studyId}/{mode}/odm/clinicalData/blinded
	GET	/v5.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded
	POST	/v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems

Data Capture

Change	Method	Endpoint
New	PUT	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/codeview
	GET	/v4.0/studies/{studyId}/{mode}/subjects/history/all
	PUT	/v4.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v4.0/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak
	GET	/v5.0/studies/{studyId}/{mode}/subjects/{subjectId}
	GET	/v8.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
Deprecated	POST	/v2.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/subject/{subjectId}/code/{code}/orgId/{orgId}

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Designer

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/cloneSystemCodelist
	POST	/v1.0/studies/{studyId}/forms/formitems
	POST	/v1.0/studies/{studyId}/forms/{formId}/choiceoptions
	GET	/v1.0/studies/{studyId}/forms/{formId}/formitems
	POST	/v1.0/studies/{studyId}/hasRandomization
	GET	/v1.0/studies/{studyId}/{mode}/forms
	GET	/v1.0/studies/{studyId}/{mode}/forms/{formId}/visits
	GET	/v5.0/studies/{studyId}/studyversionobjects
	POST	/v7.0/studies/{studyId}/studyDesign/paginated

Notifications

Change	Method	Endpoint
New	POST	/v5.0/studies/{studyId}/{mode}/notificationlog

Query

Change	Method	Endpoint
Deprecated	GET	/v1.0/studies/{studyId}/{mode}/queries/queryTable

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Change	Method	Endpoint
	GET	/v1.0/studies/{studyId}/{mode}/queries/state
	PUT	/v1.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate
	PUT	/v2.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v2.0/studies/{studyId}/{mode}/queries/{queryId}/delete
	GET	/v2.0/studies/{studyId}/{mode}/queryDetails
	GET	/v3.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v3.0/studies/{studyId}/{mode}/queries/candidate
	POST	/v3.0/studies/{studyId}/{mode}/queries/open
	GET	/v3.0/studies/{studyId}/{mode}/queryDetails
	POST	/v3.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v4.0/studies/{studyId}/{mode}/openQueryDetails
	GET	/v4.0/studies/{studyId}/{mode}/queries/{queryId}
	PUT	/v4.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v4.0/studies/{studyId}/{mode}/queries/{queryId}/open

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Change	Method	Endpoint
	POST	/v4.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v5.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v5.0/studies/{studyId}/{mode}/queries/candidate
	POST	/v5.0/studies/{studyId}/{mode}/queries/open
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/delete
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v5.0/studies/{studyId}/{mode}/queryDetails
	POST	/v5.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v6.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v6.0/studies/{studyId}/{mode}/queries/candidate
	POST	/v6.0/studies/{studyId}/{mode}/queries/open
	GET	/v6.0/studies/{studyId}/{mode}/queries/{queryId}

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Change	Method	Endpoint
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/delete
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v6.0/studies/{studyId}/{mode}/queryDetails
	POST	/v6.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v7.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v7.0/studies/{studyId}/{mode}/queries/open
	GET	/v7.0/studies/{studyId}/{mode}/queries/{queryId}
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v7.0/studies/{studyId}/{mode}/queryDetails
	POST	/v7.0/studies/{studyId}/{mode}/report/{reportName}

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Randomization and Supplies

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/reports/blindedrandreport
	GET	/v2.0/studies/{studyId}/{mode}/kits/{inventoryId}/historyById
	POST	/v2.0/studies/{studyId}/{mode}/reports/kits/blindedchainofcustody
	POST	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/quarantined
	POST	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/received
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/historyById
	PUT	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits
	GET	/v4.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	PUT	/v4.0/studies/{studyId}/{mode}/inventory/kits
	POST	/v4.0/studies/{studyId}/{mode}/inventory/kits/audit
	PUT	/v4.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId}
	GET	/v5.0/studies/{studyId}/{mode}/orders
	GET	/v5.0/studies/{studyId}/{mode}/orders/{shipmentId}

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Change	Method	Endpoint
	GET	/v6.0/studies/{studyId}/{mode}/inventory/kit-types
	POST	/v6.0/studies/{studyId}/{mode}/reports/kits/chainofcustody
	PUT	/v9.0/studies/{studyId}/{mode}/supply/settings

Rules

Change	Method	Endpoint
Deprecated	PUT	/v1.0/studies/{studyId}/{mode}/jobStatus
	PUT	/v2.0/studies/{studyId}/{mode}/deleteform

Rule Designer

Change	Method	Endpoint
Deprecated	PUT	/v1.0/rule/studies/{studyId}/bulkcopy
	POST	/v1.0/rule/studies/{studyId}/copyrules
	PUT	/v1.0/rule/studies/{studyId}/{mode}/bulkupdate
	GET	/v1.0/rule/studies/{studyId}/{mode}/item/{itemId}
	GET	/v1.0/rule/studies/{studyId}/{mode}/propertyType/{propertyType}
	GET	/v1.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId}

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Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/report/{reportName}
	PUT	/v2.0/rule/studies/{studyId}/bulkcopy
	PUT	/v2.0/rule/studies/{studyId}/{mode}/bulkupdate
	GET	/v2.0/rule/studies/{studyId}/{mode}/item/{itemId}
	GET	/v2.0/rule/studies/{studyId}/{mode}/propertyType/{propertyType}
	GET	/v2.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId}
	POST	/v2.0/studies/{studyId}/{mode}/report/{reportName}
	PUT	/v3.0/rule/studies/{studyId}/{mode}/bulkupdate
	POST	/v3.0/studies/{studyId}/{mode}/report/{reportName}
	POST	/v4.0/studies/{studyId}/{mode}/report/{reportName}

Users, Permissions and Roles

Change	Method	Endpoint
New	GET	v1.0/userinfo/bulk

- Rest API patch updates
  See the newly added endpoints of the Oracle Clinical One Platform APIs for 23.1.1, available upon the Production release.

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Rest API patch updates

See the newly added endpoints of the Oracle Clinical One Platform APIs for 23.1.1, available upon the Production release.

The following services have been updated:

- Data Hub
- Library

Data Hub

Change	Method	Endpoint
New	POST	/v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Library

Change	Method	Endpoint
New	GET	/v1.0/libraryObjects/{libraryId}
	PUT	/v1.0/libraryObjects/{libraryId}
	DELETE	/v1.0/libraryObjects/{libraryId}
	POST	/v1.0/libraryObjects/bulkUpdate
	DELETE	/v1.0/libraryUses
	GET	/v1.0/libraryUses/{libraryId}

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Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Oracle Clinical One Analytics also known as Data Hub

- Updates to a signature's status are included in the application's reports and datasets. Information related to affidavits is not included in the application's reports and datasets. This capability will be introduced in a future release.
- Data associated with the new **Temperature Excursion Number** field is not displayed in any reports or datasets. This capability will be introduced in a future release.
- Data related to screen failure visits is displayed in the application's reports and datasets, as expected. **Failure dates** specified by a user and updates to the **Reason for Change** field (for screen failures) will not be displayed in any reports or datasets. Instead, if **Screen Failure Visit** is enabled, the system date specified when a screen failure occurs will be displayed.

Oracle Life Sciences Data Management Workbench

- Data associated with the new **Temperature Excursion Number** field is not displayed in Oracle DMW. This capability will be introduced in a future release.
- Data associated with the new screen failure visit is displayed in Oracle DMW, as expected. **Failure dates** specified by a user and updates to the **Reason for Change** field (for screen failures) will not be displayed in the application. Instead, the system date specified when a screen failure occurs will be integrated.

Expected metadata changes in Oracle Life Sciences Data Management Workbench

The following updates to metadata in Oracle DMW are introduced in this release:

View/Table	Column	Variation Details
DHVW_SUBJECT_VISITS_V1	ADDRESS_COUNTRY	Attribute differences: Length (100:4000)

Clinical One Digital Gateway

- Data associated with the new **Temperature Excursion Number** field is currently not supported in Clinical One Digital Gateway. This capability will be introduced in a future release.
- Screen failure visit dates entered by users are currently not supported and will not be integrated. Only system generated failure dates are integrated.
- While you can include screen failure visits in the new study design, data related to these visits for integration configurations is not supported at this time. This capability will be introduced in a future release.

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Clinical One Cloud Service and Clinical One Digital Gateway 22.4 (March 2023)

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs for 22.4, available upon the Production release.

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.4 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway application**.

Table 12-1 Patch log

Release Number	Release Date	Notes
Release 22.4.1.1	17-April-2023	For this release, we fixed an issue related to data collection and visit branching. For more information see: • Issue **35037630** in Fixed issues for forms, visits, and rules.
Release 22.4.1	28-March-2023	For this release, we fixed two issues related to custom JavaScript rules and subject data. For more information see: • Issue **34775012** in Forms, visits, and rules. • Issue **35171156** in Fixed issues for site users and subject data.

What's new

- Data Collection
- Integrations
- Reporting, archives and analytics
- Randomization and Trial Supply Management
- Rules management

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- User experience
- Data collection
- Data review
- Integrations
- Notifications
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management
- Study design
- User experience
- User management
- Study design
- Data collection
- Randomization and trial supply management
- Integrations
- Reporting, archives, and analytics
- Notifications
- Other enhancements

Study design

- Enhancements to code lists
  Thanks to these latest enhancements, study designers and code list managers can now make better use of custom code lists and system default code lists.

Enhancements to code lists

Thanks to these latest enhancements, study designers and code list managers can now make better use of custom code lists and system default code lists.

Details for study designers and code list managers

Whether you're a study designer or code list manager, here's what you can now do with code lists:

- You can import a custom code list into the application in a CSV or XLSX format. The imported code list file must contain a maximum of 1000 rows and a minimum of 1 row.
- To import a code list, you can download the template for code lists from the application.
- You can download any code list in an XLSX format only.
- In the application, the icon indicating that a value in the code list is hidden has changed from an X to a new symbol ( ).
- Only custom code lists can be imported at a study level and at a global level (for all studies at your organization). If you import a custom code list at a global level that code list is not replicated at the study level. If you want the same changes to appear at the study level, you must manually update the custom code list for a specific study.

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- You can also copy a custom code list and rename it at both a global level (for all studies at your organization) and at a study level (for a single study). Code list titles must be unique within the study or the library.

Other enhancements

Code lists that are tagged with the Lab Test tag now dynamically add an optional user-entered column to include the Logical Observation Identifiers Names and Codes (LOINC).

Data collection

- Link two-section form data
  Study designers can now add a Link & Show Form rule to either or both sections of a two-section form and this form type can be both the source and the target of the association.
- Enhancements to Source Data Verification (SDV)
  Sponsor users can now perform Source Data Verification (SDV) more efficiently on questions, forms, and visits using an enhanced status filter, a new status icon, as well as other changes to the behavior of the SDV functionality.

Link two-section form data

Study designers can now add a Link & Show Form rule to either or both sections of a two-section form and this form type can be both the source and the target of the association.

Site users can now link two-section form data, further enhancing 's ability to recognize relationships between collected data. For example, site users can link data from a two-section form with other data from other repeating and two-section forms for the purpose of collecting relationships between medical history and medication data. Associating the information on two-section forms can make it easier to recognize possible relationships between all types of collected data, including study drugs, adverse reactions and concomitant medications, and the evaluation of target lesions.

These associations can be made in the same way as existing repeating form associations, via a question, from or to the two-section forms to provide cross-references between the form instances or individual rows of repeating data. In this way, when users display the details of one associated form, they can easily view the details of any instances of the other associated form.

If your study is set up with this feature, when the site user answers the question that creates the association, a window appears directly below the question. It is in this window where the user is presented options to create the correct links. A form can have zero-to-many associations, for example, an instance of concomitant medication can be linked to an adverse event and also to a medical condition.

> **Note**
>
> Only two-section and simple repeating forms are allowed to be the source of an association. Flat forms, however, can be the target of an association. In this way, a user could link data from a flat form (for example, vital signs) back to a two-section or repeating form.

Details for study designers

If you need to allow site users to link two-section form data, you must know that you can now create form associations for either sections (Questions Before the Table or Questions in the

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Table) for a two-section form. You can configure two-section form associations by using the Link & Show Form predefined rule.

You can find additional information in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

If you need to link forms, here's what's new for you:

- When you make an answer selection that determines whether the rule will show the associated form, a window appears which contains all possible instances of forms or records that have been associated in study design.

  > **Note**
  >
  > Data must be entered in the linked form for it to appear in the associated form window. If data has not yet been entered, it can be linked after data entry is complete.

- A new filter appears, prompting you to link the forms depending on the form and visit. An additional **Form Instance** filter is displayed if the target of the form association is a two-section form.
- A **Hide** or **Show** feature appears in the form window to either collapse or expand the associated form. When compressing the form, users can see a short summary of the links created.
- When a two-section form is the target, it displays three drop-down options to: **Select a Form**, **Visit/ Event**, and **Form Instance**. When the repeating and flat forms are the target, it will show two filters: **Design Form** and **Visit**.
- The **Associated Forms** drop-down displays all of the forms that you can link to the form that you're currently in (for example: repeating form, two-section form, and flat forms).
- If more than one form is available to be linked to the parent form, then forms are displayed in alphabetical order in the **Associated Forms** drop-down.
- If a flat form is being linked then the only option for associating data is to turn the **Link all data** toggle on.
- If a two-section form is being linked, then you have the option of linking both the flat and repeating section of form by turning the **Link all data** toggle on, or you can choose to link a specific row or specific rows, only.

You can find additional information in the *Site User Guide* after the Release Assessment Environment (RAE) upgrade.

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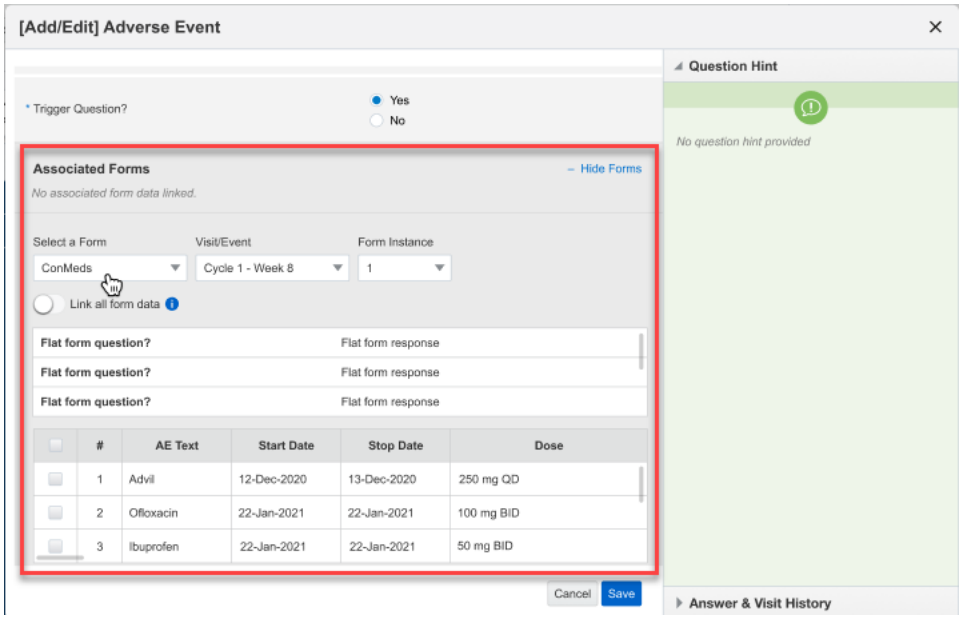
Figure 12-1 How a site user sees the new updates for linking two-section forms



Already working in a live study?

As soon as the release upgrade completes, as a study designer, you can begin creating form associations for two-section forms. After you update the study's design and the sponsor team tests and moves the updated study version to Testing and Approved, a site user can begin linking two-section forms.

Enhancements to Source Data Verification (SDV)

Sponsor users can now perform Source Data Verification (SDV) more efficiently on questions, forms, and visits using an enhanced status filter, a new status icon, as well as other changes to the behavior of the SDV functionality.

Adjustments to the SDV filter

The SDV status filter has been adjusted to make it easier for you to spot visits with outstanding SDV:

- Visits which have a status of **Not Started** are not included in the results when filtering for the status **Ready to Verify**.
- Existing subjects continue to function as they did prior to the upgrade: visits which have not been verified will not have a status icon, regardless of whether the subject has been selected for SDV. The status icons associated with all visits for a subject will be refreshed once one of the following actions is performed:
  - A user accesses a visit.
  - At least one question is unverified due to data change.
  - A subject previously with a status of **No SDV Required** is selected for inclusion in the SDV pool. For more information, see How do the source data verification settings work together in a strategy?.

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New icons in the Subjects panel

Two new icons have been added, making it easy for you to identify items that require SDV:

- A new **Verification Required** icon (

) has been added to help identify visits with outstanding SDV.
- A new **Targeted SDV** icon (

) has been added to help identify questions which have been marked as Critical Variables, for subjects which have not been selected for the SDV pool. For more information about how subjects are selected for targeted SDV, see How are subjects randomly selected for targeted source data verification?.

Already working in a live study?

As soon as the upgrade is complete, if your study uses SDV strategies, you can start making use of these new enhancements. You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- Create titrations with calculated doses
  Study designers can now create titrations that include kits with calculated doses.
- Screening and randomization limits by site
  Study managers can now set limits for sites and report on the defined limits.

Create titrations with calculated doses

Study designers can now create titrations that include kits with calculated doses.

With the introduction of this feature, studies with dosing calculations can now allow site users to adjust dosage in dispensation visits. Titration is defined in study design and it can now include both standard kit types and kits with calculated doses.

Details for study designers

When you create titrations, here's what's new for you:

- The **Create Kit Type Titration** button is now called **Create Titration**.
- On the Create Titration dialog, you can add standard kit types or kits with calculated doses. For kit types that contain calculated doses, a sub-menu is displayed so you can select the exact dose within the kit type that should be used to titrate.

> **Note**
>
> You must specify a dose for every column in a titration: Starting Kits, Down Titrate, Maintain, and Up Titrate.

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- On the Settings page in the Create Titration dialog, when you specify the Minimum Time Between Dose Changes to either up or down titration, a checkbox becomes available to enable exceptions. These exceptions allow you to define overrides for the defined time between dose changes.
- If you enable exceptions, a new step in the Create Titration dialog allows to configure exceptions, one step for Up Titration Exceptions and another one for Down Titration Exceptions. On these new sections you will enter a new Minimum Time Between Dose Change for a particular starting and ending dose combination.
- On the Kits tab, when you hover over a titration with calculated doses, you can view the exact doses that are selected for all titration options.
- A calculated dose that is used in a titration can be edited but not removed. If you make an update, the system informs you of the impact of your changes on existing titrations within the study. Also, when a form or visit that is used in the design of a calculated dose is removed from the study, that calculated dose is highlighted as broken ( ) within both the kit type and the titration.

To create titrations with alculated doses in an existing study, you must create the new titration and add it to the dispensation schedule in a draft version and then make the updated study version live. For step-by-step instructions, see Update the way that subjects titrate during the study conduct period.

You can find additional information in the *Study Designer User Guide* after the Release Assessment Environment upgrade.

Details for site users

There is no impact on the dispensation process, besides you gaining the ability to titrate kits with calculated doses. The process to complete a dispensation visit with dose changes has not changed either. For more details on how to dispense kits with dosage titration, see Complete a dispensation visit with dose changes.

Screening and randomization limits by site

Study managers can now set limits for sites and report on the defined limits.

With this new feature, study managers can control the number of screened and randomized subjects by site, adding different limits for each site even after the study is live. These limits can be set in all three modes: Production, Testing, and Training. When any of these configured limits are reached during the study, users with the *Receive Study Limits Notifications* permission receive an alert.

Details for study managers

If you want to manage site limits, here's what's new for you:

- On the Sites & Labs tab, a new **Show limits** toggle appears. You can turn it on to display the Screening Limits and Randomization Limits columns. If your study does not include randomization, limits defined for screening will be used for enrollment.
- On the Screening Limits and Randomization limits column, you can enter a number to define the limits for each site included in your study. These limits will override values indicated on the study settings, if any.
- You can leave limits undefined or with a null value in a study and this will not affect the study's development.

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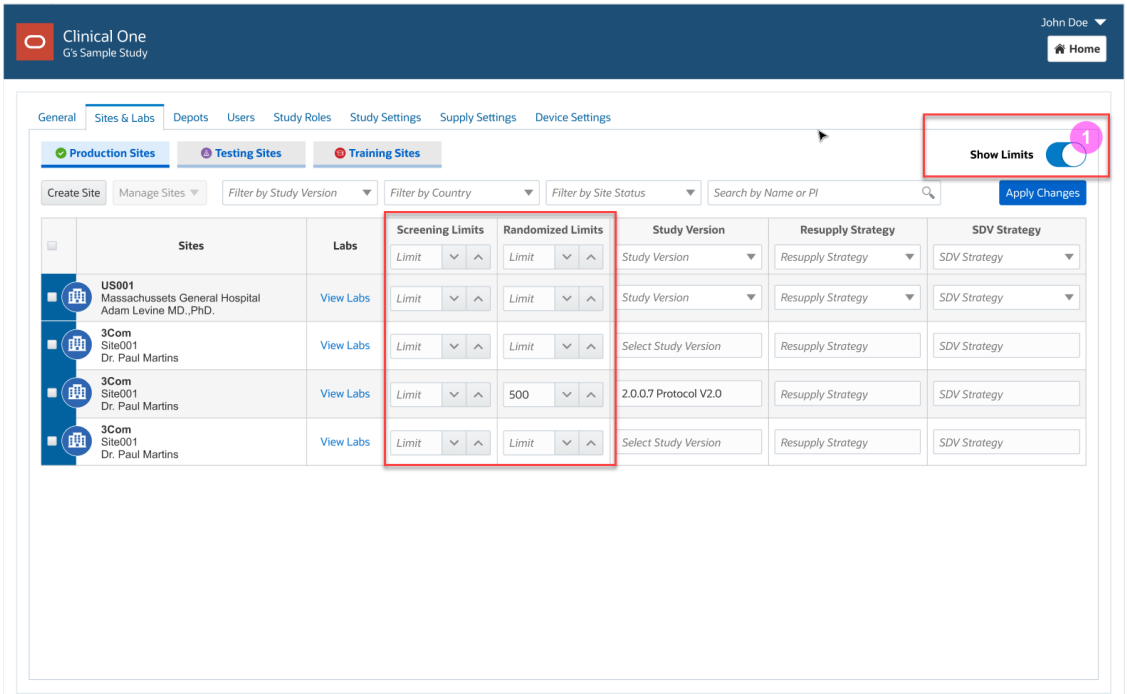
Figure 12-2 Changes in the Sites & Labs tab to define screening and randomization limits by site



You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Reporting updates

Within the Study Enrollment report, you can find a new section called **Site Enrollment** that contains the details about site limits. New columns for each site will show as Screening limit and Randomization limit.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment upgrade.

Integrations

- Clinical One Digital Gateway productized integrations now support visit date change
- Supply integration notification enhancement
- TMMCS standard integrations through Clinical One Digital Gateway now support password rotation
- Include commas in code lists for your integration configuration file
  For an integration between Oracle InForm and Oracle Argus Safety, commas are now supported for code lists in your integration configuration through Clinical One Digital Gateway.

Clinical One Digital Gateway productized integrations now support visit date change

Clear visit date is now supported for Clinical One Cloud Service to Oracle InForm and other Electronic Data Capture (EDC) productized integrations. For more information, see the Digital Gateway User Guide - EDC Systems.

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Supply integration notification enhancement

When block number is used instead of kit number for supply integrations, the **Shipment request** notification now includes the total number of blocks shipped and the unique block numbers; kit details do not appear in the notification. For more information, see Shipment request notification.

TMMCS standard integrations through Clinical One Digital Gateway now support password rotation

Password rotation is now supported for the Trial Management and Monitoring Cloud Service (TMMCS) standard integration offering.

> **Note**
>
> This enhancement is not applicable for non-standard TMMCS integrations.

You can find additional information in the *Digital Gateway User Guide* after the Release Assessment Environment upgrade.

Include commas in code lists for your integration configuration file

For an integration between Oracle InForm and Oracle Argus Safety, commas are now supported for code lists in your integration configuration through Clinical One Digital Gateway.

How does this new enhancement work?

When a code list value contains a comma, the value is properly mapped in Clinical One Digital Gateway without generating an error. The new mapping in the integration configuration file supports all existing code list requirements.

For example, a value of "KOREA, REPUBLIC OF" will be mapped to a target value of "KR". The string in the integration file will look as displayed in the example below.

```
<Entry Source="KOREA, REPUBLIC OF" Target="KR" Description="Republic of
Korea"/>
```

How can I update my current integrations?

If your integration must send code list values that contain commas, you must update the integration file to include the new configuration for code list values with commas. The existing integration should be first disabled and then you can upload the new integration template.

Additionally, with the implementation of this code list, the default code list mapper becomes deprecated. Future integrations you might configure should begin using the new code list mapper that support commas.

You can find additional information in the *Digital Gateway User Guide* after the Release Assessment Environment (RAE) upgrade.

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Reporting, archives, and analytics

- New Randomization List (Blinded) report
  With the appropriate permissions, you can now run a blinded version of the Randomization List report.
- Oracle CRF Submit archives and reports
  The following details provide an overview of enhancements for Oracle CRF Submit archives and reports.
- Enhancements to Oracle Clinical One Analytics

New Randomization List (Blinded) report

With the appropriate permissions, you can now run a blinded version of the Randomization List report.

Before working with this feature

This report is available to users assigned the *Run the Blinded Randomization Report* permission. For more information about this permission, see Descriptions of permissions in Oracle Clinical One Platform.

Details for sponsor users and CRAs

The new Randomization List (Blinded) report includes the same columns as the Randomization List (Unblinded) report, with the exception of the *Treatment Arm ID* and *Treatment Arm columns*. This is to avoid unblinding.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Oracle CRF Submit archives and reports

The following details provide an overview of enhancements for Oracle CRF Submit archives and reports.

Time only and partial time questions are now supported in PDF output

The ability to capture time only and partial time using a Date/Time question was introduced in Clinical One Cloud Service 22.3. Starting with this relase, the following enhancements are introduced:

- **Blank PDF** output includes time only and partial time questions as active controls when they are included in your study design.
- **Subject PDF** output includes time only and partial time questions and associated data when they are included in your study design.

Include Randomization and Trial Supply Management (RTSM) data in PDF output

A new setting called **Include RTSM Data** has been added to the advanced tab for Submission, Archival (both sponsor and site), and Custom PDF requests. Enable this setting to include randomization and dispensing information for subjects at your site in the PDF output.

You can find additional information in the *Reporting Guide* after the Release Assessment Environment upgrade.

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Subject number changes are now supported in the user interface and output files

Previously, the updated subject number was displayed in the user interface for the **Include In Report**, **Select Subjects**, **Subjects** drop-down and subsequently in the output files even if the **Select Date/Time** entered was prior to the subject number change.

Now, the subject number displayed is based on the **As of Date** setting when creating requests.

- If **Now** is selected, or if a date is entered that is after the update, the **Subjects** drop-down displays the updated subject number which is reflected in the output files.
- If a date is entered for **Select Date/Time** that is prior to the subject number change, the user interface and output files include the original subject number.

Enhancements to Oracle Clinical One Analytics

> **Tip**
>
> Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study, or just starting to work with analytics, reach out to your Oracle point of contact to learn more about these new dashboards.

Analyze missing form and visit data in dashboards

Use standard dashboard templates to get a holistic view of study data. The following interactive reports have been added to the CRA and Data Manager dashboard templates:

- Missing Forms Report
- Missing Visits Report

These new reports provide key performance indicators about forms and visits that have not yet been started. They can help CRAs and data managers to plan workload distribution as well as to schedule audit and monitoring visits. In these visits, the study team may provide training for site users to conduct a particular visit or collect data in a particular form, hence reducing the occurrence of missing visits and forms.

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard.

You can find additional information about these new reports in the *Analytics User Guide* after the Release Assessment Environment upgrade.

Updates to support subject number modification

To support the recently introduced feature that allows for subject number change, a new data element has been added to the subject folder for all datasets in Oracle Clinical One Analytics.

The current number assigned to a subject in the system is contained in the existing data element for `SUBJECT_NUMER`. When a subject number change is applied, the number that was assigned to the subject before the change occurred is available in the new data element `PREV_SUBJECT_NUMBER`. This newly added field allows you to keep track of updates to a subject number and to maintain study data integrity.

You can find additional information about dataset descriptions and their data elements in the *Analytics User Guide* after the Release Assessment Environment upgrade.

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Notifications

- New enrollment notifications
  New enrollment notifications can be sent to sponsor and site users to enhance the visibility of the first subject activity within the study. Notification permissions need to be updated in order to receive them.
- Other new notifications
  Other notifications in the applications are now enhanced to ensure that users receive the latest updates related to depot inventories.

New enrollment notifications

New enrollment notifications can be sent to sponsor and site users to enhance the visibility of the first subject activity within the study. Notification permissions need to be updated in order to receive them.

The following randomization and screening notifications are being introduced:

- First subject screened for a study notification
- First subject screened for a site notification
- First subject randomized for a study notification
- First subject randomized for a site notification

To receive the new notifications, user administrators must assign the *Receive the Study Limits Notifications* permission to the appropriate users. This permission allows users to receive both notification types, first subject screened and first subject randomized, only for the sites that they're assigned to.

For these notification to be sent out to the appropriate users, study managers must also configure the corresponding settings in the study's settings.

Details for study managers

Here's what you need to do if you want users to receive the new enrollment notifications:

- The enrollment settings section on the Study Settings tab now includes new columns allowing you to activate notifications for **First Subject Screened** and **First Subject Randomized** for either a study or a site.
- By selecting a checkbox, you activate the notification for that specific limit. For example, if you select First Screened Notification for the Study Total, then users with the appropriate permissions will receive a First Subject Screened notification when a site user has screened the first subject in the entire study.
- Notification activation is only required once per site or study.
- If a screened subject is transferred to another site with no screened subjects, a notification will not be sent.

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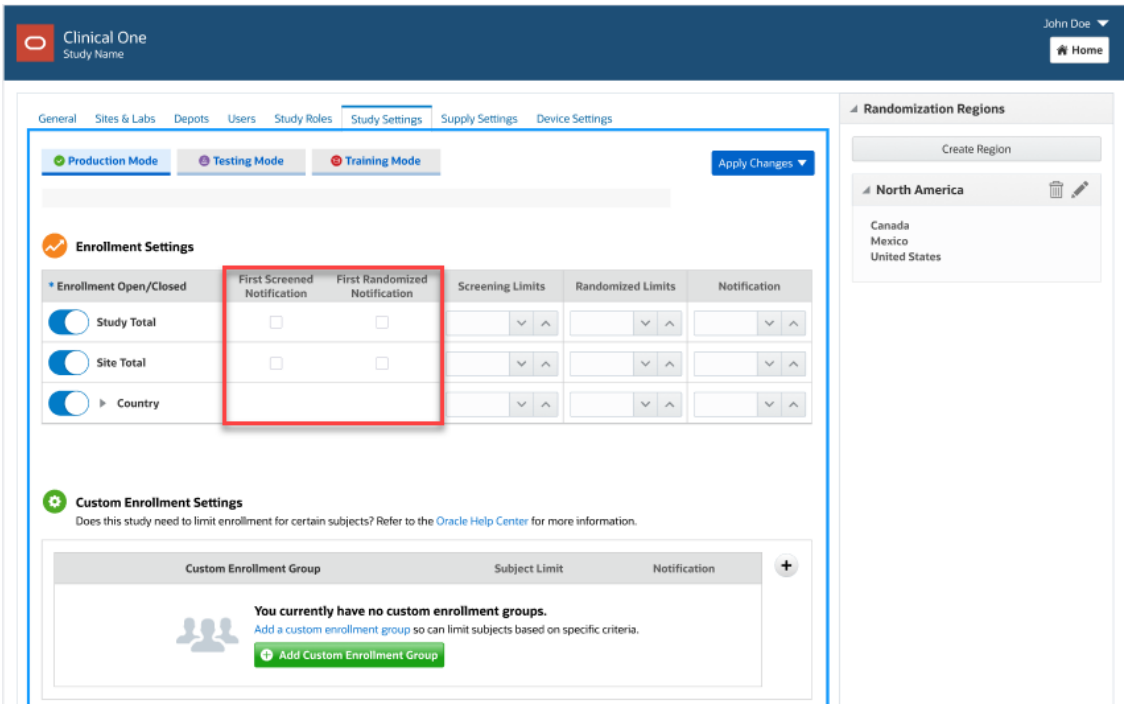
Figure 12-3 New study notification



You can find additional information on each study enrollment notification in the *Notifications and Permissions Guide* after the Release Assessment Environment upgrade.

Reporting updates

In the Study Design report, the following new columns are introduced in the Study Settings section:

- Notify when first subject screened
- Notify when first subject randomized
- Last modified
- Last modified user
- Value

In the Study Enrollment report, the following new columns are added to the **General Enrollment** and **Audit** sections:

- First subject screened
- First subject randomized

You can find additional information in the *Reporting Guide* after the Release Assessment Environment upgrade.

Other new notifications

Other notifications in the applications are now enhanced to ensure that users receive the latest updates related to depot inventories.

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When you add a depot, in the **Inventory Kit Level Alert** column, you have the option to enter a number of kits that, when reached, now generates a notification for low supplies at a depot.

The notification connects to the supplies monitoring and is intended to alert clinical supplies managers that the depot runs low on supplies. The alert will activate when the resupply algorithm triggers. Until inventory recharges, the notification will send every time that drug management runs.

To receive these notifications, assign the *Receive Notification of Depot Shipments* permission to anyone who wants to receive this notification. Users receive notifications only for the depots that they are assigned to.

More details on each study enrollment notification will be featured in the *Notifications and Permissions Guide*.

Other enhancements

New Product Verification Pack (PVP) updates!

We've made it easier for you to track any changes that we make to the Product Verification Pack (PVP) for each minor release. If you want to know more each change, see Product Verification Pack (PVP) updates.

User experience enhancements

- When collecting data, form fields no longer auto-populate based on previously entered data. Clinical One Cloud Service now suppresses any text auto-fill settings your browser may have.

Fixed issues

- All users
- Code lists
- Facilities, settings, and user management
- Forms, visits, and rules
- Oracle Clinical One Analytics
- Integrations
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

Various security updates

For this release, we made also made various security updates.

Study ID can't be longer than 50 characters (former known issue)

Study designers: Now, the limit of 64 characters for a study's ID works as expected. Even if your study's ID exceeds 50 characters (but doesn't contain more than 64 characters), your study can be successfully activated.

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Retracted workaround: You no longer have to make sure that a study's ID is less than 50 characters when the maximum number of characters is 64. (Issue **30147429**)

Training video is unexpectedly displayed for users who can skip visits

From now on, any users who is assigned the Skip Visits permission will no longer see the Dispense and Replace Kits video training within the application. Previously, users who were assigned this specific permission had to complete the Dispense and Replace Kits video training, although their work did not require that. (Issue **34955265**)

Japanese users see complete product training in English (former known issue)

All Japanese users: Now, when you first sign in Clinical One Cloud Service, as a Japanese user,you can see description of your in-product training displayed in Japanese, as expected. Previously, text surrounding your training was displayed in English.

Retracted workaround: You can continue updating your closed captions to Japanese, so the training videos are translated into Japanese. (Issue **32877184**)

Code lists

Remove Codelist option is displayed for manually entered answer options (former known issue)

Study designers: Now, in a form, when you create a question with radio buttons or checkboxes, or a drop-down question, you will no longer see the option to remove that code list even though the questions you entered were not part of a code list. This issue was only observed when a question's reference code was entered in lower case characters.

Retracted workaround: None. (Issue **34895176**)

Updating the EDCYearRange code list requires multiple renaming steps (former known issue)

Study designers: Now, you can add different code values and modify their labels in the EDCYearRange custom code list without running into any errors related to the values being duplicate in your studies. Previously, when you attempted to add more values to the custom code list, but with different labels, a validation error was displayed for each label stating that it’s not unique.

Retracted workaround: You no longer have to perform the workaround of updating your labels with different special characters so the application doesn't flag them as being duplicate. Initially, the following steps were required to work your way around this issue:

1. On the Code List tab, select the **EDCYearRange** code list.
2. Update the labels of the existing code values to **Minimum Year** and **Maximum Year**, respectively.
3. Add two new code values and update their labels to **Min_ Year** and **Max_ Year**, respectively.
4. Click **Save**.
5. Edit the last two added code values and remove the underscore (_) from the label.
6. Click **Save**.

(Issue **34783476**)

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Newly added custom code list values are not properly displayed in the Subject Data Extract

Data managers and statisticians: Now, for a live study version, when a study designer applies an update containing a new form with new custom code list values, those newly added custom code list values are properly displayed in the Subject Data Extract.

The following columns contain the correct custom code list values:

- Item: displays the Code value.
- Item_R: displays the Label value.
- Item_F: displays the Value.
- Item_D: displays the Code value.

Previously, the items listed above displayed the expected values randomly.

Retracted workaround: None. (Issue **34857896**)

Code list values are not displayed in the Subject Data Extract as expected (former known issue)

Data managers and statisticians: Now, the following Subject Data Extract columns contain the correct code list values for the code list option selected during data collection:

- Item_R (code list label);
- Item_F (code list value);
- And item_D (code list code).

Previously, the Subject Data Extract displayed incorrect or null values for a selected code list option. This issue impacted custom and system code lists differently and did not present itself in the report output in the same way. However, this fix addresses the problem for both system and custom code lists.

Retracted workaround: None (Issue **34769175**)

Facilities, settings, and user management

A subject's status is not updated to reflect source data verification (former known issue)

Clinical Research Associates (CRAs): Now, after you verify the appropriate fields that are marked for SDV, a subject's status is updated to Verified, as expected. Previously, this update did not occur even though you verified all of the fields that would consider the subject verified.

Retracted workaround: None. (Issue **33516395**)

Several issues occuring when attempting to assign new sites to a user

User administrators: Now, on the Users tab, you can assign a new site to a newly created or existing user and the application works as expected when you navigate details of a user's assigned sites. The following specific issues are now resolved on the Users tab and on the Sites & Labs tab:

- For a newly created user, you can see the newly created sites that you can assign to them.
- For an existing user, you can see the newly created sites when you want to modify their current site assignments.

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- When you select a user and expand the Assigned Sites side panel, all of their assigned sites in all study modes are displayed, as expected.
- On the Sites & Labs tab, when you scroll through the list of sites, you will notice that newly created sites that do not have an assigned study version are displayed, as expected.

(Issue **35068848**)

A custom study role with the appropriate permissions might not receive screening notifications

User administrators and global user managers: Now, a user who is assigned a custom study role with the *Receive the Subject Screening Notification* permission receives the appropriate notification whenever a subject is screened or fails screening for the sites that the user is assigned. Previously, even though a user's custom study role contained the appropriate permission, they did not receive the screening-related notification. (Issue **35111951**)

A depot's status tooltip is not fully translated to Japanese

Site administrators: Now, on the Depots tab, when you hover over the icon of a depot, you will notice that a depot's status is fully translated to Japanese in the tooltip. Previously, a depot's status tooltip was only partially translated to Japanese while some parts of the text were displayed in English.

This issue was observed when the application's preferred language was set to Japanese. (Issue **32893942**)

Freezing a row in a lab form through APIs does not work (former known issue)

Data managers and API developers: Now, you can successfully freeze a row in a completed lab form using an API endpoint. Previously, attempting to freeze a row in a completed lab form resulted in validation errors. The API endpoint used to test this Known Issue was the following: https://docs.oracle.com/en/industries/health-sciences/clinical-one/coapi/op-ec-dc-svc-rest-v3.0-studies-studyid-mode-dataelements-freeze-post.html

Retracted workaround: We recommend performing this task in the User Interface (UI) only. (Issue **34666440**)

A depot's status tooltip is partially translated to Japanese

Site administrators: Now, on the Depots tab, when you hover over a depot's status, the text displayed in the tooltip is fully translated to Japanese, as expected. Previously, the content in this tooltip was partially translated and there was text displayed in English. (Issue **32893942**)

> **Note**
>
> This issue occurred when the application's preferred language was set to Japanese.

Forms, visits, and rules

Subjects assigned to wrong branch visit

Study designers and rule developers: Now, the treatment arm assigned to a subject and the answer to a branching question determine a subject's subsequent visits. Previously, only the answer to a branching question determined the next visits, even when the subject was assigned to a treatment arm.

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Retracted workaround: None. (Issue **35037630**)

JavaScript custom rules may not work with Adverse Events (former known issue)

Study designers: Now, in a study's draft, you can configure a successful JavaScript rule for all questions in a form assigned to an Adverse Event. Previously, when a form contained many questions, configuring a custom rule for each question caused the API endpoint behind the rule to possibly fail.

Retracted workaround: Study designers are no longer discouraged from configuring custom rules for each question in a form, even if the form contains a high number of questions. (Issue **34775012**)

Study version issues can be encountered after moving a study version to the Approved container if the browser is closed prematurely (former known issue)

Study designers: Now, when you move a study version from the Testing container to the Approved container and you accidentally close your browser before this action is completed in the backend, this won't affect your study design anymore. Previously, if you closed your browser before the action was complete, you may have encountered issues with associating randomization lists to a study version or when randomizing a subject.

Retracted workaround: None. (Issue **34324333**)

Clearing a rule's variable determines the clearing of its target

Rule designers and testers: When a custom rule's variable is cleared, the rule's mechanism is updated to determine whether the target field should be cleared or updated. Previously, after a rule ran, its target field was automatically cleared every time a variable was cleared, as well. For example, if you cleared another question's answer in a form, and that question was used as variable in a Date/ Time helper function, the read-only Date/ Time field was also cleared. Instead, the target field should have been updated with the current date when the latest update in the form was performed. (Issue **34873328**)

Rule targets are not automatically updated for a DateTime rule

Rule designers and testers: Now, when a DateTime rule is configured for a Date/ Time field in a form, the target field of that rule is automatically updated whenever a data change occurs in the form. For example, if all fields in a form are completed, the rule automatically updates the Date/ Time field to the current date. If a field is left empty or cleared, the rule then clears the Date/ Time field, as well. Previously, the rule did not automatically refresh its target field. This issue occurred when the Date/ Time field was read-only. (Issue **34877289**)

An error occures for a custom rule built with the getCurrentCycle helper function

Rule designers and testers: Now, when you create a custom rule using the getCurrentCycle helper function, and its target is part of a two-section form, the rule is running as expected and no errors occur. Previously, the getCurrentCycle helper function returned the current event instance number of the rule variable, instead of the current event instance number of the rule target. (Issue **34956461**)

Automated query rules cannot run

Rule designers: Now, when you create, test, and then publish rules for automated queries, the rules work as expected. Previously, custom rules for automated queries, when published in a live study version, started failing although they passed the testing phase. (Issue **34869167**)

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The getDateDMTFormat () helper function is returning an incorrect time

Rule designers: Now, the getDateDMYFormat () helper function returns the time in the format of "HH::mm:ss", as expected. Previously, the time was displayed incorrectly using this helper function.

For example, if a site user entered the time as "10:10", the helper function would return a "10:10" value. If a site user entered the time as "10:00", the helper function would return a "10" value. Now, when a site user enters the time as "10:00", for example, the helper function returns a "10:00:00" value, counting the hour, the minutes, and the seconds. (Issue **34867905**)

The Rule Editor takes several minutes to load variables in a drop-down (former known issue)

Rule designers: Now, on the Rule Editor dialog, when you attempt to select a visit from the Variable drop-down,values in the drop-down load immediately, as expected. Previously, it took around 2.7 minutes for the variables to load in the drop-down. This used to be a performance issue caused by the high number of visits configured in a larger study.

Retracted workaround: None. (Issue **34789014**)

A validation rule for a partial date does not work (former known issue)

Study designers: Now, when you create a Date/ Time question with a Minimum Allowed Answer of YYYY and an On or After validation rule (specifying that the date must not be earlier than the year 2022), site users can complete that Date/ Time question without running into any issues.

Previously, because the validation rule used the date of its creation as the time reference, whenever a site user did not enter the complete date of when the validation rule was created, an error message was displayed in the form. This issue was fixed by modifying certain parameters in the backend of the application to ensure that site users can successfully complete a Date/Time question in this particular use case.

Retracted workaround: None. (Issue **34734551**)

Oracle Clinical One Analytics

A form's status is incorrectly displayed in the Subject Forms dataset

Now, a form's status is properly displayed in the Subject Forms dataset, on the FORM_STATUS column. Previously, even though a form was complete in the Clinical One Cloud Service UI, in the Oracle Clinical One Analytics application, the form was still displayed with a status of **IN_PROGRESS**. (Issue **35087486**)

The Unblinded Kits dataset does not properly display data related to an updated kit (former known issue)

Now, when a kit is dispensed to a subject, and you update its status to **Not Dispensed to Subject**, the Oracle Clinical One Analytics application displays a separate record for this kit with the appropriate details, such as the subject and visit details. Previously, after the status of a dispensed kit was updated to **Not Dispensed to Subject**, related data was displayed for both records of the same kit with a status of **Dispensed** and the newly updated status of **Not Dispensed to Subject**. Instead, data related to the subject, events, treatment arms, randomization, or dosage calculation should not be displayed for a kit that is considered removed from a subject's dispensation history.

Retracted workaround: None. (Issue **33533953**)

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The Unblinded Kits dataset does not properly display historic data (former known issue)

Now, the Unblinded Kits dataset displays the latest data, as well as historical records for both dispensed and lost kits. This includes data related to the subject, events, randomization, dose calculations, and many more. Previously, the dataset did not properly display historical data for certain kits in different states. For example, the dataset only displayed data for kits with a **Lost by Subject** status. This issue was due to the way the application refreshed any data updates coming from the Clinical One Cloud Service.

Retracted workaround: None. (Issue **33516214**)

Clearing a visit's date is not properly reflected in the Oracle Clinical One Analytics app (former known issue)

Now, when data is refreshed after a visit date has been cleared in the Clinical One Cloud Service, the visit's date field displays a value of Null, as expected. Previously, you may have noticed that the cleared visit date was still displayed.

Retracted workaround: None. (Issue **34773970**)

A two-section form's status changes to Incomplete or In Progress

Now, when a site user completely clears a row in the second section of a two-section form, the status of that entire two-section form changes to **Completed** in the Clinical One Cloud Service and in the Oracle Clinical One Analytics application, as well. Previously, the form's status was updated to **In Progress** or **Incomplete** instead of **Completed** and this status change was reflected in the Oracle Clinical One Analytics application, as well.

Retracted workaround: None. (Issue **34787304**)

Deleted depots in a study are not accurately reflected in the Analytics app (former known issue)

Now, when you delete a depot in the Clinical One Cloud Service, the removal of that depot is properly displayed properly in the application's database.

Retracted workaround: None. (Issue **34563971**)

The Study Design Delta report does not show added or deleted forms in a visit (former known issue)

Oracle Clinical One Analytics application users: Now, any changes to forms, items, visits, and branches in a live study appear in a separate column (**Is_Deleted**) in the Study Design Delta report. Previously, we reported that the Study Design Delta report did not show changes to forms in a visit. For example, in a live study, if you assigned Form A to Visit 3 when you've already connected Form A to Visit 1, the Study Design Delta report didn't show the new association between the existing form and the new visit. The same behavior happened when removing a form from a visit.

Retracted workaround: None. (Issue **34270507**)

Integrations

Event OID is missing from several clinical transactions

API developers: Now, the Event OID attribute is displayed for all clinical transactions related to a transferred subject. Previously, this issue was observed for subjects that were transferred to another site and that site was associated to a study version in which a visit had been

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removed. For example, subject A completed a Safety Follow-up visit at Site A1. After completing the visit, the subject was transferred to site B2. Site B2 was associated to a newer study version where the Safety Follow-up visit was removed and that caused the Event OID attribute to not appear for any clinical transactions related to subject A. (Issue **34840242**)

Randomization and kits

Cannot titrate when a previous kit is replaced (former known issue)

Site users: Now, you can titrate when a kit that was previously marked as **Not Dispensed to Subject** is successfully replaced. Previously, when a kit was marked as **Not Dispensed to Subject** and a new kit was dispensed to the subject instead, you were unable to titrate during a study. When you attempted to titrate, you received an error message that stated that you cannot dispense a kit to subject.

Retracted workaround: None. (Issue **31791917**)

An error message is displayed when uploading a kit list (former known issue)

Clinical supply managers: Now, on the Upload Kit List, when you attempt to upload a kit list a second time (after you encountered an error the first time), you can successfully re-upload the kit list. Previously, after uploading a kit list a second time, another error message was displayed stating that the title of the kit list has already been used. This error message was displayed even though the kit list was never actually uploaded in the system.

Retracted workaround: You no longer have to use a different name for the kit list that you upload multiple times (after errors were identified by the system) because you will no longer encounter an error message even though no other kit list with the same title has been uploaded. (Issue **34144529**)

Reports, archives, extracts, and notifications

OIDs are not unique in the ODM-XML metadata API (former known issue)

API developers: Now, the API response for the ODM-XML metadata no longer indicates that there are several validation errors for duplicate metadata values. Because different design elements in a study had the same reference code, their OIDs did not show up as unique in the ODM-XML metadata and clinical data extracts. Now, OID attributes contain unique GUIDs that will ensure the API no longer marks them as duplicates.

This fixed issue also ensures that there is no impact on a code list's OID, since code lists usually have the same reference codes and they showed up as duplicate in a clinical data extract.

Retracted workaround: None. (Issue **34702467**)

Notifications are not properly filtered (former known issue)

Site and sponsor users: You can now successfully filter any notifications related to randomization, dispensation, or shipments by study mode and site. Previously, the site filter was not working.

Retracted workaround: None. (Issue **33729560**)

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The Kit Chain of Custody report displays incorrect data (former known issue)

Clinical supply managers and other sponsor users: Now, in the Kit Chain of Custody report, in the column Returned, Missing, Balance Units, data points for a shipment pending destruction and containing available kits are displayed as follows:

- Missing units are displayed as "0".
- Balanced units are displayed as "0".

Previously, instead of displaying “1 -0 -0” for when a shipment contained missing units or balanced units, the column displayed “1 - -“.

Retracted workaround: None. This is a display issue only. (Issue **33689816**)

Site users with valid permissions could not view or download an Archival PDF (former known issue)

User administrators: Now, creating a role that includes the permissions, *Download Archival PDFs and Audit Reports*, and *Confirm Download of archival PDFs and content* allows site users to view, download, and confirm PDFs generated and shared by the sponsor without the need to add the permission, *Run Archival PDFs for your sites* to the role, which would allow site users also to generate PDFs.

Previously, if a site user was assigned to a role including both permissions, the user could not view or download the PDFs unless the *Run Archival PDFs for your sites* permission was added to the role.

Retracted workaround: Work with your user administrator to get temporarily assigned to the Run Archival PDFs for your site(s) permission. After downloading the archives, make sure your permission is revoked. (Issue **34655475**)

Archive download failed if the request name included Chinese characters

Sponsor users: Now, the **Download** link does not appear if a request fails to generate successfully. Previously, the link would appear even if a request did not generate successfully. In cases like this, download attempts failed. This was due to Chinese characters being included in the request name.

Retracted workaround: None (Issue **34719206**)

Chinese localization: File Type is not translated in the Download Log report

Sponsor users: Now, the File Type values: Archival PDF, Submission PDF, and Custom PDF, included in the report output, are translated correctly. Previously, the values under the File Type column appeared in English.

Retracted workaround: None (Issue: **34770064**)

Chinese localization: No Records Found is not translated in the Site Confirmation report

Sponsor users: Now, when the Site Confirmation report is run and no records are found, the value No Records Found is translated correctly. Previously, the value appeared in English.

Retracted workaround: None (Issue: **34770019**)

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Site users and subject data

Subject IDs are truncated in Clinical One Cloud Service

Site users: Now, a subject's full ID (up to 20 characters) is visible in Clinical One Cloud Service on the Subjects page and on a visit's page. Previously, subject IDs were abbreviated if the ID exceeded 13 characters. (Issue **35171156**)

A cleared form cannot be unlinked from another form (former known issue)

Site users: Now, as you clear all data in a form that is linked to another form, the link between these two forms is also removed. Previously, after you cleared all data in a form that was linked to another form, you may have noticed that you couldn't clear the question that determined the linking between the two forms. This issue has been observed with repeating forms.

Retracted workaround: You no longer have to clear questions in a linked form in any particular order. As long as you clear a form its links are also removed. (Issue **34713911**)

Cannot add new subjects in a migrated study

Site users and study managers: Now, when a site user attempts to add a new subject in a migrated study, they can create that subject successfully and select a specific subject number for the subject, as well. Previously, even though a study manager configured the Allow Site to Select Subject Number setting to Yes, a site user could still not add a subject in a migrated study. (Issue **34245534**)

Rule targets are not updated after starting a skipped visit

Site users, rule designers, and API developers: Now, when a site user enters the visit date for a visit that was previously skipped, any existing custom rules are refreshed and their target fields are highlighted accordingly, depending on the data entered in those fields. Previously, when a site user re-started a skipped visit, they may have noticed that the existing custom rules weren't working in the associated forms anymore. The custom rules may have started working only after a site user refreshed their browser's page.

This issue is now fixed, but it was initially caused by an API refresh operation that did not take place when a skipped visit was re-started. (Issue **34882471**)

Rest API updates

See the newly added and newly deprecated endpoints of the Clinical One Cloud Service APIs for 22.4, available upon the Production release.

The following services have been updated:

- Code list
- Data Actions
- Data Capture
- Data Hub
- Data Integration
- Designer
- Randomization and Supplies
- Rules

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- Sites and Depots
- User, Permissions, and Roles

Code list

Change	Method	Endpoint
New	POST	/v1.0/codelist/code/copy/{codeId}
	GET	/v1.0/codelist/values/export/{codeId}
	GET	/v3.0/codelist/values/{fieldName}
	POST	/v4.0/codelist/code
	PUT	/v4.0/codelist/code/{codeId}

Data Actions

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/signconfiguration
	GET	/v1.0/studies/{studyId}/{mode}/signconfiguration
	DELETE	/v1.0/studies/{studyId}/{mode}/signconfiguration/{id}
	PUT	/v1.0/studies/{studyId}/{mode}/signconfiguration/{signConfigurationId}
	GET	/v1.0/studies/{studyId}/{mode}/signevaluation/configchange/studysummary
	POST	/v1.0/studies/{studyId}/{mode}/signevaluation/processque

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Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/signevaluation/triggeremail
	POST	/v1.0/studies/{studyId}/{mode}/signinfo
	GET	/v1.0/studies/{studyId}/{mode}/signinfo

Data Capture

Change	Method	Endpoint
New	GET	/v2.0/studies/{studyId}/{mode}/dataelements/formassociations/history/sourceForm/{sourceFormId}
	PUT	/v2.0/studies/{studyId}/{mode}/dataelements/subject/{subjectId}/event/{eventId}/form/{formId}/formassociations
	POST	/v4.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/subject/{subjectId}/code/{code}/orgId/{orgId}
	POST	/v10.0/studies/{studyId}/{mode}/dataelements
Deprecated	GET	/v1/studies/{studyId}/{mode}/subjects
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/events
	GET	/v3.0/studies/{studyId}/{mode}/subjects/history/all
	GET	/v2.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	GET	/v7.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

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Change	Method	Endpoint
	GET	/v8.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/{transferId}
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/dateRange/{subjectId}
	GET	/v2.0/studies/{studyId}/{mode}/subjecttransfers
	GET	/v3.0/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/odmsubmit/clinicaldata/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/odmsubmit/visitsMetadata/{subjectId}
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/all
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	GET	/v4.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	GET	/v8.0/studies/{studyId}/{mode}/dataelements
	GET	/v8.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}

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Change	Method	Endpoint
	GET	/v1/studies/{studyId}/{mode}/formassociations
	GET	/v1.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/events/{eventId}/vendorCode/{vendorCode}/dataelements/withvendorcode
	GET	/v6.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	POST	/v2.0/studies/{studyId}/{mode}/visit/verify/history
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus/dateRange/{subjectId}
	GET	/v9.0/studies/{studyId}/{mode}/visitstatus
	GET	/v5.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusID}
	POST	/v9.0/studies/{studyId}/{mode}/visitstatus/subjects
	GET	/v1.0/studies/{studyId}/{mode}/codingstatus

Data Hub

Change	Method	Endpoint
New	POST	/v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits

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Change	Method	Endpoint
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits
	GET	/v4.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded
	GET	/v4.0/studies/{studyId}/{mode}/odm/clinicalData/blinded

Data Integration

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/asynch/report/{reportName}
	POST	/v1.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v1.0/studies/{studyId}/{mode}/signconfiguration/history
	GET	/v1.0/studies/{studyId}/{mode}/signeligibility/history
	GET	/v1.0/studies/{studyId}/{mode}/subjects/sitestudyversion

Designer

Change	Method	Endpoint
New	PUT	/v1.0/studies/{studyId}/versions/{version}/status/{state}/async

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Change	Method	Endpoint
	GET	/v16.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	POST	/v2.0/studies/{studyId}/lockObjectDetails
	POST	/v3.0/studies
	GET	/v3.0/studies
	GET	/v3.0/studies/library
	PUT	/v3.0/studies/{studyId}
	GET	/v3.0/studies/{studyId}/statusessummary
	GET	/v5.0/studies/{studyId}/statuses
	GET	/v5.0/studies/{studyId}/statuses/{version}
	GET	/v6.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo
Deprecated	POST	/v1.0/report/{reportName}
	POST	/v1.0/studies
	GET	/v1.0/studies
	PUT	/v1.0/studies/{studyId}

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Change	Method	Endpoint
	GET	/v1.0/studies/{studyId}/kits
	GET	/v1.0/studies/{studyId}/statuses
	GET	/v1.0/studies/{studyId}/statuses/{version}
	GET	/v1.0/studies/{studyId}/statusessummary
	GET	/v1.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v1.0/studies/{studyId}/versions/{version}/forms
	GET	/v1.0/studies/{studyId}/versions/{version}/forms
	GET	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v1.0/studies/{studyId}/versions/{version}/kits
	GET	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}
	PUT	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}

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Change	Method	Endpoint
	GET	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v1.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/ratios
	POST	/v1.0/studies/{studyId}/versions/{version}/visits
	GET	/v1.0/studies/{studyId}/versions/{version}/visits
	PUT	/v1.0/studies/{studyId}/versions/{version}/visits/{visitid}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/visits/{visitid}
	GET	/v1.0/studies/{studyId}/versions/{version}/visits/{visitid}/dispensings
	GET	/v1.0/visitschedules/{studyId}/{version}
	POST	/v2.0/report/{reportName}

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Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/kits
	GET	/v2.0/studies/{studyId}/statuses
	GET	/v2.0/studies/{studyId}/statuses/{version}
	GET	/v2.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v2.0/studies/{studyId}/versions/{version}/forms
	GET	/v2.0/studies/{studyId}/versions/{version}/forms
	POST	/v2.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v2.0/studies/{studyId}/versions/{version}/kits
	GET	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}
	GET	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings

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Change	Method	Endpoint
	POST	/v2.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v2.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	POST	/v2.0/studies/{studyId}/versions/{version}/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}
	PUT	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/dispensings
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	PUT	/v2.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	GET	/v2.0/studies/{studyId}/versions/{version}/visitschedules

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Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/visits/{visitId}/validate
	GET	/v2.0/visitschedules/{studyId}/{version}
	GET	/v3.0/studies/{studyId}/statuses
	GET	/v3.0/studies/{studyId}/statuses/{version}
	GET	/v3.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v3.0/studies/{studyId}/versions/{version}/forms
	GET	/v3.0/studies/{studyId}/versions/{version}/forms
	POST	/v3.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v3.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo
	GET	/v3.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v3.0/studies/{studyId}/versions/{version}/randomizations

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Change	Method	Endpoint
	GET	/v3.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	GET	/v3.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	GET	/v4.0/studies/{studyId}/versions/{version}/design
	GET	/v4.0/studies/{studyId}/versions/{version}/dispensings
	PUT	/v4.0/studies/{studyId}/versions/{version}/dispensings
	GET	/v4.0/studies/{studyId}/versions/{version}/forms
	GET	/v4.0/studies/{studyId}/versions/{version}/forms/randomizationfactors
	POST	/v4.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}

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Change	Method	Endpoint
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v4.0/studies/{studyId}/versions/{version}/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/visitschedules
	GET	/v5.0/studies/{studyId}/versions/{version}/design
	POST	/v5.0/studies/{studyId}/versions/{version}/forms
	PUT	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	POST	/v5.0/studies/{studyId}/versions/{version}/visits
	GET	/v5.0/studies/{studyId}/versions/{version}/visits
	POST	/v6.0/studies/{studyId}/versions/{version}/forms

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Change	Method	Endpoint
	GET	/v6.0/studies/{studyId}/versions/{version}/forms
	GET	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	POST	/v6.0/studies/{studyId}/versions/{version}/visits
	POST	/v7.0/studies/{studyId}/versions/{version}/forms
	GET	/v7.0/studies/{studyId}/versions/{version}/forms
	GET	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}/visits

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Change	Method	Endpoint
	POST	/v7.0/studies/{studyId}/versions/{version}/visits
	GET	/v7.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	POST	/v8.0/studies/{studyId}/versions/{version}/forms
	GET	/v8.0/studies/{studyId}/versions/{version}/forms
	GET	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v8.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms
	POST	/v9.0/studies/{studyId}/versions/{version}/forms
	GET	/v9.0/studies/{studyId}/versions/{version}/forms
	GET	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}

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Randomization and Supplies

Change	Method	Endpoint
New	POST	/v2.0/studies/{studyId}/{mode}/reports/titration-summary
	POST	/v3.0/studies/{studyId}/{mode}/resupply/resupply

Rules

Change	Method	Endpoint
New	POST	/v2.0/rule/studies/{studyId}/copyrules
	PUT	/v3.0/rule/studies/{studyId}/bulkcopy
	PUT	/v4.0/rule/studies/{studyId}/{mode}/bulkupdate

Sites and Depots

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties
	PUT	/v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties
	POST	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties
	PUT	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties
	DELETE	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propId}
	GET	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propName}

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Change	Method	Endpoint
	DELETE	/v1.0/studies/{studyId}/{mode}/sdfs/{sdfId}/properties/{propId}
	GET	/v2/studies/{studyId}/{mode}/sdfs/pinaddr
	GET	/v4/studies/{studyId}/{mode}/sdfcountry

Users, Permissions and Roles

Change	Method	Endpoint
New	GET	/v1.0/studyroles/{studyId}/rolesRights
Deprecated	GET	/v1.0/authroles/
	GET	/v1.0/authroles/{studyId}
	GET	/v2.0/authstudies/{studyId}/users
	GET	/v1.0/authusers/{userid}/studies/{studyId}
	GET	/v2.0/authusers/{userid}/studies/{studyId}
	PUT	/v1.0/authusers/{userid}/studies/{studyId}
	GET	/v2.0/globalroles/users
	POST	/v1.0/{studyId}/{mode}/report/{reportName}

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13

Clinical One Cloud Service and Clinical One Digital Gateway 22.3 (November 2022)

- Patch log
- What's new
- Fixed issues
- Rest API updates
  See what has been updated in the Clinical One Cloud Service API.

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.3 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Oracle Clinical One Digital Gateway application**.

Table 13-1 Patch log

Release Number	Release Date	Fixed Issues
Release 22.3.1.7	08-March-2023	The following issues were fixed: • 35118802 • 35120560 For more information, see Fixed issues for Oracle Clinical One Analytics.
Release 22.3.1.6	02-March-2023	For this release, we fixed an issue related to unscheduled and branch visits. For more information, see Fixed issues for Oracle Clinical One Analytics.
Release 22.3.1.5	25-January-2023	For this release, we fixed several issues related to data collection. For more information, see: • Fixed issues for forms, visits, and rules for details on issues **34914490** and **34909567**. • Fixed issues for randomization and kits for details on issue **34899167**. • Fixed issues for reports, archives, extracts, and notifications for details on issue **34917672**.

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Table 13-1 (Cont.) Patch log

Release Number	Release Date	Fixed Issues
Release 22.3.1.4	18-January-2023	For this release, we fixed an issue related to the Clinical One Cloud Service Support chat. For more information, see Fixed issues for all users.
Release 22.3.1.3	12-January-2023	For this release, we introduced a new live chat feature for you to easily get in contact with Oracle Support. For more information, see What's New.
Release 22.3.1.2	03-January-2023	For this release, we fixed an issue related to how questions with code lists were displayed in the Subject Data Extract. For more information, see Reports, archives, extracts, and notifications.
Release 22.3.1.1	27-December-2022	For this release, we fixed an issue related to code lists. For more information, see Fixed issues for code lists.
Release 22.3.1	18-December-2022	For this release, we fixed several issues related to forms, visits, custom rules, Oracle Clinical One Analytics, kits, and reports. For more information, see the list below: • Fixed issues for forms, visits, and rules for details on issues **34890170**. • Fixed issues for Oracle Clinical One Analytics for details on issues **34865395**, **34265433**, **34059966**, **34053211**, and **34042915**. • Fixed issues for randomization and kits for details on issue **34771269**. • Fixed issues for reports, archives, extracts, and notifications for details on issue **34769175**.
Release 22.3.0.1	02-December-2022	For this release, we fixed an issue impacting the scheduler functionality for the Clinical One Cloud Service and Clinical One Digital Gateway.

What's new

- Data collection
- Data review

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- Randomization and trial supply management
- Reporting, archives, and analytics
- User experience
- Other enhancements

Data collection

- Create and manage code lists for all studies at your organization
  Sponsor users and CROs now have dedicated spaces within the application to manage their code lists for a single study or all studies at an organization.
- Clear saved data for a subject
  You can now clear data saved for a subject to correct any known errors.
- Update a subject number during the study conduct period
- Order studies using the company filters
  A filter to order studies based on sponsor affiliation is now included on the homepage.
- Customize the welcome letters for users
  The welcome letter for new users can now be customized for all studies or a single study.
- Greater flexibility for date/time questions
  Study designers can now modify the details of **date & time, date only, and time only** questions within forms to allow for unknown values, following the approval of the study design.

Create and manage code lists for all studies at your organization

Sponsor users and CROs now have dedicated spaces within the application to manage their code lists for a single study or all studies at an organization.

You can now create your very own library of code lists! By organizing your default and custom values, you offer all sponsor users at your organization the ability to effectively manage their own data library. For example, if your organization conducts a pediatric study and an oncology study, both groups of sponsors may need to use very different values within each study. This is where the library of code lists comes in handy. Having a set of default code list values and the ability to customize those values at a study level gives you the perfect blend of data consistency and integrity, and data customization across studies.

Before you work with this feature

This new feature can impact most study team members. The following users can manage code lists:

- The study designer, as long as they are assigned with the *Manage Study Code Lists* permission. Study designers can only manage code lists that are used in form design.
- Any user at a sponsor or CRO who is assigned the new *Codelist Manager* global role.

Details about system code lists and the global library of code lists

Here's what's new for you, as a code list manager:

- On the homepage, there is a new page called Library.
- The Library page is where you can create a global library of code lists that can be used across multiple studies at your organization.

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- On the Library page, code lists are organized by groups: custom code lists and system default code lists. The system default code list group contains predefined code lists created by Oracle and you will see them on the User Interface (UI). The custom code list group contains all code lists that can only be used for form design or study filters. For more information on study filters, see Order studies using the company filters .
- The system default code list group contains code lists that exist in the system, by default. You can view and edit certain details of these default code lists, but you cannot delete them or create new ones. You can create new system code list groups, but those will only contain the default code lists (also included in the default group of code lists). You can edit certain elements of the code lists included in a system code list group that you've created yourself.
- The custom code list group contains all code lists that you create from scratch and that you can view and further edit. You can hide values in a custom code list, create new values in a code list, or create a new code list in the custom code list group.
- Code lists can be created in all languages available in the application. Upon selecting a code list, you can view the code list items by switching between language tabs in the library.
- Upon creating a study, you should assign a system code list group to that study. This way, your study uses the appropriate group of code values. You also have the option of assigning a system code list group to a study at any time during the study's development, whether it's during the design phase, the testing phase, or the conduct period of a study.

Figure 13-1 Access the Library

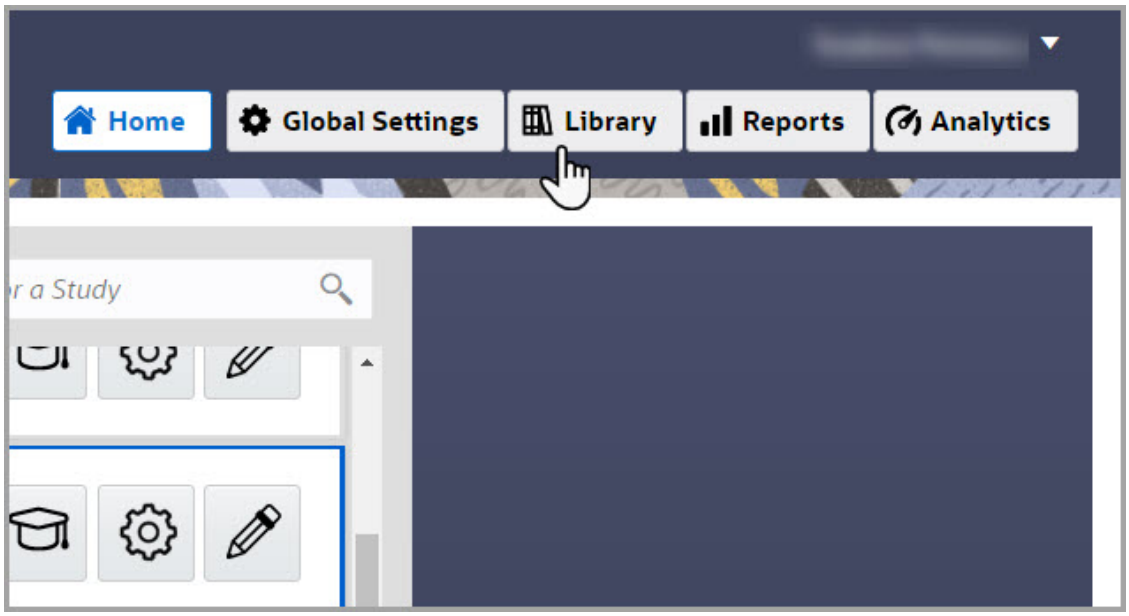

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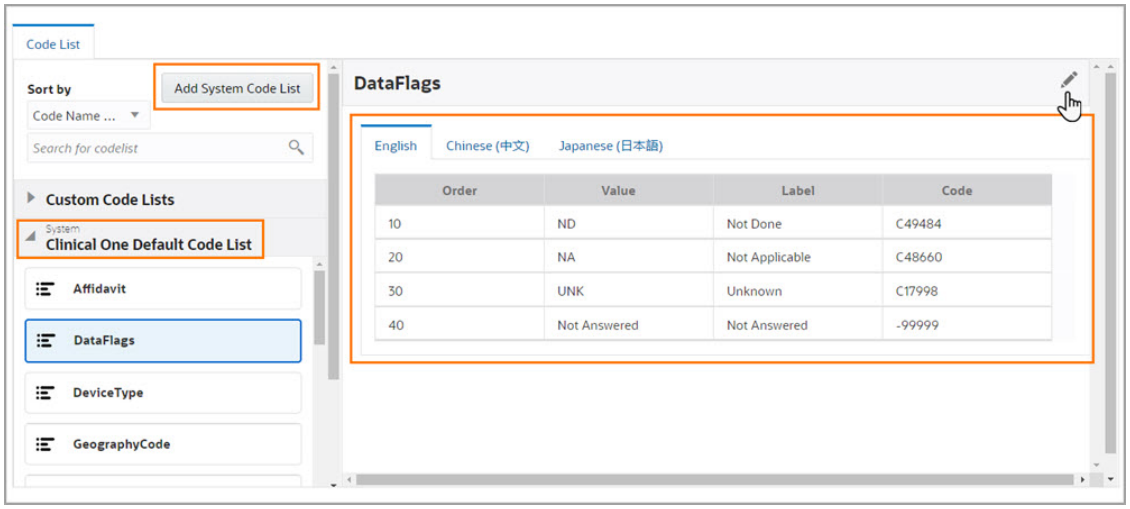
Figure 13-2 Create a system code list group



Details about study code lists and a study's individual library

Here's what's new for you, as a study designer who creates and manages code lists at a study level only:

- As a study designer, you can continue creating code lists specific for designing forms. A code list that can be used in form design can be found in the custom code list group on the Code list tab in a study's settings.
- All code lists in a single study can now be managed in a study's settings, on the new Code List tab. You can either edit certain elements in a code list from the system default code list group or you can create or delete a custom code list in the custom code list group.
- on the Code list tab, if you create a new custom code list, that newly-created custom code list is not available for all studies at your organization. If you edit elements of any system default code lists (from the system default code list group), these edits will only be available in the context of a single study.
- When new system code list groups are added at a global level (on the Library page), these new code list groups are also displayed on the Code List tab in the context of a single study.

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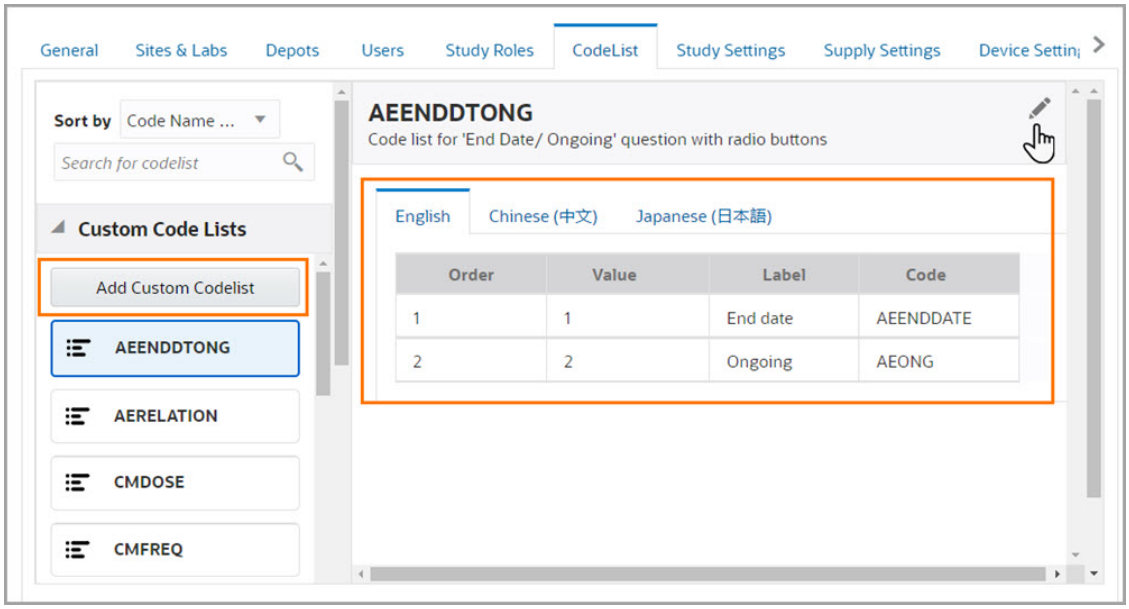
Figure 13-3 Create a custom study code list



Already working in a live study?

As soon as the upgrade for this release is complete, you can begin creating and managing code lists for specific studies or all studies at your organization. For existing studies, you can continue using the custom code lists you have created for form design and you do not have to update these code lists to accommodate the new feature. All of the existing custom code lists that were previously created for form design will now show up on the Code List tab for every study.

To assign a system code list group to an existing study, you can edit the study's details on the General tab, and select the appropriate system code list group to assign to that study.

> **Note**
>
> When you attempt to update the custom code list called EDCYearRange, you may experience some unexpected behavior related to how labels are updated. This Known Issue may potentially impact the way partial dates are defined in a form. For more information, see issue **34783476** in the Known Issues List.

Clear saved data for a subject

You can now clear data saved for a subject to correct any known errors.

Before you work with this feature

- Any permissions site users are assigned with to enter specific data allow them to also clear that data.
- **Site Edits Visit Date** must be enabled under Study Settings for the menu icon ( ) to appear for the particular visit type you would like users to be able to clear the visit date for.
- To remove data from a radio button question without returning it to a new state, you have the option to select **Reset** from the menu.

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- When **Reset** is selected for a radio button question, the Answer History will show it has been reset, while the Answer History will reflect a question has been cleared when **Clear** has been selected.

Details for site users

As a site user, here is what's new in your workflow:

- The option to clear data will only be available in the menu for an item once data has been entered and saved for that question.
- You can select **Clear** from the menu icon ( ) next to the item you would like to clear data from.
- You are prompted to select an option from the **Reason for Change** drop-down when you choose to clear data.
- Data entered for a question or visit cannot be cleared if that question or visit is locked or frozen.
- The option to clear data is available in all visit types (Scheduled, Unscheduled, Screening, Withdrawal, Completion, Dispensation, Randomization, and Adverse Events).

Report enhancements

You can now include or exclude cleared data from the Subject Data report and Subject Events report:

- When you select the Subject Data report under the Reports & Archives tab, the option to include or exclude cleared data is available in the Settings pane on the right.
- A new status, **Visit Date Cleared**, appears under the **Event Type** column in the Subject Events report.
- In addition, the Subject Data Extract will not include records of cleared forms.

Further details will be featured in the Subject Data Report, Subject Events Report, and Subject Data Extract.

Already working in a live study?

Once the upgrade for this release is complete, clearing subject data will be available for all existing studies. More information on data clearing and step-by-step instructions on how to do so will be featured in the *Site User Guide*.

Update a subject number during the study conduct period

With the appropriate permission, users at a sponsor or site now have the option of updating a subject number during the study conduct period.
If you ever need to update a subject number, there is now a simple way for you to do that! With the new ability of updating subject numbers, you can perform this update at any time and with only a few clicks. Rest assured, every change you make is saved in the system and you, as well as other sponsor users, can view the audit trail of the subject numbers that you update.

Before you work with this feature

This new feature does not only impact site users. As a user administrator, you must make sure that the site user or sponsor user who updates a subject number has the appropriate permission to do so. We recommend that you only grant site users the permission to update subject numbers temporarily. After they are done with their updates, you should remove that permission associated with their role.

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We also recommend that you create a custom study role for site users. The custom study role should contain the appropriate permissions for a site user, as well as the new permission called *Update a Subject's Number*. After a site user is done with the subject number updates, you can re-assign them with their original study role. For more information on how to create a custom study role at a study level, see Create a study role for one study.

Details for sponsor users

There are no changes in the workflow within the application. However, there are certain things that you should know:

- When a subject number is updated during the study conduct period, the system validates the new subject number to ensure it adheres to the subject number format requirements. As a best practice, we recommend you review the planned update prior to having the user's permissions updated.
- After a user updates a subject number, we recommend you work with your user administrator to ensure that the user's permission to update a subject number is revoked.
- From the moment a subject number is updated it is displayed in reports, extracts, and all other areas within the application.
- If you are assigned the *Receive the Subject Number Update Notification*, you receive a notification whenever a subject number is updated. The notification includes relevant details such as the site number, the original subject number, and the updated subject number.

Details for site users

Here's what you need to know about this new feature:

- On the Subjects page, when you click **Manage Subjects**, you see a new option called **Update Subject Number(s)**. This is option is only active if you have the appropriate permission assigned to your role and if you have previously selected a specific site (when you have access to multiple sites).
- Upon selecting a subject and clicking **Update Subject Number(s)**, a new dialog appears. On the Update Subject Number(s) dialog, you can perform the following actions:
  - View a subject's current subject number (under the **Selected Subject** column).
  - View the required subject number format.
  - Update a subject's current subject number (under the **Update To** column).
  - Add and remove subject numbers that you want or do not want to update.
  - Enter a reason for the update that you are making.
  - If you are assigned the *Receive the Subject Number Update Notification*, you receive a notification whenever a subject number is updated. The notification includes relevant details such as the site number, the original subject number, and the updated subject number.

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Figure 13-4 How a user sees the Update Subject Number(s) dialog

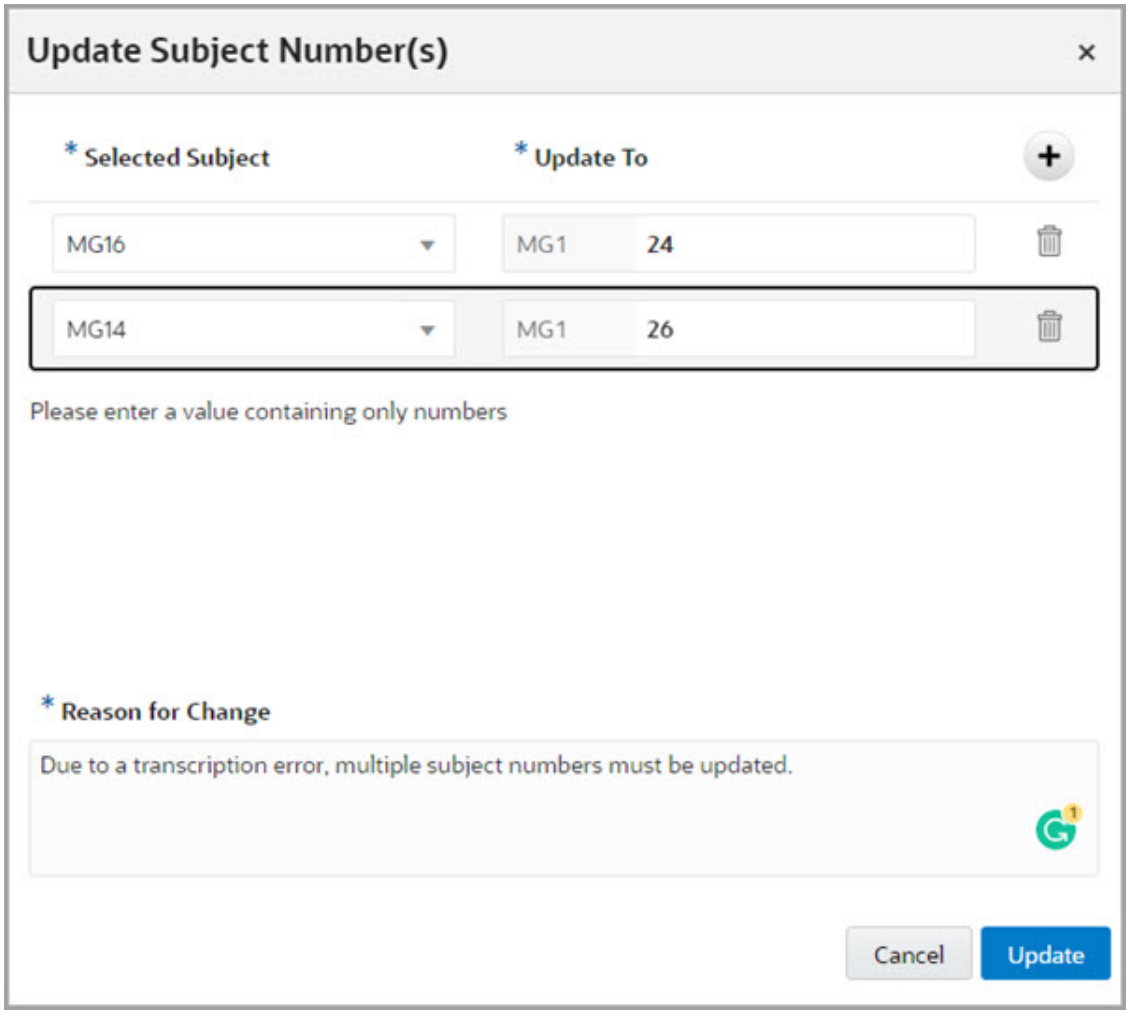

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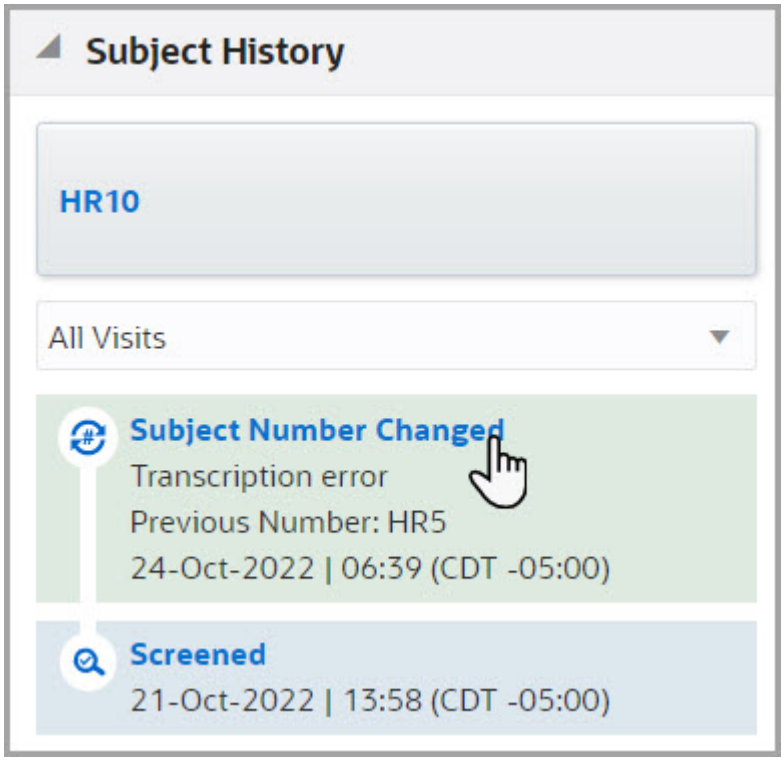
Figure 13-5 A changed subject number in a subject's history



Reporting updates

The moment a subject number is updated, it is displayed in reports, extracts, and all other areas within the application. The Subject Events report contains the following specific updates:

- There is a new column called **Previous Subject Number**. This column displays the original subject number for a subject whose number was updated during the study conduct period.
- The collumn called **Current Subject Number** displays the newly updated subject number.
- The **Event Type** column displays a value of **Subject Number Changed** when an update has occurred.

> **Note**
>
> Subject number updates will be reflected in the Oracle Clinical One Analytics custom reports and dashboards in a future release.

Impact to integrations

This feature is not compatible with all integrations configured with Clinical One Digital Gateway. If you want to change a subject's number, carefully consider how this change might impact your current integrations.

If a subject number change occurs after verbatim terms are sent to Oracle Central Coding, this will result in subject number discrepancies between the Clinical One Cloud Service and Oracle Central Coding. Verbatim terms and coding results will still be associated with the correct subject number.

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The ability to seamlessly update subject numbers without impacting your coding processes will be introduced in an upcoming Oracle Central Coding release. Until then, make sure you reach out to your Oracle point of contact for additional information before changing a subject number.

Already working in a live study?

The new permissions called *Update a Subject's Number* and *Receive the Subject Number Update Notification* can be added to study roles for existing studies as soon as the upgrade completes. There is no other action for you regarding the compatibility of this feature with existing studies.

Order studies using the company filters

A filter to order studies based on sponsor affiliation is now included on the homepage.

Before you work with this feature

This new filter allows Clinical Research Organizations (CROs) to view information about all studies from the same sponsor. You are now able to:

- Only display studies associated with the user roles.
- Associate Company names with unique code lists in English and other languages.

To create and manage a custom code list that contains company names for all studies at your organization, you must be assigned either the Study Creator or the Code List Manager global role. Users see only study filters with their assigned studies. For example, a study designer can only see the granted studies for a specific company and not others. Filters are tied to the overall study permissions the user has.

Details for study creators and code list managers

When working with code lists this is what is new for you:

- For a CRO or sponsor user to filter studies for their organization, you must first create a custom code list that contains all company names on the **Library** page. This system code list with all company names can be used for all studies at your organization.
- Upon creating a study, there is a new **Company** field where you can select the organization that is associated with your study. The options available for the **Company** field are the organizations that you previously included as code values in the custom code list created on the **Library** page.
- In a study's settings, on the **General** tab, you can add a new selection for the **Company** field for an individual study at any point during the study conduct period.

Already working in a live study?

After the upgrade is complete, you can create a custom code list with all company names and begin using it for your existing study. For more information, see the *Sponsor and CRO User Guide*.

Customize the welcome letters for users

The welcome letter for new users can now be customized for all studies or a single study.

Existing studies now have the welcome letter populated automatically. However, the updated format in the welcome letter appears in newly generated emails.

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> **Note**
>
> To populate company names for existing studies you must set them up in the Companies code-list. For more information, see Order studies using the company filters and Create and manage code lists for all studies at your organization.

Other study team members and study creators can now include relevant information in the welcome message about the study, training, or help center to guide new users. With this enhancement you are now able to:

- Customize the content to match for all studies at your organization or a specific study's details.
- Create a template that populates in all studies so you can modify as required.
- Employ a progressive disclosure of information using the roles that can edit the letter.

How you intend to use the custom letter to support team members will determine which role is more suitable. For example, some study team members might need to have information such as correct sponsor name and study scope, while others might need to identify specific studies when working with numerous data and names.

Details for study creators and study managers

The welcome message can be customized at two different levels: at the **global level** (for all studies at your organization) and the **study level**. At the global level, you must be assigned the Study Creator global role to edit the welcome letter. At a study level, you must be assigned the *Edit Welcome Details in General Study Settings* permission.

The following study template roles have the *Edit Welcome Details in General Study Settings* permission assigned by default:

- Study Manager
- Production Admin
- Rules Designer

As the study creator, you can only update the welcome message available at a global level (for all studies at your organization). You can do this on the Global Settings page, on the General tab.

As a study manager, you can only customize the welcome message at the study level. You can do this in the study's settings on the General tab.

Already working in a live study?

After the upgrade is complete, you can begin customizing welcome messages for your newly created studies. For existing studies, you can customize the welcome message, but only newly added study team members will see it. For more information see the *Sponsor and CRO User Guide*.

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Greater flexibility for date/time questions

Study designers can now modify the details of **date & time, date only, and time only** questions within forms to allow for unknown values, following the approval of the study design.

Details for study designers

For date/time questions, study designers can now increase the number of unknown elements in a question, by modifying the **Minimum Answer**. The format of the date/time cannot be modified following approval, however, study designers can now modify the minimum acceptable answers site users provide for date/time questions.

The Date/Time selector is now a set of radio buttons. Selecting any of the following limits the range of **Format** options displayed: **Date & Time**,**Date Only**, **Time Only**. For instance, if **Time Only** has been selected, the following options will be available under **Format**:**HH**; **HH:MM**; **HH:MM:SS**.

Already working in a live study?

As soon as the upgrade is complete, you will be able to modify the minimum answer subjects can provide for date/time questions.

Data review

- Lock a subject's data at the question, form, or visit level
  You can now lock a subject's questions, forms, or visits to prevent users from modifying that subject's data.

Lock a subject's data at the question, form, or visit level

You can now lock a subject's questions, forms, or visits to prevent users from modifying that subject's data.

By locking a subject's data at the question, form, or visit level, other users cannot insert new or update existing data for that subject, such as API loaded data or changing the subject number. Subjects can be locked at the form or visit level even if the visit or form is incomplete or has open queries.

Before working with this feature

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can now lock a subject's forms or visits to prevent new data from being added or updated by another user. Any user assigned this permission also has the ability to unlock a subject's data.

Any user assigned the *View Form Data for Subjects* permission will be able to see whether the subject, visit, form, and question are locked as long as they have permissions to view those elements.

Details for sponsor users

- When a subject is locked, all existing data becomes read-only.
- A Locked icon ( ) appears next to a subject to indicate it is locked.
- Locking data at the form or visit level also locks any questions that are hidden to the user.

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- The options to sign, freeze, unfreeze and verify are still available on locked questions, forms, and visits.
- Normal ranges on lab forms can still be updated even if the lab form is locked.
- Coding continues to run on locked data.
- The Subject Data Extract, Subject Data report, and Subject Queries report reflect the study's design at the time the report is run, even for locked questions.

More information and step-by-step instructions on subject data locking will be available in the *Sponsor and CRO User Guide*.

Details for site users

Site users can view locked and unlocked data, so long as they have the corresponding permissions to see that element.

- A Locked icon ( ) is visible next to a locked question for a subject with open queries.
- An Unlocked icon ( ) appears next to an unlocked question, indicating that the question has been unlocked by a sponsor user.

More information on locked and unlocked icons will be featured in the *Icon Reference*.

Impact to integrations

When it comes to your workflow for coded terms in Oracle Central Coding and locked data:

- When a subject's data is locked, site or sponsor users cannot enter new or modify existing Verbatim terms, Indication, and Route.
- Coding activities in Oracle Central Coding are still allowed even if the verbatim, context items, or coding target fields are locked.
- Updates to the coding are reflected in the audit trail.
- Queries cannot be raised, answered, or closed on locked coding items.

> **Note**
>
> Data for locked questions, forms, and visits cannot be transmitted through integrations into or out of Clinical One Cloud Service.

Impact to rules

- A custom rule will not re-run after its variables or targets are unlocked unless one or more of the questions entered as variables are updated. If a rule needs to be re-run, you must manually select the option to re-run from the Rule's menu.
- A custom rule cannot open queries or apply calculations to locked questions, forms and visits.
- A new notification called Rule Failure Notification for Locked Data is available. Users assigned the *Receive Rule Failure Notification for Locked Data* permission will receive this notification informing them that some targets were not updated due to them being locked.

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Already working in a live study?

Once the upgrade for this release is complete, users will have the ability to perform subject data locking at the question, form and visit level, and view locked and unlocked data. More information on locking subject data will be featured in the *Sponsor and CRO User Guide*.

Randomization and trial supply management

- Perform partial dispensation
  Site users can now partially dispense investigational product to adapt to a kit shortage at a site.

Perform partial dispensation

Site users can now partially dispense investigational product to adapt to a kit shortage at a site.

To allow partial dispensation, this setting must be activated and details must be defined for the partial dispensation of a particular kit type. The partial dispensation option is available when multiple kits of the same type must be dispensed during a visit, as long as you have at least one kit available of each kit type that must be dispensed.

Consider the following when working with partial dispensation:

- For kits with calculated doses, data changes after a partial dispensation will not result in the recalculation of the dose.
- The Do Not Dispense (DND) days requirement considers the initial dispensation date only.
- When a partial dispensation occurs, the Dispensation notifications now include details related to it.

Details for clinical supply managers and other sponsor users

You can now activate partial dispensation from the Supply Settings page. Settings must be defined for each kit type that is allowed for partial dispensation, but it is not necessary for all kit types to be defined for partial dispensation or to have matching settings. Additionally, you can turn the partial dispensation setting on and off as required, globally and individually defined for a given kit type at a specific visit range.

For each kit type, you must specify a visit range during which partial dispensation is allowed. Any dispensation visit, scheduled or unscheduled, will allow partial dispensation for the given kit type, as long as it is within the defined visit range and regardless of whether there was a skipped visit or not.

To prevent subsequent shortage, predictive resupply strategies consider subjects with ongoing partial dispensation in the resupply orders.

> **Note**
>
> Partial dispensation and dose holds cannot be simultaneously active in a study.

Details for site users

Site users are able to complete a visit when there are not enough kits available at the site to dispense.When performing a partial dispensation, you still need to follow the regular steps for dispensing the investigational product: complete the required forms, confirm the dispensation of kits, titrate, or dispense reusable kits, if applicable.

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Details about performed partial dispensation display on the Subjects History pane. A partial dispensation must be completed before a subsequent dispensation visit, whether it is scheduled or unscheduled, otherwise visits will be left with incomplete dispensation. In this regard, the system warns you about pending partial dispensations whenever you attempt to dispense kits for a later visit. If the site still doesn't have enough kits upon the subject's return, you can perform another partial dispensation until the full amount of pending kits is available and the dispensation is complete. For titration studies, you can perform a later unscheduled titration to decrease the dose so that the subject doesn't need to come back for additional kits.

Already working in a live study?

As soon as this upgrade is complete, clinical supply managers can define partial dispensation settings. Once these settings are applied, site users will be able to perform partial dispensation and adjust to kit availability.

More information regarding partial dispensation will be featured in the *Sponsor and CRO User Guide* and the *Site User Guide*.

Reporting, archives, and analytics

- Access customizable dashboards
  Clinical Research Associates (CRAs) and data managers (DMs) now have access to dashboard templates in Oracle Clinical One Analytics.
- Enhancements for Oracle CRF Submit archives and reports
  The following details provide an overview of enhancements for Oracle CRF Submit archives and reports included in this release.
- New notifications for scheduled reports
  You can now receive various notifications for scheduled reports depending on their configured setting.
- New User Assignment Across Studies report
  Global user managers and study creators can now run a report that identifies the roles assigned to specific users across studies.

Access customizable dashboards

Clinical Research Associates (CRAs) and data managers (DMs) now have access to dashboard templates in Oracle Clinical One Analytics.

> **Tip**
>
> Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study, or just starting work with analytics, reach out to your Oracle point of contact to learn more about these new dashboards.

With the introduction of the new standard dashboard templates in Oracle Clinical One Analytics, you can get a better, more holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to customizable, interactive dashboards containing reports and visualizations that can help improve your decision-making and data management processes.

Because they are templates, you do not have to create dashboards from scratch, but you can customize them to meet your needs. All you have to do is simply tweak the data in each dashboard and adjust their filters to make sure you are viewing data relevant to your work.

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Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. Access to a dataset is given based on a permission that you must be assigned in Clinical One Cloud Service. For more information on these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Details for Clinical Research Associates (CRAs)

With the new Clinical Research Associate (CRA) Dashboard, you can now monitor and control the data integrity and health of your study and sites. Built using the Subject and Queries datasets, this customizable dashboard offers you complex data on enrollment and query management, broken down into the following interactive reports:

- Study Overview
- Screening Overview
- Enrollment Report
- Subject Dropout Count by Reason
- Outstanding Queries by Site and Visit
- Query Ageing by Site
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Volume by Form
- Subject Counts with Outstanding Queries

The reports and visualizations grouped in this dashboard can help CRAs evaluate existing issues and identify the possible need of site training adjustments, as well as protocol and screening population redefinition.

Details for data managers

With the new Data Manager Dashboard, you can now view actionable visualizations and detailed listings of queries, subject states, and general subject data. Built using the Queries dataset, this customizable dashboard offers you the most relevant data that a clinical data manager could require in their work, exposed in the following interactive reports:

- Outstanding Queries by Site and Visit
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Ageing by Site
- Query Volume by Form

The reports and visualizations included in this dashboard can provide valuable information for workload prioritization and can help to identify the possible need of site training adjustments and monitoring visits.

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Already working in a live study?

As soon as this upgrade is complete, CRAs and data managers can access the new customizable dashboard templates in Oracle Clinical One Analytics. If you have any trouble accessing specific data, reach out to your Oracle study manager or user administrator to check your permissions.

More information regarding dashboards will be featured in the *Analytics User Guide*.

Enhancements for Oracle CRF Submit archives and reports

The following details provide an overview of enhancements for Oracle CRF Submit archives and reports included in this release.

PDF headers now include the Locked form status

The Archives PDF header, specifically the **Form Status** row, now displays the status, **Locked**, for locked forms. The locked status is only present in the output files generated for Submission, Archival, and Custom PDF requests.

All date formats are now supported in Blank Form PDF active controls

Previously, only certain date/time formats were supported for the active controls included in blank PDFs. Now, all date formats that can be defined for a date/time item during design, including partial date restrictions, are supported in active controls. For more information, see Create a date/time question

Example: if YYYY-MM-DD was defined as the date/time format for an item, this format is represented in the blank form PDF active control.

> **Note**
>
> Blank PDFs are included in Submission, Archival, Blank Form, and Custom PDF requests.

You can now view expected and completed file details during processing

Along with percent complete, the number of files expected and the number of files successfully generated are displayed on the Download Archives side panel during request processing. For more information, see Generate an Oracle CRF Submit archive or report.

Archives are now available in Simplified Chinese

You now have the option to view the Archives user interface in Chinese. Additionally, the blank PDFs and subject PDFs included in the output zip file for Submission, Archival, Blank Form, and Custom PDF requests, including bookmarks, are now available in Chinese.

The default language is English, however, you can dynamically switch to any of the offered languages, Japanese and now Chinese by clicking your name in the upper right corner and choosing from the available languages in the **Change Language** control. For more information, see Conduct studies in Simplified Chinese.

New notifications for scheduled reports

You can now receive various notifications for scheduled reports depending on their configured setting.

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A variation of notifications are sent to the user who creates, activates, or deactivates a scheduled report.

Notifications

Users with the *Schedule Reports to Run* permission can now receive several new notifications for scheduled reports:

- The **Report Scheduled Created notification** is sent when a scheduled report has been created.
- The **Report Scheduled Activated notification** is sent when the **Scheduled Report** toggle for a report is turned on.
- The **Report Scheduled Deactivated notification** is sent when the **Scheduled Report** toggle is turned off.

Each notification includes the following details:

- Study name, ID, and mode
- Report name
- Report schedule
- sFTP location
- Date scheduled
- The user the report was scheduled by
- Notification recipients

New User Assignment Across Studies report

Global user managers and study creators can now run a report that identifies the roles assigned to specific users across studies.

About this feature

The User Assignment Across Studies report can help Clinical Research Associate (CRAs) with the following:

- Provide a dashboard to view users and their roles across studies.
- Compare permissions of the roles across studies.
- Recognize specific user activity to find a suitable replacement.
- Identify users from studies that had access temporarily or permanently removed.
- Find users that should be removed across studies.

Details for global user managers and study creators

Here's what's new for you:

- On the **Reports** tab, you will see a new report called **User Assignment Across Studies**.
- When you select that report, a **Settings** side panel will appear on the right, prompting you to filter data in your report. You can perform the following actions:
  - Select one or multiple user names, but never all.
  - Select the study mode in which the study user has access (under **Study Mode**)

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- Include or exclude permissions assigned to users in one or multiple study roles across studies.
- Include or exclude decommissioned studies.
- Select the file type of the report export whether it's **CSV, HTML**, or **PDF**).

Already working in a live study?

Use the report for existing studies as soon as the upgrade completes.

More information is featured in the *Reporting Guide* in User Assignment Report .

User experience

- Chat in real time with your Support team
  With the new Clinical One Cloud Service chat feature, you can now quickly get in touch with our Oracle Support team and discuss your issues in real time.
- Conduct studies in Simplified Chinese
  Clinical One Cloud Service now gives you the option to design studies and collect subject data using Simplified Chinese.

Chat in real time with your Support team

With the new Clinical One Cloud Service chat feature, you can now quickly get in touch with our Oracle Support team and discuss your issues in real time.

The Clinical One Cloud Service chat lets you engage directly with technical support and will be available starting with 16-January-2023, at 08:00 GMT.

Details for all users

On the home page, when you click Chat & Help, a new Chat & Help dialog is displayed. On that newly displayed dialog, you'll see several options to click:

- **View Documentation**: this opens the Clinical One Cloud Service Oracle Help Center homepage where you can browse the application's documentation.
- **My Training Videos**: this displays the videos assigned to your user based on your permissions in the application.
- **Live Chat**: clicking this option displays several new mandatory fields that you can fill in to start your live chat session: First Name, Last Name, Email Address, and How may we help you? By default, the fields First Name, Last Name, and Email Address are automatically populated with the details associated with your Clinical One Cloud Service account.

When you click Live Chat and fill in the details, a new dialog called Live Assistance is displayed. In there, you can either start your conversation with a Support agent or get a notice that informs you when there are no agents available to chat.

For more information on how to use this feature, see Chat in real time with Oracle Support.

Conduct studies in Simplified Chinese

Clinical One Cloud Service now gives you the option to design studies and collect subject data using Simplified Chinese.

As an end user, you now have the option to view and use the Clinical One Cloud Service application in the Simplified Chinese language.

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The first time you sign into the application, you will notice that the default language of the application is English. To switch to Simplified Chinese, click your user name on the Home page and choose **Chinese** from the **Choose Language** drop-down at any time. After you select the Chinese language, the user interface refreshes, allowing you to see the product and common functionality translated into Simplified Chinese. Your language preference is then preserved for the next login session.

Localizing the Clinical One Cloud Service application to accommodate the needs of users who speak different languages is part of a broader project that our team is currently working on. For this release, the major focus is to translate all product areas that impact the site user's experience. These areas include core labels, titles, system messages, site-facing code lists, as well as support for form design, clinical data collection and specific site-facing reports, and notifications. The remaining reports and notifications will be translated as part of an upcoming feature.

> **Note**
>
> MEDDRAC and WHODDC Chinese dictionaries are going to be supported in Oracle Central Coding and in Clinical One Cloud Service as part of an upcoming release.

Form design and clinical data collection

A study designer is now able to define form items using Simplified Chinese characters and the preferred date and time formats used in the Chinese language: YYYY-MM-DD and YYYY-MM-DD HH:MM. Similarly, the site user is able to enter form data using the same Simplified Chinese characters and respective date and time formats.

In order to maintain data integrity, the user language preference will not influence form design or collected data. Forms will remain as they were defined by the sponsor, as well as collected data will remain as entered by the site user, regardless of the application language preference. For example, if forms within a study are designed in English, site users will see English forms even if they select Chinese as their preferred language and vice versa. Similarly, if data is collected in English, it will remain as that even if the language preference changes.

Reports and archives

As a site user, if you select your language preference as Chinese, you can access the following reports and extracts in the Simplified Chinese language:

- Subject Data Extract
- Subject Visits
- Subject Visits (Unblinded)
- Kit Dispensation
- Subject Queries
- Study Design
- Titration Summary
- Titration Summary (Unblinded)
- Chain of Custody
- Chain of Custody (Unblinded)
- Clinical One Training

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> **Note**
>
> Clinical data will never be translated and will be reported exactly as collected despite the user's language preference.

Notifications

When the preferred language is set to Chinese, the following notifications are translated:

- Code Break
- Randomization Failed
- Dispensation Failed
- Subject Randomization Complete
- Subject Dispensation Complete
- Unblinded Pharmacist dispensation
- New Shipment Request
- Cancel Shipment
- Insufficient Shipments, Shipment Failure notifications
- Cohorts Limits Reached
- New Shipment for Destruction created
- Kit Missing from Shipment for Destruction
- Disable Kit List
- Subject added
- Subject transferred
- Subject withdrawal
- Subject screening/ screen failure
- Subject visit complete
- Training complete (Clinical One Cloud Service training only)
- Training status reminder
- Custom notifications
- User added to study
- State of a site has changed
- Rule re-run
- Report is ready
- Report failed to generate

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> **Note**
>
> - Notifications intended for non-Clinical One Cloud Service users, such as depot email addresses, will always be sent in English.
> - Oracle Health Learn course certificates and notifications for other applications are *not* translated.

User documentation

To make sure your user experience is complete, we have translated our entire Clinical One Cloud Service documentation set to Simplified Chinese. From now on, not only can you conduct your study in Chinese, but if you ever need user assistance, you can browse the documentation in the same language.

To learn more, see the translated documentation on the Oracle Help Center.

Other enhancements

Report enhancements

The following reports have been updated in this release:

- The Subject Queries report now includes information about three new fields- *Created By*, *Last Modified By*, and *Created By Role*. More information about the new fields will be featured in the Subject Queries report.
- The User Upload Error report has been reformatted to match the User Upload Template. This allows you to download the report, correct errors directly in the report, then simply import it to create user accounts. For more information, see the User Upload Error report.

Additional information on these reports will be featured in the *Reporting Guide*.

Kit lists can now contain special characters

Kit lists will now be stored as UTF-8, a standard which covers a broad range of characters. This means that dashes, decimals, along with other special characters ("|" "/" "$" "&") will now be allowed within kit numbers.

On the Study Inventory and Site Inventory pages, users can now search for individual kits only if the list contains UTF-8 characters.

On the Study Inventory page, provided that kit numbers include non-numerical characters, these will be sorted based on numerical characters first, followed by alphabetical (i.e. non-digit) characters.

As on the Study Inventory page, a range filter is now available on the Site Inventory page which searches across kit types.

Randomize subjects only when kits are available at site

You can now let site users randomize subjects only if specific kits are available at a site. On the Supply Settings tab, there is a new setting called **Randomize Only when All Kits Are Available at Site**. With it, you can choose to either allow randomization regardless of site inventory or prevent randomization when kits are not available. If you choose to confirm kits' availability at randomization, you can select the specific kit types required in the inventory to be able to randomize a subject.

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Before this feature was introduced, there was no configuration available to set this behavior. Existing studies will have the setting set to **No** by default, to preserve the existing configuration. This allows sites to randomize subjects regardless of site inventory. As soon as this upgrade is complete, authorized sponsor users will be able to modify this setting to either allow or prevent randomization after kits' availability confirmation.

Fixed issues

- All users
- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

All users

The Clinical One Cloud Service chat landing page points to a different URL

Now, when you open the Clinical One Cloud Service live chat in the application, the chat connects to the appropriate Oracle Support URL (which is https://hsgbu.custhelp.com). Previously, the live chat was pointing to a different instance of the same URL. (Issue **34982023**)

Login dialog title is not translated to Japanese

Now, when you sign out of the application and sign back in, the Login dialog title is translated to Japanese, as expected. Previously, even though your language preference was set to Japanese, the Login dialog title was still displayed in English. (Issue **32941159**)

Facilities, settings, and user management

Default label for a stratum group is now translated

Study designers: Now, when your application's language preference is set to Japanese, and you create a central stratified randomization, you will notice that the default label for the stratum group is displayed in Japanese. Previously, these default labels were still displayed in English (Issue **32902693**)

Some error messages related to custom enrollment groups are not translated

Study managers: Now, when your application's language preference is set to Japanese, validation error messages for custom enrollment groups are fully translated. Previously, on the Create Custom Enrollment Group dialog, when you entered incorrect text in fields or left them blank, you may have noticed that the validation error messages were not fully translated in Japanese. (Issue **32891833**)

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Regions with similar titles are allowed in the system (former known issue)

Study managers: On the Study Settings tab, there is now a validation that prevents you from using duplicate titles for the regions in your study. Previously, you may have noticed that you were allowed to create regions with similar titles. For example, you could create a region called “Region A” and another region called “Region a”. That is because the Title field was not case sensitive.

Retracted workaround: We recommend you do not use duplicate or similar titles for multiple regions in your study. (Issue **34251662**)

Oracle Help link for custom enrollment settings not working (former known issue)

Study managers: Now, the Oracle Help Center URL displayed in the Custom Enrollment Settings section works as expected. Previously, when you clicked the link, you may have noticed that it did not work.

Retracted workaround: None. (Issue **32956426**)

Certain columns on the Study Settings tab are not translated to Japanese

Study managers: In the Visit Settings table, the columns titled Site Enters Visit Dates and Site Edits Visit Dates are properly translated to Japanese. Previously, the titles of these columns were not translated to Japanese, even though you had selected Japanese as your preferred language.

Retracted workaround: None. (Issue **32908869**)

Local lab values not translated to Japanese

Sponsor users: Certain local lab values (such as years, months, days) are now properly translated to Japanese. Previously, these values were still displayed in English. Keep in mind that local labs may use custom code values that are added in English (and not translated by the system). The following values are now translated:

- **Lab Unit**: the default code value called "Sample";
- **Normal Text Result**: the default code value called "Sample";
- **Fasting**: The code value called "All";
- **Gender**: The code value called "All";
- **Race**: "The code value called "A".

(Issue **32910370**)

Delayed user creation when uploading duplicate files in parallel

User administrators: Now, all users are created without delay when you upload a template containing identical user and role details, while the first upload is still in progress. Previously, when you attempted to upload a duplicate file, while the first file was still in progress for a study or multiple studies at your organization, you could encounter a delay in user creation in Clinical One Cloud Service. This was caused by a delay in the service responsible for user creation in Clinical One Cloud Service. (Issue **34039516**).

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Forms, visits, and rules

Send Notification rule doesn't work as expected

Study designers: Now, when you create a Send Notification rule and specify the study roles that should receive the notification, all users who are assigned that study role receive the appropriate notification when it is generated. Previously, users assigned a specific study role (specified in the Send Notification rule) didn't get a notification when expected. Instead, the rule only worked when you specified the recipients' email addresses. (Issue **34914490**)

Duplicate automated queries are unexpectedly created

Rule designers: Now, when a site user enters data manually into a form, the fields that have any automated query rules associated with them will work as expected. Previously, when a site user manually entered data into a field with an automated query rule created for it, that automated query rule may have created multiple queries. (Issue **34909567**)

Selecting a value from the Select Lab drop-down results in an error

Site users: Now, after selecting a lab value from the Select Lab drop-down on a lab form, you are no longer presented with an error. Previously, when you made a selection, you were presented with, An issue just occurred in the system. Try performing this action again.

Retracted Workaround: None. (Issue **34783047**)

Signing out is required to see updates to a live study (former known issue)

Site users and sponsor users: Now, when a study designer applies a study design update to a live study version (such as adding a new question to a form or adding a new form to an existing visit), that update is properly reflected in the updated study version for a site user to see. Previously, it would take up to 15 minutes for the change to be displayed for the site staff.

Retracted workaround: A site user no longer has to refresh the Subjects page or sign out and back in for the study design updates to become effective. (Issue **33418179**)

Removing lab unit or test from code list also removes it from normal ranges list (former known issue)

Study designers: Starting with this release, you no longer can or have to delete a code value from a code list, including lab units or tests. You can only hide a value from a code list. This will ensure that any lab unit or test that you hide from a code list does not remove it from the normal ranges list. For more information, see Create and manage code lists for all studies at your organization.

From now on, on the Subjects page, in the visit view, the lab unit that you hide is still displayed in previously completed lab forms. This ensures that hiding a code value from a code list does not cause any normal ranges that were previously entered to become invalid.

Retracted workaround: You can no longer delete Test Names and Units from tagged code lists, you can only hide these values from the code list. (Issue **31938228**)

Icons on a duplicated form are no longer displayed (former known issue)

Study designers: Now, after you duplicate a form, you may notice that its icons are displayed, as expected. Previously, the appropriate icons were not displayed for duplicate forms. For example, if you copied form A, that contained questions related to randomization, calculated doses, rollover visits, and branches, you may have noticed that the copied form A did not display the expected icons that indicated the presence of those questions.

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Retracted workaround: You no longer have to refresh your browser's page to have the duplication icons displayed. (Issue **34296461**)

A dialog's title is not translated to Japanese (former known issue)

Study designers: Now, with your preferred language set to Japanese, you will notice that the All Visits in Branches dialog title is properly translated to Japanese. Previously, after selecting individual cycles for assigning a form to a branch, this dialog's title was still displayed in English.

Retracted workaround: None. (Issue **33659421**)

Closed captions are not generated for a video in Japanese

Study designers: Now, the video called Create and Copy Forms is displaying Closed Captions (CC) in Japanese, as expected. Previously, this video in Clinical One Cloud Service did not display Japanese Closed Captions (CC). This complicated the user's experience with their in-product training. (Issue **34474875**)

The hover text of a branch is not translated to Japanese

Study designers: While the application's preferred language is set to Japanese, when you hover your mouse cursor over a branch's title, the hover text is translated to Japanese, as expected. Previously, the displayed hover text was not translated and the English text also contained a typo. (Issue **32916654**)

The Rule Editor dialog title overlaps with a rule's title (former known issue)

Rule designers: Now, when the application language preference is set to Japanese, the rule's title (that you add in the Rule Name field) is properly displayed in the Rule Editor dialog. Previously, you may have noticed that a rule's title was overlapping with the Rule Editor dialog title.

Retracted workaround: None. (Issue **34224726**)

An error displays when completing a visit or event with a radio button in Testing Mode

Study Designers: Now, users are able to complete a visit or event with a radio button from a study live in **Testing Mode** without an error prompting. Previously, when study designers completed a visit or event, the error '*An issue occurred in the system. Try performing this action again*' displayed when saved. The error showed after saving a subject screening in a **Baseline** visit. (Issue **34890170**)

Integrations

A job is failing with an unexpected error message (former known issue)

Integration managers: For an integration between the Clinical One Cloud Service and Oracle InForm, you can now send data on a subject who previously failed screening. Previously, after you successfully screened a subject and ran the integration, a job would fail with the following message: "The initial submit for a subject is not the screening form."

Retracted workaround: None. (Issue **34313755**)

An integration may not send screening data to Oracle InForm

Integration managers: Now, for an integration between Clinical One Cloud Service and Oracle InForm, data related to screen failures is sent to Oracle InForm, as expected. Previously, you may have noticed that jobs associated with an integration were marked as

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successful in the system, even though the appropriate screen failure data wasn't even sent through the integration. (Issue **34145697**)

Oracle Digital Gateway Builder integrations cannot be properly configured

Oracle Services: Now, you can configure and run integration with the Oracle Digital Gateway Builder applica

Unable to properly view a job's details in Clinical One Digital Gateway (former known issue)

Integration managers: Now, while an integration is running, you can properly view details about its associated jobs on the Job side panel. Previously, the Jobs side panel did not expand enough for you to view any of the details of a job.

Retracted workaround: You no longer have to check your browser's resolution settings and adjust them in a way that will make the Jobs side panel expand. Job details display as expected already. (Issue **34276537**)

Treatment arm details cannot be integrated with Oracle InForm (former known issue)

Integration managers: Now, for an integration between the Clinical One Cloud Service and Oracle InForm, you can integrate treatment arm details for a randomized subject, as expected. Previously, when you attempted to do this, an error message stated that it could not find certain parameters to synchronize the data between the two applications. This issue was caused by a misconfiguration between parameters in the integration configuration file.

Retracted workaround: You no longer need to use the GUID of the treatment arm to ensure that data is synchronized between the two applications. For more information on this fixed issue, reach out to your Oracle point of contact. (Issue **34334378**)

Oracle Clinical One Analytics

Oracle Clinical One Analytics displayed two-section form data as deleted even though it wasn't

Now, the data from the flat and repeating sections of a two-section form is displayed correctly even if you delete the last entry in a repeating section of a two-section form or the last instance of a two-section form entirely.

Previously, data sets that contained data from two-section forms displayed all flat and repeating section data as deleted if the last entry in a repeating section was deleted or a two-section form was deleted entirely. This issue was observed after completing two-section forms in an unscheduled visit. (Issue **35118802**)

Oracle Clinical One Analytics displayed two-section form data incorrectly

Now, the last entry in the repeating section of a two-section form no longer appears in the flat section record in the data set. Previously, data collected in the last instance of a repeating section of a two-section form was displayed in the flat section within a data set when it should not have been. (Issue **35120560**)

Data for unscheduled visits and cyclic branch visits are overwritten in data extract form tables

Now, unscheduled visits are verified in data extract tables, and cyclic and non-cyclic branches are supported in runtime in Oracle Clinical One Analytics. Previously, after moving a study design with screening, non-cyclic branch, cyclic branch, and unscheduled visits from Draft to

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Testing mode, then adding data for each branch and unscheduled visit, data for each instance was overwritten in data extract form tables. (Issue **34981114**)

Edited data integrated with Oracle Clinical One Analytics does not reflect in reports

Sponsor users and services consultants: Users can now see the data edits reflected in the Oracle Clinical One Analytics reports. Previously, after modifying data, such as subjects or events in Clinical One, the edits did not show in the Analytics reports. For Clinical One studies integrated with Clinical One Analytics certain data were not integrated. For example, when users ended visits or changed the subject's data, the back end displayed a differed status. The error ‘Error while inserting and updating form data row' prompted. For more details on the back-end process, contact your Oracle point of contact. (Issue **34865395**)

Data not displayed in data sets when dispensation occurs during screening (former know issue)

Users working with Oracle Clinical One Analytics: Now, the Analytics report shows that the screening visit has dispensed the kits. Previously, we reported that in Clinical One Cloud Service, when you assigned kits for dispensation to the screening visit, those same kits did not appear in the **Kits and Randomization Design** data set in Oracle Clinical One Analytics

Retracted workaround: None (Issue **34042915**)

The Study Design Delta report does not show deleted visits or forms (former known issue)

Study designers: Now, the changes show in the correct columns in the Study Design Delta report. Previously we noted that the Study Design Delta report would not indicate any changes, such as deleting a form or visit from a study. Also, the report column did not record the details of events and forms in the appropriate columns.

Retracted workaround: None (Issue **34053211**)

Non-existent study changes are displayed in the Study Design Delta report (former know issue)

Study Designers: Now, the study versions display the correct data with no registered differences. Previously, we reported that when you attempted to build a report with the study differences in the Study Design Delta report, unsolicited changes in the **Item Details** table appeared in your study in Clinical One Cloud Service. The report indicated changes between study versions, even when you made none. This behavior happened when moving the study to a different mode and running the Study Delta report.

Retracted workaround: None (Issue **34059966**)

The ACTION_RULES data element does not display the expected data (former know issue)

Study Designers: Now, the columns report displays the expected data in the correct order with no changes. Previously, we reported that in the Study Design Delta report, the **ACTION_RULES** column did not display data in the same order for different study versions when the forms contain multiple predefined rules. This behavior happened even when users made no changes.

Retracted workaround: None (Issue **34265433**)

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Data related to subject visits may not be properly displayed in Analytics (former known issue)

Now, data related to all types of visits is properly displayed in all corresponding datasets in the Analytics app. Previously, because data between the Clinical One Cloud Service and the Oracle Clinical One Analytics was not updated as expected, the same data wasn't properly displayed in datasets either. This behavior was observed with cycle and non-cycle visits, as well as branches. This was a backend issue caused by an unexpected error message that appeared when data is refreshed in the Analytics app.

Retracted workaround: None. (Issue **34284115**)

Expired user accounts in Clinical One Cloud Service can still access Analytics (former known issue)

Now, a user in Clinical One Cloud Service whose access has expired can no longer use the Oracle Clinical One Analytics application. Previously, even though a user's access may have expired, they could still access datasets and reports in Oracle Clinical One Analytics.

Retracted workaround: None. (Issue **34274952**)

The Study Design dataset displays confusing error message (former known issue)

Now, when you include a combination of the ITEM_NAME and READONLY data elements, in the Rows portion of a Data Canvas, you can view the newly introduced data as expected. Previously, you may have noticed that a confusing error message was displayed after adding these data elements to the canvas. The message stated "Unable to Display Table – Query Canceled".

Retracted workaround: None. (Issue **33742720**)

Data on upcoming visits is not properly displayed in certain datasets (former known issue)

Now, for a completed or withdrawn subject, data on upcoming visits in the study is no longer displayed in the Subject Forms datasets. Previously, whenever a subject was marked as **Complete** or **Withdrawn** in a study in Clinical One Cloud Service, data on upcoming visits in Oracle Clinical One Analytics was displayed as missing from the study.

Retracted workaround: None. (Issue **34288471**)

The Templates folder should be read-only for sponsor users (former known issue)

In Oracle Clinical One Analytics, the Clinical One Report Templates (located underneath the Shared Folders) is now read-only. Any modified reports or dashboards need to be saved in other folders within the application for you to further edit them.

Sponsor users can perform the following actions related to these templates only when they're located in a different folder:

- Add filters.
- Update filter values.
- Export reports and dashboards as a DVA file and import them into a different folder in the application. This lets sponsor users perform any other changes and save them into the exported file.

Retracted workaround: None. (Issue **34241618**)

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Data related to dispensation may not be properly displayed in Oracle Clinical One Analytics

Now, whenever a dispensation visit without prior randomization is complete, the data from Clinical One Cloud Service is sent to Oracle Clinical One Analytics, as expected. Previously data related to dispensation visits was not properly displayed in certain datasets, such as the Blinded Subject Event, Unblinded Subject Event, and the Unblinded Kits dataset.

Retracted workaround: None. (Issue **34274613**)

Randomization and kits

A kit's expiration date is displayed incorrectly

Clinical supply managers: Now, kits that are present in a study or site inventory have their expiration date displayed as expected according to the lot that they belong to. Previously, you may have noticed that a kit may have had an earlier expiration date than the date specified in the lot. The kit's expiration date was displayed in both inventories (for a study or a site) on the Expiration Date column. (Issue **34899167**)

Japanese characters not allowed in the title of a list (former known issue)

Clinical supply managers and statisticians: Now, on the Supply Settings tab, you can upload a kit or randomization list that contains Japanese characters in their file name, without receiving any error messages. Previously, the system raised an error message whenever the filename of a list contained Japanese characters.

Retracted workaround: You no longer have to make sure your kit or randomization lists do not contain Japanese characters in their file name. (Issue **32577227**)

Receiving kits quarantined notification when kits were not in quarantine.

Users subscribed to Quarantined Depot or Site Shipments notifications: Now, when a site user registers a shipment that is not quarantined, other users with the *Receive the Quarantined Depot Shipment Notification* or *Receive the Quarantined Site Shipment Notification* permission do not receive unsolicited notifications. Previously, whenever site users generated a shipment without any quarantined kits, other subscribed users would receive unrequested notifications about raised shipments with no quarantined kits. (Issue **34771269**)

Reports, archives, extracts, and notifications

Questions with measurement units were not integrated as expected with Oracle DMW

Data managers and statisticians: When a question with numbers contains an associated measurement unit, that type of question is now displayed as NUMBER in the Type column, in the data extracts generated for the integration with Oracle DMW. Previously, a question with measurement units was displayed as VARCHAR2 (data that is varying) in the Type column. (Issue **34917672**)

Questions with code lists were not properly displayed in the Subject Data Extract

Data managers and statisticians: Now, in a Subject Data Extract, the following types of questions are displayed as expected:

- Questions with a code list applied to them where the code list's name contains special characters such as a forward slash (/).

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- Questions with a code list applied to them where the code value is not defined.
- Questions with a code list applied to them where the code list was renamed prior to the 22.3 release.

Previously, these types of questions were not properly displayed in the Subject Data Extract. Moreover, there were times when generating this extract failed due to several validation issues. (Issue **34939373**)

The User Assignment report is not populating a user's username (former known issue)

User managers: Now, when you generate a User Assignment report with historical data, all usernames are displayed in the report, aspected. Whether a user is removed from a study, retired, active, newly created, or their account has been deactivated in Oracle Life Sciences IAMS, their username is properly displayed in the report. Previously, some usernames were displayed as "N/A". This happened when a user was deleted from the study and deactivated in Oracle Life Sciences IAMS.

Retracted workaround: Although this issue has been fixed, we still recommend you do not delete a user from a study. Instead, when required, set a specific End Date for their access to the study. That way, after the specified date, they will no longer be a part of your study and you can also maintain a record of their study association. (Issue **34483826**)

Date range issues in the Kit Chain of Custody (Blinded) report (former known issue)

Sponsor users: Now, the Kit Chain of Custody (Blinded) report displays the kit transitions that have occurred on a certain date in the system, as expected. For example, if you choose 27-June-2022 as one of the dates in the **Transaction Date** setting, you may notice that kit transactions from that date are displayed in the report. Previously, kit transactions for specific dates were not properly displayed in this report. This issue was caused by a time zone inconsistency occurring in your browser.

Retracted workaround: None. (Issue **34300162**)

A subject's status is displayed in English in a Japanese Kit Dispensation report

Site users: Now, when you generate the Kit Dispensation report, you will notice that a subject's status is displayed in Japanese, as expected. Previously, when your language preference was set to Japanese, you may have noticed that a subject's status was still displayed in English, despite the report having been generated in Japanese.

> **Note**
>
> A subject's status is located in the header bar of the Kit Dispensation report.

(Issue **33087630**)

Shipment creation notifications are not sent to depots (former known issue)

Clinical supply managers and depot users: Now, if you're working in multiple studies at your organization, you may notice that depot facilities are receiving email notifications when a new shipment is created, as expected. Previously, the email associated with a customer depot did not receive shipment creation notifications when a new shipment was created.

Retracted workaround: None. (Issue **34307434**)

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Sequence numbers in the Submission PDF are not properly sorted

Sponsor and site users: Now, sequence numbers for repeating forms are sorted in numeric order only (for example: 1, 2, 3, 4, 5). Previously, sequence numbers were sorted in an alphanumeric order. For example, if a repeating form contained 10 instances, the 10th instance would be placed after the first and you would see 1, 10, 2, 3, 4. (Issue **34343692**)

The Subject Queries report does not properly display query-related data (former known issue)

Sponsor and site users: Now, when you transfer a subject at another site and you modify an existing query at the previous site, the query update is properly displayed in the Subject Queries report. Previously, when you transferred a subject at another site and then you updated an existing query associated with that subject and their initial site, this update was not displayed in the report. For example, you updated an existing query at site A (their initial site) and then you added a new query at site B (the site where they were transferred). In the Subject Queries report, on the Last Updated On Site column, you may have noticed that the initial site was displayed, instead of the site where the subject was transferred to.

Retracted workaround: None. (Issue **34271619**)

Lab ID and lab name only displayed for predefined lab rows (former known issue)

> **Note**
>
> Lab IDs and names will only be displayed for labs going forward. IDs and names of existing labs in your study will not be displayed in the extract.

Study designers: Now, for a lab form, when you switch the **Add Additional Rows** toggle on, several users will get to experience the appropriate impact in the User Interface (UI).

- Data managers and statisticians can now see all additional repeating rows in the Subject Data Extract. Columns in the extract are populated with data whether the additional rows are manually added by a site user (in the UI) or automatically through an integration.
- Data managers and statisticians can only see the lab name and ID associated with these additional rows. Lab normal values are not displayed in the Subject Data Extract or the UI for additional repeating rows.

Retracted workaround: None. (Issue **32079296**)

Inconsistent month format between blank and subject PDF (former known issue)

Sponsor users: Now, the month value in the Blank Form PDF file matches the month value in the subject PDF file. Previously, the month drop-down in the blank PDF file displayed Japanese characters which did not match the subject PDF output.

Retracted workaround: None. (Issue **32699964**)

Site Confirmation and Download Log incorrectly displays data when administrative data contains commas

Sponsor users: Now, if administrative data such as a site's name includes a comma, the CSV output for the Site Confirmation & Download Log archive reports display administrative data in the correct cells. Previously, if a comma existed in a site's name (for example 'Health Center, ABC') the 'ABC' portion was inserted in the next cell. (Issue **33139699**)

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The Subject Data Extract does not display all code list values (former known issue)

Study designers, code list managers, and statisticians: The Subject Data Extract report now displays the code values in the expected format. Previously, we reported that for new and existing questions in a study, when you assigned a system default code list group to a study or a custom code list to a question, certain code values were not displayed properly in the Subject Data Extract. As an example, when you flagged a question with the "Not Applicable" option, the code value was not displayed in the Subject Data Extract.

Retracted workaround: None (Issue **34769175**)

Site users and subject data

Cannot update visit date for a reinstated subject (former known issue)

Site users: Now, after you reinstate a subject in the study (Undo Subject Completion or Undo Withdrawal), you can clear the previously entered visit date (in the Visit Start Date field) and continue with a subject's visits. Previously, whenever you had to reinstate a subject, you could not change a visit's date for the subject's next scheduled visit. An error message was displayed stating that the visit date that you entered must be on or after a certain date.

For more information on clearing data, see Clear saved data for a subject.

Retracted workaround: A study designer no longer has to extend the start window of the Completion or Withdrawal event to enable a lengthier visit window for the subject's next visit (that appears after they are reinstated). (Issues **33839734** and **33839744**)

A repeating form tool tip is not properly translated

Site users: Now, in a repeating form table, when you hover over the status icon of a repeating form instance (or row), the tool tip is displayed in your application's preferred language. Previously, for example, if your language preference was set to Japanese and you hovered over a status icon in a repeating form, you may have noticed that the text was still displayed in English. (Issue **32920898**)

Failed screening visits must be displayed with a status of Incomplete (former known issue)

Site users: Now, when a subject fails their screening visit and that specific visit has any incomplete forms or opened queries, the visit's status is not only displayed as **Failed Screening**. The hover text also indicates whether there are any opened queries, if the visit is considered incomplete (when there are are incomplete forms), in progress, or complete.

Retracted workaround: None. (Issue **34290221**)

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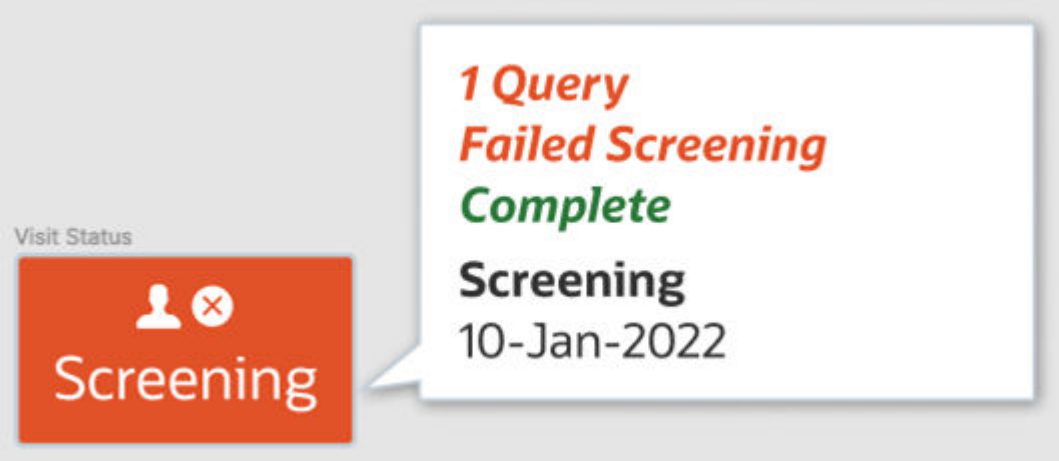
Figure 13-6 How a visit's status is displayed



A query's age is not translated to Japanese

Data managers: On the Queries side panel, a query's age is now translated to Japanese. For example, if you just created a Candidate query a few seconds ago, the part "a few seconds ago" that is displayed next to the query is properly translated to Japanese. Previously, a query's age was displayed in English. (Issue **32920602**)

A question's status of Signed is not translated to Japanese

Principal investigators and site users: Now, when your language preference is set to Japanese, a question's status of Signed is properly translated to Japanese, as expected. Previously, in the Answer History and Visit History sidebars, the Signed status was not translated to Japanese. (Issue **32916685**)

Tooltip text for signed, verified, and frozen questions is not translated to Japanese

Site users: Now, when you hover your mouse cursor over a question's icon for Signed, Verified, or Frozen, the tooltip text that is translated to Japanese, as expected. Previously, the tooltip text was still displayed in English. (Issue **32919376**)

The Subject Rollover dialog title is not translated to Japanese

Site users: Now, when you roll a subject over to another study, the Subject Rollover confirmation dialog title is translated to Japanese, as expected. Previously, once the Subject Rollover dialog was displayed, you may have noticed that the dialog's title was still displayed in English although the content of the dialog was translated to Japanese. (Issue **32934262**)

Rest API updates

See what has been updated in the Clinical One Cloud Service API.

The following services have been updated:

- Code list
- Coding
- Data Action
- Data Hub

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- Data Integration
- Data Capture
- Designer
- Notifications
- Randomization and Supplies
- Reporting
- Sites and Depots
- Users, Permissions and Roles

Code list

Change	Method	Endpoint
New	DELETE	/v2.0/codelist/code/{codeId}
	PUT	/v3.0/codelist/code/{codeId}
Deprecated	GET	/v1.0/codelist/values/{fieldName}
	GET	/v2.0/codelist
	POST	/v2.0/codelist/code
	PUT	/v2.0/codelist/code/{codeId}
	GET	/v2.0/codelist/history/{name}
	GET	/v2.0/codelist/{name}
	GET	/v3.0/codelist
	GET	/v3.0/codelist/{name}

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Coding

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/subjectNumberChange

Data Action

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/lockedstatus
	POST	/v1.0/studies/{studyId}/{mode}/cleardatacheck/{scope}
	GET	/v1.0/studies/{studyId}/{mode}/subjects-with-locked-data
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks/all
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks/visits
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/unlocks
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/multipleitems/locks
	PUT	/v1.0/studies/{studyId}/{mode}/unsign-unverify

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Data Hub

Change	Method	Endpoint
New	POST	/v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/lockedstatus

Data Capture

Change	Method	Endpoint
New	PUT	/v1.0/studies/{studyId}/{mode}/dataelements/clear/{scope}
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata
	PUT	/v1/studies/{studyId}/{mode}/subjects/subjectnumber
	GET	/v10.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v10.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v10.0/studies/{studyId}/{mode}/visitstatus
	POST	/v10.0/studies/{studyId}/{mode}/visitstatus/subjects

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Change	Method	Endpoint
	PUT	/v10.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/{dataelementId}
	GET	/v2.0/studies/{studyId}/{mode}/subjects/dateRange
	GET	/v2.0/studies/{studyId}/{mode}/subjects/history/all
	POST	/v2.0/studies/{studyId}/{mode}/subjects/visitschedule
	GET	/v3.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	POST	/v3.0/studies/{studyId}/{mode}/subjects/randomizeordispense
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v6.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
	GET	/v7.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	PUT	/v8.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/subjectnumber
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/subjectnumber
Deprecated	POST	/v1.0/studies/{studyId}/{mode}/dataelements/freeze

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Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/dataelements/verify
	POST	/v1.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/subject/{subjectId}/code/{code}/orgId/{orgId}
	POST	/v1/studies/{studyId}/{mode}/dataelements
	GET	/v1/studies/{studyId}/{mode}/dataelements
	PUT	/v1/studies/{studyId}/{mode}/dataelements
	GET	/v1/studies/{studyId}/{mode}/dataelements/all
	GET	/v1/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	POST	/v1/studies/{studyId}/{mode}/dataelements/multiple
	POST	/v1/studies/{studyId}/{mode}/dataelements/multirepeatingform
	GET	/v1/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v1/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v1/studies/{studyId}/{mode}/forms/{formId}/dataelements
	GET	/v1/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements

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Change	Method	Endpoint
	GET	/v1/studies/{studyId}/{mode}/sites/{siteId}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/formassociations
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	DELETE	/v1/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements
	POST	/v1/studies/{studyId}/{mode}/subjects
	GET	/v1/studies/{studyId}/{mode}/subjects
	GET	/v1/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	POST	/v1/studies/{studyId}/{mode}/subjects/randomizeordispense
	GET	/v1/studies/{studyId}/{mode}/subjects/sitestudyversion
	DELETE	/v1/studies/{studyId}/{mode}/subjects/state/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/codeview

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Change	Method	Endpoint
	POST	/v1/studies/{studyId}/{mode}/subjectsettings
	GET	/v1/studies/{studyId}/{mode}/subjectsettings
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/{transferId}
	POST	/v1/studies/{studyId}/{mode}/visitstatus
	GET	/v1/studies/{studyId}/{mode}/visitstatus
	GET	/v1/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v1/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v1/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v2.0/studies/{studyId}/{mode}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	POST	/v2.0/studies/{studyId}/{mode}/dataelements/multiple

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Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v2.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v2.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/formassociations
	GET	/v2.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	POST	/v2.0/studies/{studyId}/{mode}/subjects
	GET	/v2.0/studies/{studyId}/{mode}/subjects
	GET	/v2.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
	POST	/v2.0/studies/{studyId}/{mode}/subjects/randomizeordispense
	GET	/v2.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak

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Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	POST	/v2.0/studies/{studyId}/{mode}/visitstatus
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus/dateRange
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v2.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v2.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v3.0/studies/{studyId}/{mode}/dataelements
	GET	/v3.0/studies/{studyId}/{mode}/dataelements
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v3.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v3.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/ dataelements
	GET	/v3.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

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Change	Method	Endpoint
	GET	/v3.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}
	POST	/v3.0/studies/{studyId}/{mode}/visitstatus
	GET	/v3.0/studies/{studyId}/{mode}/visitstatus
	GET	/v3.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v3.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v3.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v4.0/studies/{studyId}/{mode}/dataelements
	GET	/v4.0/studies/{studyId}/{mode}/dataelements
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v4.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v4.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/ dataelements
	GET	/v4.0/studies/{studyId}/{mode}/subjects/sitestudyversion

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Change	Method	Endpoint
	POST	/v4.0/studies/{studyId}/{mode}/visitstatus
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v4.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v4.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v5.0/studies/{studyId}/{mode}/dataelements
	GET	/v5.0/studies/{studyId}/{mode}/dataelements
	GET	/v5.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v5.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v5.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v5.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v5.0/studies/{studyId}/{mode}/visitstatus
	POST	/v5.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v5.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}

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Change	Method	Endpoint
	POST	/v6.0/studies/{studyId}/{mode}/dataelements
	GET	/v6.0/studies/{studyId}/{mode}/dataelements
	GET	/v6.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v6.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v6.0/studies/{studyId}/{mode}/eventsCount
	GET	/v6.0/studies/{studyId}/{mode}/repeatInstanceNumbers
	GET	/v6.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v6.0/studies/{studyId}/{mode}/visitstatus
	PUT	/v6.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	GET	/v7.0/studies/{studyId}/{mode}/dataelements
	GET	/v7.0/studies/{studyId}/{mode}/visitstatus
	POST	/v8.0/studies/{studyId}/{mode}/dataelements

Designer

Change	Method	Endpoint
New	POST	/v1.0/studies/welcome

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Change	Method	Endpoint
	GET	/v1.0/studies/welcome
	PUT	/v1.0/studies/welcome
	DELETE	/v1.0/studies/welcome
	GET	/v4.0/studies/{studyId}/statuses
	GET	/v4.0/studies/{studyId}/statuses/{version}
	POST	/v1.0/studies/{studyId}/lockObjectDetails

Notifications

Change	Method	Endpoint
New	POST	/v1.0/i18support/email/{templatetype}

Randomization and Supplies

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/events/resume_dosehold_dispensation/{eventId}
	GET	/v1.0/studies/{studyId}/{mode}/events/resume_partial_dispensation/{eventId}
	GET	/v1.0/studies/{studyId}/{mode}/kits/{inventoryId}/historyById
	GET	/v1.0/studies/{studyId}/{mode}/kits/{inventoryId}/lastStatusById

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Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings
	GET	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings
	GET	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	PUT	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	DELETE	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	POST	/v1.0/studies/{studyId}/{mode}/reports/partialdispensations
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/historyById
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/lastStatusById
	POST	/v1.0/studies/{studyId}/{mode}/subject-partial-dispensations
	POST	/v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	GET	/v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	POST	/v15.0/studies/{studyId}/{mode}/visits/subjectvisit
	PUT	/v2.0/studies/{studyId}/{mode}/barcode
	GET	/v2.0/studies/{studyId}/{mode}/events/codebreak/{eventId}

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Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/{mode}/kits/{kitNumberUTF}/lastStatus
	GET	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumberUTF}/lastStatus
	POST	/v2.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits
	GET	/v3.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	GET	/v3.0/studies/{studyId}/{mode}/kits/{kitNumberUTF}/history
	GET	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumberUTF}/history
	GET	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits
	POST	/v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/doseheld
	POST	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/reuse-kits
	GET	/v4.0/studies/{studyId}/{mode}/inventory/kit-types
	GET	/v5.0/studies/{studyId}/{mode}/inventory/kit-types
	GET	/v7.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits

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Change	Method	Endpoint
	GET	/v8.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	PUT	/v8.0/studies/{studyId}/{mode}/supply/settings
	GET	/v9.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
Deprecated	GET	/v1.0/studies/{studyId}/{mode}/kits/{kitNumber}/history
	GET	/v1.0/studies/{studyId}/{mode}/kits/{kitNumber}/lastStatus
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumber}/lastStatus
	GET	/v2.0/studies/{studyId}/{mode}/kits/{kitNumber}/history
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumber}/history

Reporting

Change	Method	Endpoint
New	POST	/v1.0/notification/{notificationType}

Sites and Depots

Change	Method	Endpoint
New	DELETE	/v1/studies/{studyId}/{mode}/sdfs/deleteDepotEmail
	GET	/v2/studies/{studyId}/{mode}/country/{countryId}/states

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Change	Method	Endpoint
	GET	/v2/studies/{studyId}/{mode}/sdfs/countries
	GET	/v3/studies/{studyId}/{mode}/regions
	GET	/v3/studies/{studyId}/{mode}/regions/{regionId}
	GET	/v3/studies/{studyId}/{mode}/regions/{regionId}/countries
	GET	/v3/studies/{studyId}/{mode}/sdfcountry
	GET	/v4/studies/{studyId}/{mode}/country

Users, Pemissions and Roles

Change	Method	Endpoint
New	POST	/v1.0/report/globalstudyrole/{reportName}
	POST	/v2.0/{studyId}/{mode}/report/uploaderror/{reportName}

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14

Clinical One Cloud Service and Clinical One Digital Gateway 22.2 (June 2022)

- Patch log
- What's new
- Fixed issues

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.2 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway application.**

Table 14-1 Patch log

Release Number	Release Date	Notes
Release 22.2.3	20-October-2022	For this release, Clinical One Cloud Service renewed its Statistical Analysis System license. The ongoing SAS technology facilitates compliant study data analysis for data managers and statisticians. The SAS yearly update doesn't impact users working with Clinical One Cloud Service and Clinical One Digital Gateway.
Release 22.2.2	10-October-2022	For this release, we fixed several issues related to subject visits, integrations, and Oracle Clinical One Analytics. For more information, see: • Other enhancements to review details for enhancement **31374245** related to the integration with Fisher Clinical Services. • Site users and subject data to review details for fixed issue **34625379**. For this release, we also improved the performance of Oracle Clinical One Analytics by dedicating a server group, creating a more stable environment.

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Table 14-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 22.2.1	08-August-2022	For this release, we fixed issues related to notifications and data collection. For more information, see: • Reports, archives, extracts, and notifications to review details for fixed issues **34307434** and **34399461**. • Forms, visits, and rules to review details for fixed issues **34287424** and **34314729**. • Integrations to review details for fixed issue **34376688**. A new enhancement has been added for this release, as well. To learn more, see: • Hide the visit window projection

What's new

- Data collection
- Randomization and trial management
- Reporting and analytics
- Rules management
- Other enhancements
- Documentation updates
  Learn more about the updates to our documentation.

Data collection

- Enhanced queries management experience
  You can now manage queries directly on the **Queries** sidebar, on the right side of the page.
- Hide the visit window projection
  Sponsor users can now hide the visit window information using the Hide the Visit Window Projection option on the Study Settings page.

Enhanced queries management experience

You can now manage queries directly on the **Queries** sidebar, on the right side of the page.

Details for sponsor and site users

Queries are used to question clinical data correctness and to ensure data quality by promoting conversations between sponsor and site users. Previously, queries could only be managed by directly interacting with the question on the form. This could lead to situations where queries

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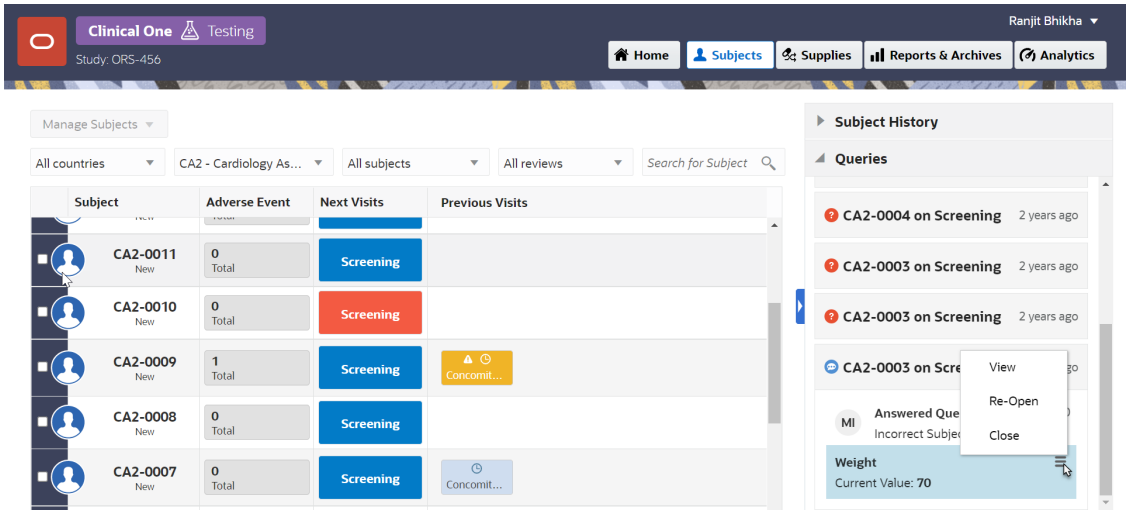
became inaccessible through the User Interface (UI), such as when a question is hidden due to a design change or a user's action.

With this new feature, you can now manage queries directly on the **Queries** sidebar. There are several menu options available for each query item. Menu options are displayed depending on your user role and permissions, the type of query, and the status of the query you want to manage. With each query, you may be able to perform the following actions:

- **View** a query in a visit form.
- **Answer** an opened query.
- **Open** a candidate query.
- **Close** a query.
- **Re-Open** an answered query.
- **Delete** a candidate query.



Already working in a live study?

As soon as this release is available, you can use this menu to manage any new and existing queries on the sidebar. Details on how to manage queries from the **Queries** sidebar will be featured in the *Sponsor and CRO User Guide* and the *Site User Guide*.

Hide the visit window projection

Sponsor users can now hide the visit window information using the Hide the Visit Window Projection option on the Study Settings page.

Currently, projected visit dates and time frames for upcoming scheduled visits are displayed on the Subjects page. Now, the new **Hide the Visit Window Projection** setting allows sponsor users to hide the time frame for scheduled visits for an active subject.

Details for sponsor users

A new field, **Hide the Visit Window Projection**, has been added to the Study Settings page. Selecting **Yes** for the **Hide the Visit Window Projection** configuration hides the date and date range for scheduled visits under the visit title. If **No** is selected , the system displays the projected visit date, or date range, for upcoming scheduled visits.

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This configuration can be updated during the study conduct period, and there is no restriction to edit it once a study version is promoted to the Approved container.

Already working in a live study?

Once the upgrade for this release is complete, the **Hide the Visit Window Projection** configuration will be available for all studies. This setting will be set to **No** by default for all existing and newly created studies. For step-by-step instructions on how to update this setting, see Specify study, enrollment, and visits settings.

Randomization and trial management

- Notification and report enhancements for shipment receipts
  Sponsor users can now get notified about individual kits and shipments being quarantined and released.
- Organize kits by block numbers
  Now, when they define their kit lists, clinical supply managers can now organize kits by block numbers.

Notification and report enhancements for shipment receipts

Sponsor users can now get notified about individual kits and shipments being quarantined and released.

Details for user administrators and global user managers

Users assigned the *Receive the Quarantined Shipment Notification* permission will be able to receive both the Shipment Quarantined and Kits Quarantined notifications, while users assigned the *Receive the Released from Quarantine Notification* permission will be able to receive both the Shipment Released from Quarantine and Kits Released from Quarantine notifications.

> **Note**
>
> These permissions are differentiated between site and depot users with corresponding notifications.

About the new shipment receipt notifications

The Shipment Quarantined and Shipment Released from Quarantined notifications provide details regarding the:

- Study Name and Study ID
- Study Mode
- Shipment ID
- Origin and Origin ID
- Destination and Destination ID
- Shipping Address and Date Performed
- User who performed the status update

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The Kits Quarantined and Kits Released from Quarantine notifications include details identical to the Shipment Quarantined and Shipment Released from Quarantine notifications, but features additional information on the number of kits quarantined and their IDs.

Additional information on these notifications and permissions will be featured in the *Notifications and Permissions Guide*.

Details for other sponsor users

The Shipment Order Summary report now includes a new column indicating the shipments temperature monitor status with one of the following displayed in the column:

- **Yes**: Indicates a temperature monitor went off
- **No**: Indicates a temperature monitor did not go off
- **Missing**: Indicates there was no temperature monitor present in the shipment

> **Note**
>
> If the study's supply settings are configured to disallow temperature excursions, data in the column displays N/A.

The shipment status column displays a value of Quarantined if the entire shipment has been quarantined and Received if the shipment has been partially quarantined.

More information will be featured in the Shipment Order Summary report.

Already working in a live study?

Once the upgrade for this release is complete, users assigned the *Receive the Quarantined Shipment Notification* and *Receive the Shipment Released from Quarantine Notification* permissions will be able to receive the associated notifications, and temperature monitor status will be visible in the Shipment Order Summary report.

Organize kits by block numbers

Now, when they define their kit lists, clinical supply managers can now organize kits by block numbers.

Organizing kits by block numbers allows you to protect your kits that are prone to breakage and need to be packaged together. With the new option for block numbers, you can meet the distribution vendors' needs by sending kit data as a whole unit, not for each individual kit.

Details for clinical supply managers

Here's what's new for you:

- On the Kits tab, when you upload a kit list, you can now map the Block Number imported header to the appropriate value, whether it's Don't Import or Block Number.
- On the Shipments tab, when you create a shipment, a kit type may describe its block size. For example, a placebo kit type may indicate that the block size for this kit type is 4 units.
- When you create a new shipment, if you add a number of kits that is lower than its block size, the system adds additional kits to complete the block. For example, if you include 2 placebo kits in a shipment, the system includes 2 additional kits to complete the block of 4 units.

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- On the Study Inventory page, there is a new column called Block. On this column, the system indicates how many units are included in a block for each kit.

Already working in a live study?

As soon as the upgrade is complete for this release, you can begin uploading kit lists and organize your kits by block numbers. More information on how to set up block numbers when uploading a kit list can be found in the *Sponsor and CRO User Guide*.

Reporting and analytics

- Future and skipped visits and forms data included in Oracle Clinical One Analytics datasets
  Data of not-yet-started (future) visits and forms is now included in Oracle Clinical One Analytics datasets, allowing data managers to view future and skipped visits alongside completed visits, as well as to perform analysis of not-yet-started visits and data to be collected in a subject's journey.

Future and skipped visits and forms data included in Oracle Clinical One Analytics datasets

Data of not-yet-started (future) visits and forms is now included in Oracle Clinical One Analytics datasets, allowing data managers to view future and skipped visits alongside completed visits, as well as to perform analysis of not-yet-started visits and data to be collected in a subject's journey.

Data managers can now build custom reports including not-yet-started visits and forms data.This includes skipped and scheduled future visits, all forms attached to them, and any other not-started form. With this enhancement you are now able to:

- Build a report that displays all skipped visits for a subject.
- Build a report to view all missing forms and pending data to be collected for a subject.
- Project how much data will be collected at a site over a fixed period of time.
- Create a schedule of when forms should be started for a subject.

> **Note**
>
> Dynamic visits and forms, as well as cycle visits, are not included until an event happens that causes the visit or form creation as part of a subject's schedule. This may cause variations between any projected data and real data.

The following datasets have been updated to include missing visits data:

- Blinded Subject Events Data Set
- Unblinded Subject Event Data Set
- Subject Forms Dataset

This enhancement represents the addition of not-yet-started visits data to the data already available through each of these datatsets. No new folders or data elements were added. Also, all previous reports and visualizations you have created using these datasets will still be available and possible to recreate and maintain. To differentiate between data associated with completed visits and data associated with future or skipped visits, you can filter visits by status. For more information, see the *Analytics User Guide*.

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Rules management

- Helper functions for two-section forms
  Additional helper functions have been created to support rules on two-section forms.

Helper functions for two-section forms

Additional helper functions have been created to support rules on two-section forms.

Details for rule designers

Rule designers can use new helper functions to simplify their workflow when working in two-section forms. The following helper functions have been created to support custom rules on repeating sections of two-section forms:

- findMinIn2SForms()
- findMaxIn2SForms()
- findMinDateIn2SForm()
- findMaxDateIn2SForm()
- findMatching2SFormWithinRange()
- findDuplicate2SFormWithinRange()
- find2SFormInstance()
- getMatching2SFormsCount()

These helper functions mirror the functionality of existing helper functions for repeating forms.

Already working in a live study?

As soon as this release is available, these helper functions can be used in any existing or newly created rules and two-section forms. More information about new and existing helper functions will be featured in the Two section form functions section in the *Rules Developer Guide*.

Other enhancements

The Fisher Clinical Services integration now manages shipments for mapped depots only

The Clinical One Digital Gateway now omits shipments for non-Fisher depots. Clinical One Digital Gateway filters all shipment statuses for the unmapped depots and does not include them in the integration. Shipment statuses outside of its configured map are no longer sent to Fisher Clinical Services.

Previously, Clinical One Digital Gateway did not distinguish between Fisher and non-Fisher depot shipments. The integration failed when a non-Fisher depot was not mapped in the integration template. (Issue **31374245**)

System maintenance page and status notifications

Upon signing in, a new maintenance page displays when the Clinical One Cloud Service, all studies for an organization, or a specific study is undergoing maintenance.

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The maintenance page includes a link to the Clinical One Cloud Service status page which provides status information for the Clinical One Cloud Service as well as the Clinical One Digital Gateway, Oracle Clinical One Analytics, Oracle CRF Submit, and other Clinical One Cloud Service systems and services. To subscribe to status notifications, see System maintenance page and status notifications.

User study access expires at the end of the day for the date defined

The value you enter in the To field of an Effective Date Range, either populated using **Create/ Assign User** through the user interface or if included in the User Upload Template, now allows users to access a study through the end of the day for the date defined. For example, if the date 11-May has been defined as the end date, the user can access the study until 11:59 PM UTC of that day. Previously, user access would expire at 12:01 AM UTC of the date defined.

Study roles populate the User Upload Template upon download

Study roles, including template roles, now populate the Study Roles tab of the User Upload Template upon download. For additional details, see Create user accounts using the upload template.

Recommission a study

Your organization can now request the recommissioning of a study that was previously decommissioned by Oracle in Clinical One Cloud Service. More information about this enhancement will be featured in the Recommission a Study section of the *Sponsor and CRO User Guide*.

Format question hint text using rich text HTML tags

Study designers can now format question hint text using the following rich text HTML options, making it easier to communicate data collection requirements to your users.

- **Styles**: header, footer, and paragraph.
- **Font**: bold, underline, italics, and six color options.
- **Links**: Email and external links can be embedded in the text.

More information about this enhancement will be featured in the Create Question Hint text section of the *Study Designer User Guide*.

Define regions for your study in Clinical One Cloud Service

Clinical supply managers can now define regions by subsets of states of a country or a geographical area, allowing study designers to stratify in a more granular manner, based on region. A single country can be included in multiple regions, however, states can only be included in one region.

When study designers select the option to stratify based on region, the randomization algorithm works with randomization designs blocked by region and using minimization by region.

Step-by-step instructions on how to define regions will be featured in the *Sponsor and CRO User Guide*.

Edit scheduled reports

If you work with scheduled reports, you can now edit an existing schedule directly from the **Schedule reports** section on the Reports sidebar.

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> **Note**
>
> To access a given report and to schedule reports, you must have the required permissions. For more information, see the *Add Users Guide*.

More information about this feature will be included in Schedule a report within the *Sponsor and CRO User Guide*.

Documentation updates

Learn more about the updates to our documentation.

New in this release

The new *Notifications and Permissions Guide* allows users to easily locate descriptions for the different notifications and their required permissions in Clinical One Cloud Service.

Changes to user guide titles

- The *Information for Depot Users* guide has been changed to the *Depot User Guide*.
- The *Information for Site Users* guide has been changed to the *Site User Guide*.
- The *Information for Sponsor and CRO Users* guide has been changed to the *Sponsor and CRO User Guide*.

Fixed issues

- Facilities, settings, and user management
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits
- Reports, archives, extracts, and notifications
- Site users and subject data

Facilities, settings, and user management

An issue with a full SDV strategy occurs (former known issue)

Study managers: Now, when you work with a full SDV strategy, subject statuses are displayed as expected, in the API response and in the system. Previously, even though the SDV strategy was meant for a full verification of subjects' data, certain subjects seemed to not be selected for verification by the strategy's algorithm. For example, a subject's status appeared as NULL, even though they should've been selected for verification. In particular, this issue occurred when settings of the strategy were modified during the course of the study. The cause of this issue was due to certain values not being automatically updated in the application's database. (Issue **34053138**)

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A user's access to the study expires at the end of the specified date

User administrators: Now, the date that you specify in the To field of an Effective Date Range allows users access to a study through the end of that day. For example, if the date 11-May is defined as the end date, the user can access the study until 11:59 PM UTC of that day. Previously, a user's access would expire at 12:01 AM UTC of that day. For more details, see Other enhancements. (Issue **25475146**)

Japanese characters cannot be used in naming an SDV strategy

Study managers: Now, when your language preference is set to Japanese, you can add a Japanese title for your Source Data Verification strategy. Previously, when you attempted to complete the Title field, an error message was displayed stating that only letters and numbers are allowed. (Issue **32705148**)

Forms, visits, and rules

Subject visit shows as incomplete or unsaved when a Show Form rule is applied

Site users: Now, the form saves the data and the visit is complete when a dynamically displayed form is present in that visit. Previously, the subject visit showed incomplete or unsaved data, even when the subject already completed the screening or did not select the question that dynamically displayed a form.

> **Note**
>
> This issue occurred when the Show Form rule was modified and applied to a new study version, as an advanced study versioning change.

(Issue **34314729**)

Frozen, dynamic questions, do not update when unfreeze action applied

Site users: Now, dynamically displayed questions unfreeze successfully allowing the site user to edit the question. The appropriate icon is also displayed. Previously, a dynamically displayed question was not successfully unfrozen limiting the user's ability to edit the question. The appropriate icon was also not displayed.

Retracted Workaround: None. (Issue **34287424**)

A visit's status is not updated when a subject fails screening

Site users: Now, when a subject fails screening during a screening visit that contains both screening and randomization events, the status of that screening visit is marked as Complete with Errors, as expected. Previously, the screening visit's status was not updated and remained as In Progress. This caused several issues in the system, particularly with signing the data for a visit like this.

Inconsistent rule behavior for automated queries

Rule designers: When an automated query rule is configured for unscheduled or study completion visits, you may notice that queries are not displayed, as expected. This issue can be reproduced when the operand and target items are configured in the Questions Before the Table section of a two-section form. (Issue **34183025**)

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Duplicate emails might be sent out based on a custom rule (former known issue)

Rule designers: Now, when you create a rule to send an e-mail notification, if the email address of a user is specified twice as a testing email address or both as a Testing and Production email address, one single email is sent out to that specific email address. Previously, duplicate e-mail messages were sent out to that specific user.

Retracted workaround: Although the email is now sent only once for the same email address, you should still make sure that you only specify each email address once, when you create a custom rule for an email notification. (Issue **33987346**)

Large code lists take longer time to save (former known issue)

Study designers: Now, when a code list contains over 200, you can save that code list without any interruptions or delays. Previously, with larger code lists, you may have noticed that the application was taking longer than usual to save any of your changes, such as applying it to a question in a form.

Retracted workaround: None. (Issue **33948251**)

Long questions are not properly displayed in a notification email (former known issue)

Study designers and other sponsor users: Now, you can use longer question titles and they will be displayed appropriately in a notification email. Previously, when the questions included in a form were too long, the users receiving any notifications related to changes for those questions were not able to properly view the entire list of questions that generated a notification.

Retracted workaround: You no longer have to avoid using question titles that are longer than usual (typically over 200 characters). (Issue **33938985**)

Skipped visit is marked as In Progress after being frozen (former known issue)

Data managers: Now, when you freeze data in a skipped visit and do not create a new study version that you assign to a site, that visit's status remains Skipped, as expected. Previously, when you froze data in a skipped visit, that visit’s status was updated to In Progress. This issue occurred when several settings and actions were previously performed:

- The settings Site Enters Visit Dates, Site Edits Visit Dates, and Visit Can Be Skipped were configured for a Dispensation, Option, and Non-Dispensation visits.
- A new study version was generated and moved to Testing or Production.

Retracted workaround: None. (Issue **34122179**)

Clearing a custom rule error message leads to clearing a coding item target (former known issue)

Site users and rule designers: Now, after a custom rule's error message is no longer displayed on the screen, the associated coding target items aren't cleared, as expected. Previously, after a custom rule's error message was cleared from the User Interface (UI), the system also cleared any verbatim terms from the forms. This interfered with the way terms were coded in a form.

This issue was reproduced in an Adverse Event.

Retracted workaround: None. (Issue **34111603**)

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Cannot enter lab result in a lab form's row (former known issue)

Site users: Now, in a lab form, when you open a row in a new dialog (to fill in fields), you can enter data straight into the lab form table. Previously, you may have noticed that you were no longer allowed to enter data straight into the lab form table. Instead, you could only fill in fields in the form by opening each row in a separate dialog.

Retracted workaround: You no longer have to return to the Subject page and then re-open the visit that contains your lab form. (Issue **33905908**)

A designer must refresh the page to see a lock icon (former known issue)

Study designers: Now, when working along multiple study designers, you no longer need to constantly refresh your browser's page to make sure that the lock icon is displayed or not (depending on whether other designers are working in the study or not). Previously, you had to refresh your browser page when working with multiple study designers.

This was caused by a backend issue that determined the system to not display the appropriate lock icons after data was refreshed.

Retracted workaround: You no longer have to constantly refresh your browser's page to make sure that the lock icon is either displayed or not, or that newly created forms by other designers are displayed. (Issue **33665785**)

Data flags in dynamic lab forms not displayed when user changes the parent question values (former known issue)

Study designers: Now, when testing forms in Testing mode, you will see that data flags are properly displayed in a dynamic lab form. Previously, after modifying the answer to a determining question, you may have noticed that the data flags that were previously applied in a lab form were no longer displayed.

Retracted workaround: None. (Issue **32723537**)

Target field in two-section form is not updated (former known issue)

Rule designers and testers: Now, after you define a custom rule with a read-only target field located in a two-section form, you may notice that the target field is updated after that rule is run, as expected.

Retracted workaround: After the rule runs, you no longer have to refresh your browser's page. The system automatically refreshes the data and the updated value appears in the target read-only field. (Issue **33047748**)

The Rules Editor dialog title is now translated to Japanese

Rule designers: When the application's language preference is set to Japanese, you may notice that the Rule Editor dialog title is properly translated to Japanese. Previously, this title was not translated and was displayed in English. (Issue **32914076**)

The Rules sidebar does not display data from the current form (former known issue)

Rule designers and testers: Now, when navigating between forms, the Rules sidebar displays data related to the form that you are currently accessing. Previously, the Rules sidebar displayed rules-related data from the previous form you just accessed.

Retracted workaround: None. (Issue **33635407**)

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Schedule Above First section is properly formatted in Japanese

Study designers: On the Data Collection page, the Schedule Above First section (displayed in-between unscheduled visits in a branch) is now properly displayed on the user interface. Previously, the words did not fit and looked misaligned. This issue only occurred when the application's language preference was set to Japanese. (Issue **32903499**)

Advanced study versioning updates do not work during multiple study updates (former known issue)

Study designers: Now, when you perform an advanced study versioning update and then attempt to move the study version from Testing to Approved (in one type of browser) and then create a new study version (in another type of browser), an error message is displayed. The error message states that the creation of a new draft study version has failed, as expected. Previously, after performing these two simultaneous study updates, you may have noticed that your advanced study versioning updates were no longer reflected in the updated study version.

Retracted workaround: None. (Issue **33416734**)

The lock icon disappears from a locked form (former known issue)

Study designers: Now, the lock icon continues to be displayed on a form while you (as a study designer) are deleting another form in the study. Previously, when you attempted to delete a form (for example, Form A) and another study designer was editing another form (for example, Form B), you may have noticed that the lock icon disappeared from Form B.

Retracted workaround: You no longer have to refresh your browser's page to have the lock icon reappear. (Issue **34058105**)

Integrations

Oracle Central Coding system timeout when attempting to process duplicate records

Now, duplicate source ID entries are not being entered in the CODING_AUDIT table when a GET request job retry fails. Previously, duplicate entries were made in the CODING_AUDIT table when the Get Request job failed and a retry was attempted. Subsequent GET requests would attempt to process the duplicates resulting in a system timeout. (Issue **34087438**)

API endpoints can now be used for adding subjects in a study

For integration managers who use Clinical One Digital Gateway

Now, the API endpoint typically used to add subjects can be used to add subjects through an integration with Clinical One Digital Gateway, as expected. This task can be performed even when the corresponding setting is set to **No** in a study. Previously, when a study manager had configured the study to prevent site users from manually adding subjects (setting the value for **Allow Subjects to be Manually Added** to **No**), that study setting would also apply to the API endpoint. This prevented both site users from adding subjects in a study, as well as adding them through an integration. (Issue **34376688**)

For API users who only operate in Clinical One Cloud Service

Now, if you need to add subjects through the APIs, while the **Allow Subjects to be Manually Added** setting is set to **No**, you can do so by using the *Add transferred subject* API endpoint.

This API endpoint does not validate the command of adding subjects against the **Allow Subjects to be Manually Added** setting, as well as other subject-related settings in Clinical

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One Cloud Service. To ensure that no duplicate subject numbers are created in a study, the API endpoint does validate the newly added subject against existing subject numbers.

For specific details related to the API endpoint, see Add a transferred subject.

Oracle Clinical One Analytics

Site records not properly displayed in datasets (former known issue)

From now on, data related to a site's start date or end date will be properly reflected in the Oracle Clinical One Analytics application and its datasets.

Retracted workaround: You no longer need to reach out specifically to your Oracle point of contact to refresh data in the Analytics application. (Issue **33940889**)

Audit data is not displayed in Oracle Clinical One Analytics (former known issue)

Now, a subject's kit data also display audit data, as expected. Here is what you will be able to see when it comes to a subject's kit audit data:

- For a replaced kit (with a reason of Not dispensed to subject), subject and visit details are also risplayed until the kit is updated as Available in the system. For a new kit, only a subject's details are displayed, without any associated visit details.
- For a replaced kit (with a reason of Lost/Damaged), subject and visit details are displayed until the kit is updated as Available in the system. For a new kit, only a subject's details are displayed, without any associated visit details.
- For a reused kit, details of the associated visit before the kit's reuse are displayed. After the kit is reused, the latest visit details are displayed.
- For a misallocated kit, details of the newly assigned subject are displayed.

Retracted workaround: None. (Issue **33563978**)

Shipment records are not properly updated in the Unblinded Kits dataset (former known issue)

Now, when you attempt to include historic records of kit shipment details in your custom report, the data is displayed as expected. Previously, data was not properly updated. For example, if the status of a kit was updated from **Pending Destruction** to **Destroyed**, this update was not reflected in your report.

Retracted workaround: None. (Issue **33485267**)

Kits' data is not properly displayed in datasets (former known issue)

Now, in the Unblinded Kits dataset, when you attempt to display a kit with an updated shipment date, you may notice that the element DH_TIMESTAMP is updated, as expected. Previously, this element was not displayed accordingly.

Retracted workaround: None. (Issue **33448065**)

Randomization and kits

Cannot move study version after removing a treatment arm (former known issue)

Study designers: Now, after you remove a treatment arm from a live study version, you can successfully move that study version from Draft to Testing. Previously, a confusing error message was displayed indicating that moving this study version to Testing failed.

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Retracted workaround: None. (Issue **33520150**)

Kit type titration assigned to visit in branch can still be edited (former known issue)

Study designers: Now, you can no longer remove kits from a kit type titration that was already assigned to a visit in a branch. Previously, after assigning a kit type titration to a visit in a branch, you may have noticed that you were still able to remove kits from the kit type titration.

Retracted workaround: None. (Issue **32101959**)

Reports, archives, extracts, and notifications

The Archival PDF is not generated properly when a site user is deleted

Sponsor users: In the Archival PDF, the Subject Archives PDF is now generated appropriately even though the site user who entered data for a subject is deleted from a study. Previously, when the site user who collected data for a subject was deleted from a study, the Subject Archives PDF did not generate as expected. (Issue **34412995**)

The Subject Events report takes longer to generate than expected

Site and sponsor users: Now, when you run the Subject Events report you will no longer notice that it takes longer than expected to generate the report (in any mode or format). Previously, running the Subject Events report either took longer than usual or you could not generate the report at all. This was a database issue that has now been fixed by implementing a clearing mechanism to ensure that the performance of reports is optimal going forward. (Issue **34399461**)

The Archival PDF takes a long time to generate

Sponsor users: Now, when you run the Archival PDF in a study that contains a larger volume of data, you will notice that the archive is generated in the expected amount of time. Previously, the system may have been slow and your Archival PDF took too long to generate.

This issue was due to the queryDetails API endpoint. The API did not properly retrieve the study version associated with the Archival PDF and this affected the system's performance. (Issue **34161625**)

Kit Dispensation report displays data from all sites

Site and sponsor users: When you run the Kit Dispensation report, and select a specific site for the Location setting, you may notice that the report displays data from all sites in a study. Instead, the report should only display data for the specific site you previously selected. (Issue **34294108**)

The Subject Query report must not display data on candidate or deleted queries

Site users: Now, as a site user, when you're running the Subject Query report you will notice that you can no longer see data on candidate queries or deleted queries. That is the expected behavior, since only sponsor users should be able to view data on candidate or deleted queries. (Issue **34091418**)

The Subject Events report displays data discrepancies (former known issue)

Sponsor and site users: Now, when you generate the Subject Events report, you will notice that data related to event instance numbers is properly displayed, even if you run this report at the same time with other reports in the system. Previously, you may have noticed certain data

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discrepancies in this report. This issue was caused by the use of multiple data columns (in the application's backend) for multiple reports at the same time.

Retracted workaround: You no longer have to actively avoid running multiple reports at the same time. For example, you can now run the Subject Data report and the Subject Events report at the same time. (Issue **34060530**)

Values in the Subject Query report are not properly displayed in Japanese

Sponsor and site users: In the Japanese version of the Subject Query report, all values in the Query State column are now displayed in Japanese, as expected. Previously, values in the Query State column were displayed in English. (Issue **33130514**)

Subject Data Extract in a CSV format is empty

Data managers and statisticians: You will no longer run the risk of generating a Subject Data Extract (in a CSV format) that is completely empty. This issue was caused by a database limitation, where data records that exceeded a certain character limit were not displayed in the extract at all. (Issue **34135585**)

Deleted columns displayed with an incorrect status in extracts (former known issue)

Data managers and statisticians: Now, in a Subject Data Extract, modified data records are no longer displayed as deleted. Instead, when a data record is modified by a site user, its status is properly reflected in the extract. Previously, you may have noticed that certain data records were displayed as deleted, even though they were still present in the application. This issue could be observed when a site user opened the application in multiple browser sessions and updated the same data record in different ways (for example, they removed the data record in one session and then modified the same data record in another session).

Retracted workaround: None. (Issue **33743917**)

The CPORT format is now clearly displayed for SAS extracts

Data managers and statisticians: Now, when you extract subject data in a CPORT format, the extract displays the .CPT extension that is needed to differentiate between extract formats. Previously, this extension was not displayed. (Issue **34227314**)

Tool tips for reports are not displayed in the preferred language

Sponsor and site users: Now, when you change your application's preferred language after having generated reports in your study, you may notice that the report-related tool tips appear in the preferred language, as expected. Previously, if you switched between preferred languages during the generation of a report, you may have noticed that the tool tip texts were displayed using a mix of English and Japanese. (Issue **33103591**)

Japanese characters are not displayed in a SAS dataset (former known issue)

Data managers and statisticians: Now, Japanese characters are displayed correctly in a Subject Data Extract generated in a sas7bdat format. Previously, Japanese characters were not properly displayed in this type of data extract. This issue was encountered when you opened the SAS dataset with SAS Universal Viewer, version 1.5.

Retracted workaround: None. (Issue **33279322**)

Column name in the Subject Queries report might be confusing (former known issue)

Sponsor users: Now, both the Subject Queries report and the Subject Data report display a column called Repeating Section Number, as expected. Previously, the column was called

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Repeating Form Number without taking into account the number of repeating form instances in a two-section form.

Retracted workaround: None. (Issue **33508078**)

The User Assignment and User Assignment by Site reports do not display correct data for removed users (former known issue)

User administrators: Now, after a user is removed from a study, the Status column is updated with a new status of "Removed" for that specific user, as expected. Moreover, when you add a new user to a study, its status is displayed as "New" in the report. After the newly added user signin in the application for the first time, their status is displayed as "Active" in the report. Previously, a user that was removed from the study was still displayed with a status of "New/ Active" in the User Assignment reports. This issue occurred when you included historical data in your reports.

Retracted workaround: None. (Issue: **34018392**)

Candidate or deleted queries should not be displayed in the Subject Queries report for site users

Site users: Now, when you run the Subject Queries report, you can only see the queries that you are also allowed to see on the user interface (typically queries with a status of Opened, Answered, or Closed - depending on your permissions). Previously, as a site user, you could also see queries with a status of Candidate or Deleted, even though you did not have the permission to view or manage those types of queries on the user interface. (Issue **34091418**)

Site users and subject data

Signing subject visit fails if screening starts and completes in different study versions

Site users: Now, signing data is error-free, and the status is updated in the correct study version. Previously, signing subjects' data failed whenever they were screened in a different study version. You could not sign data as expected because the screening data was associated with the wrong study version. (Issue **34625379**)

Coded terms are not properly formatted to be send to Oracle Central Coding (former known issue)

Site users: Now, you can no longer copy and paste coded terms into a repeating form table cell, to avoid any potential errors in the coding process. Previously, not only did the application not remove any extra spaces that you added into the form, but it also did not prevent you from copying and pasting data that must have been integrated with another system. Because extra spaces were not cleared or avoided, the integration of those coded terms with Oracle Central Coding may have failed.

Retracted workaround: Although this issue is now fixed, we recommend you avoid adding coded terms straight into the repeating form table. Instead, open a repeating form instance in a separate dialog and enter your coded terms. (Issue **34027154**)

New validation error message for exceeding a text field's character limit

Site users: Now, when you exceed the character limit of a text field in a form, an appropriate validation error message is displayed. The new validation message states that the value cannot exceed a specified number of characters in length. Previously, the validation message stated that the value in that field must be less than a specified number of characters. (Issue **34151882**)

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Cannot update kit status from Expired to Misallocated (former known issue)

Site users and sponsor users: Now, on the Site Inventory tab, you can update an expired kit's status to Misallocated. Previously, you did not have that option. When clicking **Update Kit**, the Misallocated option was not displayed. (Issue **33920822**)

Frozen icon is missing from a frozen adverse event

Data managers: In Clinical One Cloud Service, on the Subjects page, every adverse that contains frozen data is marked with the Frozen icon, as expected. Previously, even though data was frozen in an adverse event (and this status was reflected in reports in both the Clinical One Cloud Service and the Oracle Clinical One Analytics), the Clinical One Cloud Service UI did not display the expected icon on the visit card. (Issue **34217709**)

Manually entering a date does not work in a repeating form table (former known issue)

Site users: Now, when Japanese is set as your preferred language in the application, and you attempt to manually enter a date in the repeating form table view, the date remains the way you set it. Previously, you may have noticed that the date was automatically set to the current date.

Retracted workaround: You can always update a date field either by using the calendar widget or opening the repeating form instance in a new pop-up window. (Issue **33698622**)

Dynamic form not displayed when multiple answers are selected (former known issue)

Site users: Now, when a one-section form contains multiple questions with a Show Form dynamic rule that is supposed to display the same dynamic form, this configuration works, as expected. The same dynamic form can be dynamically displayed when multiple determining questions are answered. Previously, this was not possible.

Retracted workaround: None. (Issue **33282026**)

Field incorrectly displaying as frozen

Site users: Now, fields not frozen by a user do not appear as frozen in the Clinical One Cloud Service user interface and audit trail. Previously, a field could appear as frozen in the user interface even when the field was not frozen by a user.

Retracted workaround: You no longer have to manually freeze the field again, and then unfreeze it. (Issue **34086892**)

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Clinical One Cloud Service and Clinical One Digital Gateway 22.1 (April 2022)

- Patch log
- What's new
- Fixed issues

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.1 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades **do not affect users working with the Clinical One Digital Gateway application.**

Release number	Release date	Notes
Release 22.1.0.7	10-June-2022	For this release, we fixed an issue related to tenant on boarding in the identity management system.
Release 22.1.0.6	16-May-2022	For this release, we fixed several issues related to rules, integrations, and randomization and trial supplies. For more information, see: • Fixed issues for forms, visits, and rules to review details for bug **34151802** . • Fixed issues for integrations to review details for bug **34142164**. • Fixed issues for randomization and kits to review details for bug **33899730** .

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Release number	Release date	Notes
Release 22.1.0.5	09-May-2022	For this release, we fixed several issues related to data collection, integrations, reports, analytics, and notifications. For more information, see: • Fixed issues for forms, visits, and rules to review details for bugs **34098859** and **34052489**. • Fixed issues for integrations to review details for bug **34064421**. • Fixed issues for reports, archives, extracts, and notifications to review details for bugs, **34087670**, **33920237**, **34062042**, **34058969**, and **33985315**. • Fixed issues for Oracle Clinical One Analytics to review details for bug **34084687**. • Fixed issues for all users to review details for bugs **34120146** and **34086950**.
Release 22.1.0.4	28-Apr-2022	For this release, we disabled the cache size limit in the application to improve the product's performance. No functionality has been changed and no testing is required.
Release 22.1.0.3	26-Apr-2022	For this release, we fixed an issue related to extracts and reports. For more information, see Fixed issues for reports, archives, extracts, and notifications to review details for bug **34109490**.
Release 22.1.0.2	22-Apr-2022	For this release, we fixed an issue related to extracts and reports. For more information, see Fixed issues for reports, archives, extracts, and notifications to review details for bug **34087227**.
Release 22.1.0.1	16-Apr-2022	For this release, we fixed several issues related to data collection. For more information, see Fixed issues for forms, visits, and rules to review details for bugs **34036119** and **34056494**.

What's new

- Integrations
- Notifications
- Randomization and trial supply management
- Reporting and analytics
- Rules management
- User experience

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- User management
- Other enhancements

Integrations

- Integrate screening and randomization data
  Clinical One Digital Gateway now supports a web service based, two-way integration between iMednet EDC and Clinical One Cloud Service RTSM.

Integrate screening and randomization data

Clinical One Digital Gateway now supports a web service based, two-way integration between iMednet EDC and Clinical One Cloud Service RTSM.

How is data integrated between the systems?

Subjects are first screened in iMednet EDC. A schedule, configured in Clinical One Cloud Service, calls Mednet APIs to retrieve a list of screened subjects who are marked as Ready for Randomization. Screening data is then sent to Clinical One Cloud Service to automatically screen subjects.

Subjects can then be randomized in Clinical One Cloud Service, resulting in randomization data being sent back to the iMednet EDC system.

How can I get more information about this integration?

Additional details about this integration can be found at Access Your Data, under *Use a pre-built data integration*.

Notifications

- New rule for follow-up notifications on data changes
  Study designers can now configure rules in form design to send email notifications. These notifications can be sent upon specific response entries and for data changes in choice type questions, with the option to set follow-up notifications.

New rule for follow-up notifications on data changes

Study designers can now configure rules in form design to send email notifications. These notifications can be sent upon specific response entries and for data changes in choice type questions, with the option to set follow-up notifications.

What are the benefits?

Email notifications are frequently sent to specific sponsor users based on custom JavaScript rules. With this new feature, study designers can additionally set rules to send notifications while designing a form. These rules can generate email notifications based on choice type questions for a specific answer or for changes to a specific question. To follow an initial notification sent based on a specific answer, you can configure follow-up notifications for data changes in multiple selected questions.

Even though these new rules settings are limited, as opposed to custom JavaScript rules, this process makes it easier for study designers to configure important notifications related to choice type questions and makes it possible to monitor data changes and send follow-up notifications upon an initial email. For example, this feature can help in monitoring Adverse Events after they have been identified as serious. After specific data points are updated, the

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follow-up notifications are sent for any changes in the questions specified by the study designer.

Details for study designers

Here is what is new for you if you want to start including this type of rule in your form:

- When creating or editing a form, upon selecting a question, you now see a new type of rule that you can configure for that question. This new rule is called **Send Notification**.
- There are two conditions available to generate a notification. If you select **Is**, then you must specify the answer of the selected question that generates the notification. If you select **Changes**, an email notification will be sent every time the answer to that specific question is updated.
- If you choose to send an initial notification for a specific answer (using **Is** option), you can activate **Notify when response changes to the selected questions** and then select the questions that, when modified, will send follow-up notifications after the initial email.
- A link to **Specify recipients and messages** will open a dialog window where you can set user roles and email addresses or distribution lists as recipients, as well as the subject line and body message of the notification and follow-up notifications, when applicable.

Details for rule developers

While you can still use custom rules to send notifications to other study team members, you may want to consider working with your study design team to implement these notifications using the built-in functionality when possible. This reduces your need for custom code. However, keep in mind that rules in form design to send notifications can only be based on choice type questions and set for specific answers and data changes. Contrastingly, while in the Rule Editor you can reference any type of question to send notifications in different scenarios, notifications and follow-up notificiations on data changes are not feasible.

In addition, the email notification template has been updated to unify notifications, whether they are configured based on custom JavaScript rules or based on rules in Study Design. Work with your study design team to avoid sending duplicate notifications and make the most out of this feature.

Working with reports?

Data on notification rules in Study Design mode are included in the Rules report.

Already working in a live study?

As soon as this release is available, study designers can begin configuring rules in Study Design mode to send email notifications and follow-up notifications on data changes.

To make your new rules and updates effective, the Draft version must be moved to the appropriate mode container: Testing, or Approved. For step-by-step instructions on how to manage study versions, see Make a study version available in Testing mode and Make a study version available (for Production and Training mode).

Randomization and trial supply management

- Allow depots to supply other depots
  Clinical supply managers can now create depots that will supply other depots with kits throughout the study conduct period.

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- Improved shipment receipt process
  You can gather detailed information on the state of a received shipment with an improved receipt process.

Allow depots to supply other depots

Clinical supply managers can now create depots that will supply other depots with kits throughout the study conduct period.

Details for user administrators and global user managers

Your workflow hasn't changed, but there are some new permissions that you need to be aware of. We recommend you add these new permissions to study roles created (or existing) at a study level. Assigning new permissions to an organization study role is allowed, but the updates are not reflected in study roles at a study level.

Permission	Study role (predefined by Oracle)
Create Shipments to Depots	• Clinical Supply Manager • Production Admin • Unblinded Depot User
Assign a Resupply Strategy to a Depot	• Clinical Supply Manager • Production Admin
Receive New Shipments at the Depot	• Clinical Supply Manager • Production Admin • Unblinded Depot User
Release Shipments from Quarantine	• Clinical Supply Manager • Production Admin
Receive Notification of Depot Shipments	• Clinical Supply Manager • Production Admin • Unblinded Depot User

Details for clinical supply managers

Here's what's changed in your workflow when it comes to creating a depot:

- In the Create Depot dialog, when you specify the kit types that a depot can include in a shipment, you can also specify the supplying depot. In the new Supplying Depot column, you can select the depot that will be supplying the depot you are creating.
- On the Depots tab, depots now have different corresponding columns including Depot Location, Contact, Supply Countries, and Resupply Strategy. In the Resupply Strategy column, you can choose to specify a resupply strategy for the supplying depot.
- Use the new **Create Resupply Group** button to access the Create Min/Max Resupply Group dialog. In this new dialog, you can configure a new resupply group for the supplying depot by specifying whether the resupply strategy is for a site or a depot, and specifying the minimum and maximum buffer for each kit type. Resupply strategies that you create using this dialog are displayed in the Min/Max Resupply side panel on the Supply Settings tab.
- In the Create Shipment dialog, you can specify the exact destination of a shipment, to a site or to a depot.
- Whenever changes occur in the supply chain between two depots, you may receive several notifications, depending on the permissions that you have in the system. There is also a new notification called Depot Shipment, that you receive whenever a depot shipment is created.

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Details for depot users

When it comes to your workflow, here's what's new:

- On the Shipments tab, when you create a depot shipment, you can specify the destination depot and the source depot.
- The receiving depot must confirm that they have received supplying shipments from another depot.
- As with shipments for sites, a depot user can indicate if kits are missing or damaged in the depot order form. You can also indicate if a temperature excursion occurred and if the kits associated with the order should be quarantined.
- You can mark kits as Pending Destruction in the inventory and then add them to a depot shipment for destruction.
- On the Shipments tab, when you click **Create Shipment**, a second option is displayed called Shipment for Destruction. That shipment automatically includes all kits marked as Pending Destruction.
- Every shipment now indicates its source and destination.

Already working in a live study?

As soon as the upgrade for this release is complete, you can create depot-to-depot shipments in your live study. Existing depots are not impacted by this new feature.

Improved shipment receipt process

You can gather detailed information on the state of a received shipment with an improved receipt process.

The updated prompts during intake allow you to collect in depth information on received shipments, facilitating a more detailed shipment receipt process. Before you can capture further details on the state of a shipment, you must record information about the temperature monitors within the shipment. Step-by-step instructions on how to identify temperature excursions in your kits will be featured in the *Sponsor and CRO User Guide* guide.

Details for sponsor users

When it comes to your workflow, here's what's new:

- Users with the *Release Shipments from Quarantine* permission can move shipments or individual kits out of quarantine and update their status to either Damaged or Available.
- When you select Yes for the Allow for Temperature Excursions setting, the system displays a new setting called **Shipments Received without a Temperature Monitor Should Be**. For this setting, you must specify the process to follow when receiving a shipment without a temperature monitor at a site.

Details for site users

Here's what's changed in your workflow:

- After receiving a shipment, when you click **Add Shipment to Inventory** a new Add Shipment to Inventory dialog appears to guide you through the normal process of setting kit statuses to Quarantined, Missing, Damaged, and Available.
- You may be required to enter information about the temperature monitors in your shipment in the Add Shipment to Inventory before proceeding with your receipt confirmation.

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Depending on what is configured in the supply settings, you can continue the normal receipt process or update the whole shipment and kits' statuses to Quarantined.

Already working in a live study?

As soon as the upgrade for this release is complete, you can record detailed information about the state of your shipments when they are received. These enhancements apply to all studies with the default value for **Allow Temperature Excursion** set to No, therefore, it will not affect current data in ongoing trials.

For more information on inventory management, see Inventory management and dispensation FAQs (for clinical supply managers). Step-by-step instructions on how to configure and release from temperature excursions, and quarantine single kits and shipments will be featured in the *Sponsor and CRO User Guide* guide.

Reporting and analytics

- New data fields added to Oracle Clinical One Analytics datasets
  Data fields are being added to Oracle Clinical One Analytics datasets to support different features available in Clinical One Cloud Service.
- New Study Design Delta report in Oracle Clinical One Analytics
  Study designers can now identify study configuration differences between study versions.
- New Kit Chain of Custody (Blinded) report
  Site users and blinded study team members can now view kit transitions from *In Transit* through their return to depots by running the Kit Chain of Custody (Blinded) report.
- Reports can now be scheduled
  Some reports can now be scheduled to run automatically based on a schedule that you define in the Clinical One Cloud Service user interface.

New data fields added to Oracle Clinical One Analytics datasets

Data fields are being added to Oracle Clinical One Analytics datasets to support different features available in Clinical One Cloud Service.

Support for two-section form data

In order to easily identify *repeating forms*, *lab forms*, and *two-section forms* data, new fields have been added to the following datasets in Oracle Clinical One Analytics:

- Subject Forms Dataset
- Subject Form Items Dataset
- Queries Dataset
- Data Collection Design Dataset
- Kits and Randomization Design Dataset

These new fields let you see all data collected through repeating sections and repeating forms. Also, this new organized structure facilitates identifying when repeating data is present and differentiating non-repeating section data from repeating section data.

Support for form associations

New fields have been added to the Subject Forms Dataset in Oracle Clinical One Analytics to support form associations. This lets data managers identify related information that is collected

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in two or more forms. This is particularly relevant, but not limited to, Adverse Events (AE) and Concomitant Medications (CM) forms.

For more information on form associations, see Create and manage links between forms. Details on these new fields are available in the Subject Forms Dataset description.

Already working in a live study?

As soon as this release is available, data managers can use these new data fields in Oracle Clinical One Analytics for custom reports on any new or existing studies, and in any mode. For more information review the Dataset descriptions in the *Analytics User Guide*.

New Study Design Delta report in Oracle Clinical One Analytics

Study designers can now identify study configuration differences between study versions.

The Study Design Delta report allows you to identify study configuration differences between study versions, creating an easier review process and reducing the amount of validation required when implementing changes to your study. The Study Design Delta report includes the following sections:

- Study Design Differences
- Branch Details
- Event Details
- Form Details
- Item Details

This report can be found in the Report Templates folder in Oracle Clinical One Analytics. Any user assigned the *Run the Data Collection Design Dataset* is able to view, but not save over this report.

Already working in a live study?

Once the upgrade for this release is done, you will be able to run the Study Design Delta report in Oracle Clinical One Analytics for any live study. More information about this report will be featured in the *Sponsor and CRO User Guide* guide.

New Kit Chain of Custody (Blinded) report

Site users and blinded study team members can now view kit transitions from *In Transit* through their return to depots by running the Kit Chain of Custody (Blinded) report.

You are now provided with the Kit Chain of Custody (Blinded) report, which allows you to follow every kit transition throughout the study. When run at the site level, the report reveals details on every change to a kit, both virtual and physical. It also includes information on the user who created the change, when the change occurred, and any comments that may have been provided.

> **Note**
>
> You are only able to run the report for kits that are assigned to the site you have access to. Site users cannot see kits in the report that are in transit from the depot to the site until the kits are received at the site. Kits appear on the report even after they've been returned to the depot as part of the reconciliation process.

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Users assigned the *Run the Blinded Chain of Custody Report* permission can generate this report. Once you've successfully run this report, you receive an email that lets you know that the Kit Chain of Custody (Blinded) report is available to view and download in Clinical One Cloud Service. For more information on this notification, see Report is ready notification.

Already working in a live study?

Once the upgrade for this release is complete and you have been assigned the required permission, you can run the Kit Chain of Custody (Blinded) report for a live study. More information about this report will be featured in the *Sponsor and CRO User Guide* guide.

Reports can now be scheduled

Some reports can now be scheduled to run automatically based on a schedule that you define in the Clinical One Cloud Service user interface.

On the Reports tab, several reports now feature a new side panel, called **Schedule Reports**, where authorized users can define a schedule to generate reports automatically.

Additional reports will be available for scheduling in future releases. For this release, the following reports can be scheduled:

- Subject Data Extract
- Subject Data
- Kit Chain of Custody (Blinded)
- Kit Chain of Custody (Unblinded)
- Subject Events
- Subject Visits (Blinded)
- Subject Visits (Unblinded)

Before you work with this feature

The permission **Schedule Reports to Run** are included in the following template study roles: Clinical Supply Manager, CRA, Data Manager, ODM Extract, Production Admin, Study Manager, Unblinded Depot User, User Administrator, and View Only for Unblinded Support User.

As a user administrator or global user manager, you will need to add the permission manually to custom roles to take advantage of this feature.

New settings for scheduling reports

The following settings can be configured when scheduling reports:

- Start date
- Time Zone
- Frequency
- Notifications
- File Type

You can still configure existing report settings (such as File Name, Study Version, User Name, Event Type, and more) for every selected report.

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Information on the report output

Once generated, all reports will be available for download in the **Download Reports** side panel in Clinical One Cloud Service. If needed, reports can also be delivered to a pre-determined sFTP folder. In order to use this option, additional setup steps are required.

> **Note**
>
> Scheduled reports set to be delivered to sFTP cannot exceed seven (7) scheduled reports per day, per study.

Additional information on this enhancement will be featured in the *Sponsor and CRO User Guide* guide.

Rules management

- Debug custom rules
  Rule designers can now use logs and debug custom JavaScript rules when editing to understand the logic behind rule behavior.

Debug custom rules

Rule designers can now use logs and debug custom JavaScript rules when editing to understand the logic behind rule behavior.

What are the benefits?

Now, in the Rules Editor, you can create and debug a rule at the same time, allowing you to understand a rule's behavior and to identify and correct failures before testing. The new debug functionality is used by calling the logMsg() helper function when running a rule in debug aginst existing subject's data. Adding log statements at different key points of the rule expression allows you to get relevant information on the rule's performance, by displaying values of defined variables and messages that reveal the logic behind rule behavior. Additionally, you get error descriptions whenever an exception occurs.

Details for rule designers

Here's what's new for you when creating or editing rules in Testing mode:

- While working in the Rule Editor, you can place log statements where needed in the JavaScript expression to reveal how data is being processed at specific points of the code when the rule is running.
- A new **Debug** button is introduced in the Rule Editor screen. When clicked, changes to the JavaScript expression are saved and executed against the current subject's existing data.
- When the debug process starts, a log window appears at the right of the Rule Editor dialog and outputs log information. In the event an exception occurs, the stack trace details and error messages are displayed along with the logs, providing additional information about the rule's failure or unexpected behavior.
- After reviewing log information, you can change the rule expression and repeat the process for further debugging until the rule works as expected.

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All rule saving requirements must be fulfilled prior to clicking **Debug**, which saves the JavaScript expression. Any compilation error or missing requirement will not allow the debug process to complete.

To make the most out of this new feature,don't forget to review the logMsg() helper function documentation and usage tips.

Already working in a live study?

As soon as this release is available, rule designers can begin to debug any newly created or existing custom rule for all studies in Testing mode. The debug functionality is not available for live studies in Production mode due to security constraints.

More information about this functionality will be featured in *Information for CRO and Sponsor Users*. See Create and manage custom rules.

User experience

- Get a filtered view of your subjects
  Site and sponsor users can now get a more granular view of subjects in a study, using the brand new subject filters.

Get a filtered view of your subjects

Site and sponsor users can now get a more granular view of subjects in a study, using the brand new subject filters.

On the Subjects tab, depending on your study role and site assignment, you may see any of the new subject filters introduced in this release. As a site or sponsor user, you can use these filters to get a more precise view of subjects in your study and get faster access to specific data.

You can use these filters individually or they can be combined. The filters you select are preserved until you sign out of the application, but they are not preserved if you switch to another study. Filters can also be cleared.

The new filters introduced in this release are:

- The **Countries** filter: This filter includes the countries that you have access to. By default, the filter is set to All countries.
- The **Sites** filter: This filter includes the sites that you have access to. By default, this filter is set to All sites.
- The **Subjects** filter: This filter includes all of the statuses a subject can have. By default, this filter is set to All subjects.
- The **Review** Status filter: This filter includes all of the review-related statuses that a visit can have. By default, this filter is set to All reviews.

Already working in a live study?

As soon as the release upgrade is complete, you can view and use the new subject filters, whether you are already part of a live study or about to start working in a brand new study.

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User management

- Create user accounts in Clinical One Cloud Service
  Create Single Sign-On (SSO) user accounts, assign roles, sites, and depots directly in Clinical One Cloud Service.

Create user accounts in Clinical One Cloud Service

Create Single Sign-On (SSO) user accounts, assign roles, sites, and depots directly in Clinical One Cloud Service.

In addition to the ability to assign an individual user to a role, sites, and depots, user administrators can now create and manage SSO user accounts in bulk directly in Clinical One Cloud Service using the new **User Upload** template.

Details for user administrators

- The User Upload template can be downloaded from the **Users** tab.
- The User Upload template can be used to update the end date for existing users.
- Users are created at the global level in Clinical One Cloud Service

> **Note**
>
> If an account already exists, the user will be assigned to the study, and the role, sites, and depots defined in the template.

- User accounts are automatically created in Oracle Life Sciences Identity and Access Management Service (IAMS).
- Users are loaded in Production mode by default. The setting, **Upload users to Training mode** can be enabled if you want to import users to both Production and Training mode.
- New users will receive the **New Study Assignment** notification.
- The **User Upload Error** report is available to easily identify and address user upload errors..

More information on this enhancement will be featured in About creating user accounts using the upload template in the *Add Users Guide* guide.

Already working in a live study?

Once the upgrade for this release is complete, users assigned the *Upload Users in Bulk* permission will be able to download the Upload Users template, upload users in bulk for existing studies, and access to the User Upload Error report.

Other enhancements

New permission for updating a depot order form

Clinical supply managers are assigned the new *Update the Shipment Order Form* permission, allowing them to restrict sites' ability to resend the deport order form. This permission is designed to eliminate errors when receiving shipments and fulfilling orders.

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> **Note**
>
> The template study role will be automatically updated. User administrators must update any custom study roles required with this new permission.

More information will be featured in *Add Users Guide* in the following topics:

- Clinical supply manager
- Descriptions of permissions in Clinical One

New notifications on subjects

As a sponsor user, you can now be notified when a subject completes an unscheduled visit, when they are enrolled into a rollover study, and when they complete a study. To receive these notifications, you must be assigned new permissions.

Permission	Study roles
Receive the Subject Completion Notification	• CRA • Data Manager
Receive the Subject Rollover Notification	• Clinical Supply Manager • CRA • Data Manager
Receive the Unscheduled Visit Notification	• Clinical Supply Manager • CRA

New reports available in Japanese

When you set your language preference as Japanese, the following reports are now available in the Japanese language in all formats:

- Titration Summary report (CSV, HTML, PDF)
- Titration Summary (Unblinded) report (CSV, HTML, PDF)

Keep in mind, clinical data will never be translated and will be reported exactly as collected, regardless of the user's language preference.

New options in Oracle CRF Submit to enhance your work flow

Sponsor and site users can now monitor the progress of an archive request, as well as pause, resume, and cancel requests while they are generating. Also, failed requests can now be resubmitted.

Also, sponsor users can now generate a Custom PDF. The Custom PDF request type gives you access to all settings available in Oracle CRF Submit.

For more information, see Oracle CRF Submit archives and reports in the Clinical One Cloud Service Reporting Guide.

New integration with SAP system for additional kit identifiers

Sponsor users can now include additional identifiers for kits in the Clinical One Cloud Service database. These fields are accessible through the SAP system and are populated via an integration.

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Although this information will not be available through the Clinical One Cloud Service interface, kit identifiers will be available to data managers in Oracle Clinical One Analytics as part of an upcoming release.

Introducing the new Redwood design!

The Clinical One Cloud Service user interface has been refreshed to align better with Redwood, Oracle's new user experience design language. Redwood represents an effort to develop a new Oracle UI to bring natural elements into our products, including Clinical One Cloud Service. A darker global header with the new Redwood stripe is introduced, as well as sharper fonts and icons.

What is not changing: The Oracle Redwood theme is a UI change only and **does not** impact:

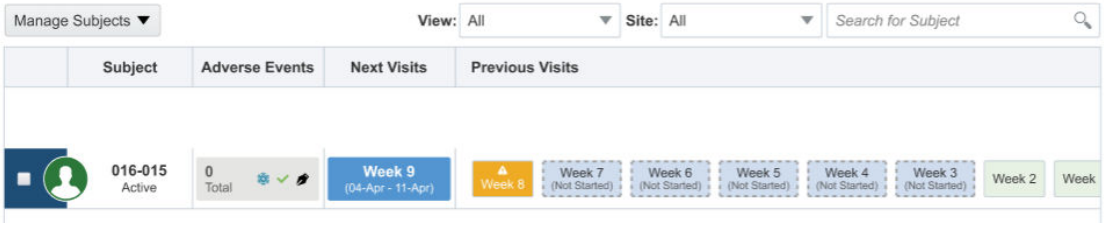
- System performance.
- The underlying database.
- Data within the application.
- Your ability to perform daily tasks and functions.
- Integrations or external systems.

User interface behavior when the data intake integration populates a future visit

When data is automatically loaded in forms through a data intake integration, the data may be populated in visits out of chronological order as defined in a study's visit schedule. If data is loaded in a future visit, the user interface logically displays any preceding visits available for data entry.

For example, data entry has been completed for visits **Week 1** and **Week 2** but has not yet been started for visits **Week 3** through **Week 7**. When the data intake integrations, defined for **Week 8** and **Week 9** are processed:

- **Week 3** through **Week 7**, the preceding, not-yet-started visits are displayed in order, as defined in the visit schedule, have a dotted outline and are labeled *(Not Started)*.
- **Week 8** is displayed as the last entry under Previous Visits.
- **Week 9** is displayed under Next Visits.



More information will be featured in the Icon Reference Guide, section What statuses can a visit have?.

Fixed issues

- All users
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Randomization and kits

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- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data

All users

Notification rule should not trigger on initial entry when it is set as 'Change'

All users: Now, the notification email is not sent upon initial data entry but is sent only after the initial value entered has been changed. Previously, the notification email was sent upon initial data entry as the rule triggered under the assumption that initial data entry constituted a change.

Retracted Workaround: None. (Issue **34120146**)

Audit trail – answer history showing wrong user performing action

All users: Now, the correct user ID is logged in the audit trail regardless of the number of actions performed in a visit or on a form. Previously, in certain instances, the audit trail logged a different user ID than that of the user who performed the action.

Retracted Workaround: None. (Issue **34086950**)

Sign in dialog displayed randomly (former known issue)

All users: Now, the Log In dialog no longer appears in the application either while you're working or you've stopped using the application for some time. If you've stopped working in the application, the expected timeout dialog is displayed. Previously, you may have noticed that a Log In dialog was displayed in your browser asking you to enter your username and password to sign in even though you were working in the application.

Retracted workaround: None. (Issue **33803206**)

Forms, visits, and rules

Rule re-run fails due to changes for notification rules

Rule designers: Now, rule re-run completes successfully when publishing a rule in Testing mode and re-running the rule in Active mode. In both cases, no errors are encountered in the UI and the Rule re-run complete emails are received. Previously, rule re-run and debugging would encounter failures when rule re-run and debugging were null.

Retracted workaround: None. (Issue **34151802**)

Signing subject visit fails when data is captured for the same visit under different study versions

Sponsor and Site users: Now, you no longer encounter the error, *Due to an unexpected error, subject xxxxxx couldn't be signed*, when signing a subject visit where data entry occurs prior to and after a new study version is applied. Previously, the error would be encountered in those cases where data entry was started at a visit and additional data was entered after a new study version was applied to a site.

Retracted workaround: None. (Issue **34098859**)

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Dynamic section of a two-section form cannot be saved (former known issue)

Site users: Now, when you enter data using the dialog and not by inline editing of the repeating table of a two-section form, you can save all data. Previously, when you attempted to save data that was added in the dynamic section of a two-section form, you could not save the data. This occurred when data was entered using the dialog and not by inline editing a repeating table of a two-section form.

Retracted workaround: You no longer have to fill out and save the questions before the table, then enter and save data for the second section (the questions in the repeating table). (Issue **34052489**)

Visit details are not returned as expected by the getValues JavaScript expression (former known issue)

Rule designers: Now, when you run a rule using the getValues JavaScript expression, you will see visit data returned according to the visit schedule. The issue was originally caused by the presence of dynamic visits in a visit schedule.

Retracted workaround: None. (Issue **33088502**)

You cannot assign a locked form to a visit

Study designers: Now, you can assign a locked form to a visit in a study. Previously, while a form was edited and locked by one study designer, another study designer could not assign that form to a visit in the study. (Issue **33773027**)

A copied study’s title is truncated (former known issue)

Study designers: Now, when you copy a design from one study to another, and the study's name is too long, an ellipses is displayed to indicate that there is additional text that is not shown. Previously, after copying a study's design, the study’s title was truncated on the Home page.

Retracted workaround: You can still hover over the study title and you’ll see the complete study title. (Issue **33605369**)

Another study designer can delete a locked form (former known issue)

Study designers: Now, you can no longer delete a locked form, as expected. Previously, you could delete a locked form while another study designer was editing that form. After deleting the locked form, when the other study designer attempted to save their changes, an error message was displayed.

Retracted workaround: None. (Issue **33664784**)

Questions are not properly ordered in a lab form (former known issue)

Study designers: Now, in a lab form, when you re-order questions in the repeating form table, questions preserve the order you just created and are also numbered consecutively, as expected. Previously, when you attempted to re-order questions in a lab form repeating table, upon saving your changes, you may have noticed that those questions were not properly numbered in the table.

Retracted workaround: None. (Issue **33699473**)

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A Show Form dynamic rule is still effective despite being removed (former known issue)

Study designers: Now, when you remove a Show Form rule from a question and you apply that change to a live study version, the form that was previously displayed dynamically is now displayed all of the time, as a static form. Previously, in Draft mode, when you removed a Show Form rule from a question for a live study version, you may have noticed that the dynamic form was still displayed dynamically, when it should have been displayed as a static form.

Retracted workaround: None. (Issue **33736682**)

Getvalues helper function does not work for flat forms (former known issue)

Rule designers: In a standard form (a form that is not repeating), whenever you run a Getvalues rule on an empty field, the rule returns the expected null value. Previously, running the Getvalues rule helper function only returned a null value when the field was specifically cleared.

Retracted workaround: None. (Issue **33067140**)

A question is removed from a question group when dynamic rules are added

Study designers: Now, when the determining question of a dynamic form is placed within a question group, the question preserves its place within the group when you move the study from Draft to Testing. Moreover, all questions in the respective question group are properly ordered. Previously, the determining question of a dynamic form, if placed in a question group, was removed from the group whenever you moved the study from Draft to Testing. (Issue **33821413**)

GetCurrentCycle helper function does not retrieve the proper result

Rule designers: Now, when you attempt to modify an operand for a GetCurrentCycle custom rule for cycle visits, the appropriate result is displayed. Previously, upon modifying the rule's operand, you may have noticed that the rule was retrieving data for another cycle than the one that you just indicated. (Issue **33825640**)

The Visit Status API is not working properly (former known issue)

API users: Now, when attempting to configure a Show Visit dynamic rule and running a POST API command, you may notice that the API is working as expected. This fix is also available for inserting visits into the schedule of a live study. Previously, when a site user answered the determining question in a way that did not display the dynamic visit, and you ran the API command, you may have noticed that the response indicated a successful command. Instead, the API should have returned an error response because the determining question was not answered in a way that would display the dynamic visit.

Retracted workaround: None. (Issue **33615686**)

Associated form does not properly display data (former known issue)

Site users: Now, when you associate two forms in study design, all details of the question generating the link between the two forms are displayed, as expected. Previously, in Testing mode, when answering the determining question that would link a repeating form to another, you may have noticed that only the row number and visit label were displayed.

Retracted workaround: None. (Issue **33856160**)

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Dynamic form does not work when assigned to cycle visit (former known issue)

Site users: Now, when you assign a dynamic form to a specific visit cycle, that dynamic form is working as expected and the status of the impacted visit is properly updated. Previously, in Testing mode, whenever a dynamic form was displayed as associated with a visit cycle, the status of the impacted visit was not updated properly in the selected cycle.

Retracted workaround: None. (Issue **33733658**)

API returns empty array instead of returning null when study design includes at least two items in a repeating form

API users: Now, when a study design includes a repeating form with two or more items, and data is only entered for the first item, null data-elements are being created for the second item as part of the API response. Previously, null data-elements were not being created as part of the API response when there was no data entered for the second item.

Retracted workaround: None. (Issue **34036119**)

API returns extra records when study design includes a repeating form and data is entered in a specific manner

API users: Now, when a study design includes a repeating form and data is entered in a specific manner, the correct records are returned in the API response. Previously, the API response would include extra records in the return. This was addressed by adding additional conditions to ensure there is no duplication.

Retracted workaround: None. (Issue **34056494**)

Integrations

Fisher Clinical Services integration is failing after upgrade of Apache Mina to version 2.7.0

Integration managers: To address this issue, the SHA1 algorithm has been added to the newer version of Apache Mina 2.7.0.

Retracted workaround: None. (Issue **34142164**)

Generic error message displayed when Oracle Central Coding Return Codes job fails

Oracle Central Coding administrators: Now, if the Oracle Central Coding Return Codes job fails when attempting to return medical coding data to a Clinical One Cloud Service study, Oracle Central Coding displays an error message that is relevant to the error. Previously, Oracle Central Coding would display a generic error message making it difficult to troubleshoot the issue.

Retracted workaround: None. (Issue **34064421**)

Multiple answers to a question are not supported in an integration (former known issue)

> **Note**
>
> This fixed issue does not impact the Oracle InForm to Oracle Argus Safety integration.

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Integration managers: Now, you can integrate multiple answer options for a drop-down or a question with checkboxes (options introduced through a code list) without running into any issues. Previously, you could not select several answer options to integrate for a multiple-choice question.

(Issue **33520631**)

Out-of-range data can still be loaded into Clinical One Cloud Service forms (former known issue)

Integration managers: Now, when you attempt to load data that does not match the criteria specified in Clinical One Cloud Service, an appropriate validation error is displayed in the application. Previously, you may have noticed that the integration could load data that was out of range. For example, when a text field's limit for the number of characters was 3, and you loaded a data point that contained more than 3 characters, the job was successfully completed. Moreover, the Clinical One Cloud Service UI did not highlight the field. Instead, anything that exceeded the 3-character limit was truncated and not displayed in the text field.

Retracted workaround: None. (Issue **33367269**)

Oracle Clinical One Analytics

Improved dashboard response time when using the Subject Queries dataset

Now, when including Subject Queries Dataset elements, the Oracle Clinical One Analytics dashboard loads in a more acceptable time. Previously, users may have experienced a longer than acceptable load time.

Retracted workaround: None. (Issue **34084687**)

Unexpected values displayed for a data element (former known issue)

The value NOT_APPLICABLE and NEVER_VERIFIED are no longer displayed for the FREEZE, VERIFIED, or SIGNED data elements in the following datasets:

- The Queries dataset
- The Subject Forms dataset
- The Subject Form Items dataset
- The Blinded Subject Events dataset
- The Unblinded Subject Events dataset

Retracted workaround: None. (Issue **33815975**)

Cannot export reports in a CSV format (former known issue)

Now, when attempting to export a report as CSV, columns are displayed as expected. Specifically, values in the Comments column are no longer displayed in different columns within the CSV report. Previously, values in the Comments column were not integrating new line characters and, as a result, values from that column may have appeared in a different column instead.

Retracted workaround: None. (Issue: **32976885**)

The Suppress Repeating Values feature is now available

You can now turn the Suppress Repeating Values setting on and off for your datasets. When the setting is turned off, expected values are displayed for each row in the report and no table

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cells are merged. When the setting is turned on, certain cells of the table may be merged for data records that have the same value.

For example, if the value for the REPEAT_SEQUENCE_NUMBER is the same for all forms, then the cells in that column can be merged to display the same value for all forms in a study.

Workaround: None. (Issue **32797889**)

Randomization and kits

The minimization algorithm currently uses the probability factor as the final calculation for a treatment arm to be assigned (former known issue)

Clinical supply managers and statisticians: Previously, the minimization list used the probability factor to determine how subjects are assigned to each treatment arm in a study. Now, the minimization algorithm uses the probability factor to determine the final calculation to balance out the number of subjects on each treatment arm.

Retracted workaround: None. (Issue **33899730**)

Open label randomization type available for randomization with cohorts (former known issue)

Study designers: Now, on the Create Randomization dialog, when you select **Unblinded** for the randomization type, and **Adaptive or Demography** for the Cohorts field, the **None – Open Label** option is no longer available for selection, as expected. Previously, on the Randomization drop-down, you could see the **None – Open Label** available for selection even though, for a randomization with cohorts, this option should not have been available

Retracted workaround: None. (Issue **33082175**)

Randomization and kit lists must not contain randomization or kit numbers as decimals (former known issue)

Clinical supply managers and statisticians: Now, when you attempt to upload a kit or randomization list that contains randomization or kit numbers with decimals, the system displays an error message that describes this specific issue. Previously, if you ever uploaded a randomization or kit list with decimal numbers in it, the system did not warn you about the issue.

Retracted workaround: None. (Issue **32565975**)

Reports, archives, extracts, and notifications

Study Design report displaying incorrect treatment group description after edit

Study designers: Now, the correct description appears in the Study Design report after editing the description. Previously, both the original and the updated descriptions were appearing in the report. This issue was encountered due to a missing study version constraint in the reporting query that is used to join the treatment arms. This resulted in the query picking up both the old and new descriptions in the report.

Retracted workaround: None. (Issue **34087670**)

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The Subject Visits (Unblinded) report does not predict drug needs properly (former known issue)

Site users: The Subject Visits (Unblinded) report now includes study drug prediction data for all applicable visits in the study. Previously, you may have noticed that there was no study drug prediction for certain visits in the study. Specifically, those visits that have the option for a site user to down titrate a subject to a lower dose. Based on the study's design, you must be able to view the study drug prediction in this report.

This issue was specifically occurring when the first dispensed kit in a study was a kit type titration.

Retracted workaround: None. (Issue **33920237**)

The Unblinded Kits Dataset returns duplicate records

Clinical Supply Managers: Now, the Unblinded Kits Dataset returns unique records only. Previously, records were being stored in two separate database tables and were considered unique. This resulted in duplicate records being inserted into the dataset.

Retracted workaround: None. (Issue **34062042**)

Report-related emails are not sent to valid email addresses (former known issue)

Sponsor and site users: Now, when you include a list of email addresses in the scheduled reports configuration, all users receive the notifications. Previously, no one included in the email notification configuration received the email. This was caused by additional spaces in the email list resulting in both valid and invalid email addresses included in the configuration not receiving the completion notification.

Retracted workaround: You no longer have to specifically look for extra spaces between email addresses in the scheduled report configuration, although we still recommend that you make sure the email addresses you specify are correct. (Issue **34058969**)

Blank PDFs do not match study design when forms are copied

Sponsor and site users: Now, when a Sponsor or site user generates an Archival PDF in Testing mode, for a study that includes copied forms, the blank PDFs included in the Archival package include the correct question labels. Previously, the blank PDF would display the label of the question copied from, and not the renamed, new question label.

Retracted workaround: None. (Issue **33985315**)

Subject Data Extract report fails using SAS format when a decimal contains leading zeros

Sponsor users: Now, when generating a Subject Data Extract report that includes form items containing a decimal with leading zeros, you no longer receive an error indicating a report failure. Previously, when you attempted to generate a report, the report failed if an item contained a decimal with leading zeros (0.5 for example). This failure was caused by a newer version of the org.json library that incorrectly removed leading zeros from a decimal value.

Retracted workaround: None. (Issue **34109490**)

Subject Data Extract report fails when using SAS format due to leading zeros

Sponsor users: Now, when generating a Subject Data Extract report that includes numeric form items containing data with leading zeros, you no longer receive an error indicating a report generation failure. Previously, when you attempted to generate a report, the report failed

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if a numeric form item included leading zeros (05, or 005, for example). This failure was caused by a newer version of the org.json library that did not correctly remove leading zeros from numeric form items.

Retracted workaround: None. (Issue **34087227**)

Options in the Study Version dropdown are not all displayed for a Blank Form PDF (former known issue)

Sponsor users: For a Blank Form PDF request, when you attempt to configure the Select Versions filter, all available study versions are displayed in the dropdown list. The number of displayed study versions has now increased from 15 to 30. If more than 30 study versions exist for your study, a More results available, please filter further prompt is displayed.

Retracted workaround: None. (Issue **33531303**)

Subject PDFs now display a note for subjects who once exited the study

Sponsor users: In a Subject PDF, for subjects who were once withdrawn or who completed their study (but their completion or withdrawal was undone), a note is displayed that indicates that a form's status as either:

- Superseded due to Withdrawal reversal
- Or Superseded due to Study Complete reversal (Issue **33861203**)

Some notifications must be site-specific (former known issue)

Site users: From now on, you will only receive notifications for the sites that you are assigned to and for which you have the corresponding permissions. Previously, you may have received certain notifications that were not specific to the site that you were assigned to.

For example, you may have received the following notifications without you being assigned to any of the related sites:

- Not Dispensed to Subject (Unblinded)
- Not Dispensed to Subject
- Not Dispensed to Subject (Unblinded Pharmacist)

Retracted workaround: None. (Issue **33775119**)

Numeric data not properly displayed in the Subject Data Extract (former known issue)

Data managers and statisticians: Now, in the Subject Data Extract, all numeric data is displayed as expected. Previously, null numbers interfered with the way other numbers were displayed in the extract. This issue was observed for extracts generated in a sas7bdat. format only.

Retracted workaround: None. (Issue **33860587**)

Data flags are not properly displayed in the ODM-XML extract (former known issue)

Sponsor users and API developers: Now, data flags that a user applies to a field in Clinical One Cloud Service are displayed as expected in the ODM Clinical Data XML extract. Previously, data flags in the ODM-XML extract did not match the data flags in Clinical One Cloud Service. This issue was caused by an API error that is now fixed.

Retracted workaround: None. (Issue **33722382**)

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Sites, labs, depots, settings, and user management

The statistician role includes unnecessary rights (former known issue)

Global user managers or user administrators: Now, the predefined statistician template role provided by Oracle no longer includes additional rights that are not required for this type of user. Because these additional rights are no longer associated with the study role, a statistician can no longer see features that they should not see on the User Interface (UI). Previously, they encountered inconsistent behavior throughout the application, such as:

- On the Subjects tab, although the option for reconciling kits was available in the user interface, a statistician could not select and update a kit's status. An error message appeared stating that they didn't have enough permissions to perform this task. Now, a statistician can no longer see the option for reconciling kits.
- On the Study Inventory tab, a statistician received multiple Oops error messages when attempting to update a kit's location or status. Now, a statistician can no longer see the options for updating a kit's location or status.
- On the Confirm Dispensation dialog, when a statistician attempts to confirm the dispensation of a kit, the kit number disappears and the kit cannot be confirmed. Now, a statistician can no longer see the **Confirm Dispensation** button.

Retracted workaround: None. A statistician was not supposed to perform the above-mentioned tasks. However, seeing these options available in the user interface caused confusion as to what tasks a statistician can or cannot perform in the application. (Issues **31624774**, **31628276**, **31624449**, and **31624589**)

A pharmacy user cannot create DDF shipments (former known issue)

Global user managers or user administrators: Now, when you create a custom study role for a pharmacy user and assign the permissions typically associated with that user type, they can create shipments for destruction (also known as DDF shipments). Previously, even though the pharmacist role may have had the appropriate permission assigned to them (and in the template, as well), a pharmacist could not raise shipments for destruction.

Retracted workaround: When creating a study role for a pharmacy user, you no longer have to include the Perform Source Data Verification and Reconcile Inventory permissions to ensure that the user can create DDF shipments. (Issue **31610928**)

A Production Admin can create a shipment without the required permission (former known issue)

Global user managers and user administrators: Now, when you create a Production Admin user who is assigned the corresponding Oracle template study role, they can no longer see the Create Shipment button, on the Shipments tab, as expected. Previously, a Production Admin could create manual shipments in the system without having the required Create Manual Shipment permission assigned to their study role.

Retracted workaround: None. (Issue **33326742**)

A user account’s effective dates may change in the UI and reports (former known issue)

User administrators: Now, on the Users tab, when you attempt to change a user’s study role, its effective start and end dates remain the same, as expected, in both the user interface and the User Assignment report. Previously, when you edited a user, its start and end dates were both modified. This issue was caused by the difference between the time zone during which the user was created and the time zone during which the user was edited.

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Retracted workaround: None. (Issue **33362166**)

A study role cannot be updated in the Japanese application (former known issue)

User administrators: Now, while the application’s language is set to Japanese, you can update a user’s study role at any time. Previously, whenever you attempted to update a user's study role, on the Edit User dialog, the drop-down for each study mode displayed a message that said: ”The text which matches your search is not found.” instead of the study role options.

Retracted workaround: None. (Issue **33767546**)

Site users and subject data

Visit details not displayed on Site Inventory page (former known issue)

Site users: Now, when a kit is reused and dispensed in another visit, the visit details associated with the newly dispensed kit are displayed on the Site Inventory page, as expected. Previously, the visit details were not displayed on the Site Inventory page.

Retracted workaround: Although the information is now displayed on the Site Inventory page, you can still run the Kit Dispensation report to view these details, as well. (Issue **33713547**)

A subject's ID and visit ID are displayed as "null" in an error message

Site users: Now, when you attempt to dispense kits to a subject outside of their visit window, the error message that is displayed indicates the appropriate subject ID and visit ID. Previously, when you waned to dispense kit to a subject outside of their visit window, the error message that followed displayed the subject's ID and the visit ID as "null". (Issue **32917100**)

A dynamically displayed visit interferes with a dynamic form (former known issue)

Site users: Now, when you modify the answer to a determining question for a dynamically displayed visit it no longer interferes with other determining questions for dynamic forms and it does not modify the status of previously completed visits.

Retracted workaround: None. (Issue **33703557**)

The Tab key does not work for a date field (former known issue)

Site users: Now, when you use the Tab key on your keyboard to navigate between date fields, the cursor moves in the right direction when it lands on a date field with a format of YYYY-MM-DD. Previously, when you used the Tab key on your keyboard to navigate between date fields, the cursor moved in the opposite direction in the date field.

Retracted workaround: None. (Issue **33633003**)

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Revision history

Date	Part number	Description
08 June 2026	G56766-02	Made structural changes to the publication.
27 May 2026	G56766-01	Original version of the document.

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