Oracle® Life Sciences Clinical One Platform and Oracle® Life Sciences Clinical One Digital Gateway

Release Notes

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Oracle Life Sciences Clinical One Platform and Oracle Life Sciences Clinical One Digital Gateway Release Notes, Release 25.1.1

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Preface

This preface contains the following sections:

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

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Patch log

This page briefly describes the history of fixed issues and new functionality applied on top of the 25.1 release.

Table 1-1 Patch log

Release Number	Release Date	Notes
Release 25.1.1	18-March-2025	For this release, we introduced new features, enhancements, and fixes. For more information, see the following: • What's new in 25.1 • Fixed issues in 25.1.1
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

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What's new in 25.1.1

Data collection

- Import Electronic Health Record (EHR) data
  Site users can now import EHR data into Oracle Clinical One Platform 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.

Import Electronic Health Record (EHR) data

Site users can now import EHR data into Oracle Clinical One Platform 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 Oracle Clinical One Platform. 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 Oracle Clinical One Platform 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 Oracle Clinical One Platform site administrator maps each site to their connector.
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.
- 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, Oracle Clinical One Platform 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 Oracle Clinical One Platform 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 Oracle Clinical One Platform, 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:

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.

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:

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.

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

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.

> **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.

- 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.

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 Oracle Clinical One Platform, 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 Oracle Clinical One Platform, 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.

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.

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.

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.

- 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 Oracle Clinical One Platform 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 Oracle Clinical One Platform 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 Oracle Clinical One Platform, 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*.

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

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 Oracle Clinical One Digital Gateway integrations with Oracle Clinical One Platform studies.

Support for undoing subject events

The undoing of a subject's Withdrawal and Study Completion visits is now supported for specific Oracle Clinical One Digital Gateway integrations with Oracle Clinical One Platform studies.

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.

Details for integration managers

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 Oracle Clinical One Platform and Oracle InForm
- The integration with Medidata Rave
- The integration between Oracle Clinical One Platform 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

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*
- *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*.

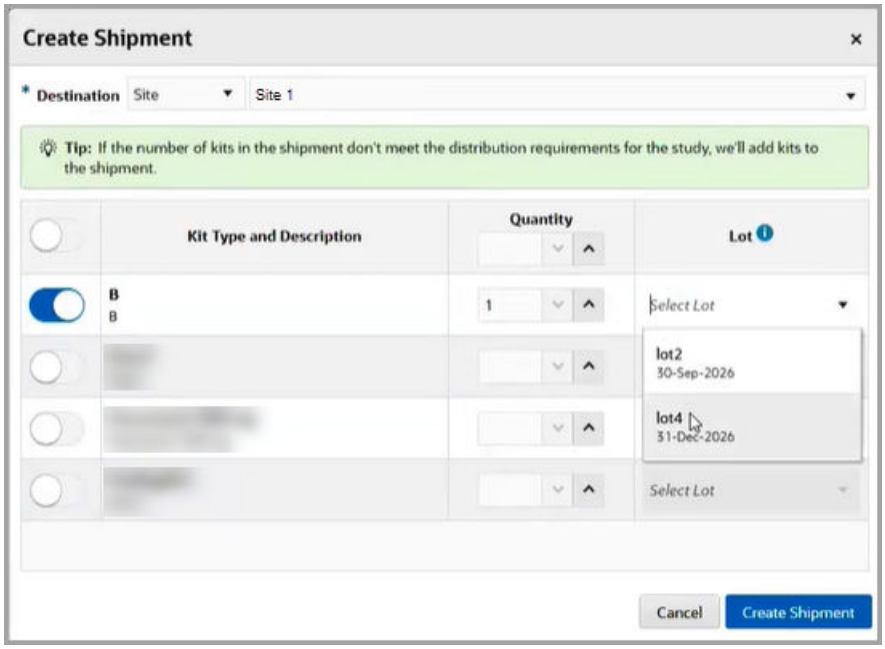
Details for clinical supply managers

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:

Figure 2-1 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*

Reporting, archives, and analytics

- 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.
- 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.
- 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 Oracle Clinical One Platform.

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.

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.

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 Oracle Clinical One Platform.

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.

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 Oracle Clinical One Platform. 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 Oracle Clinical One Platform, 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 Oracle Clinical One Platform 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 Oracle Clinical One Platform. 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 the unblinded randomization number. This is a change required for the previous release of blinded 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`.
- 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**.

3
What's new in 25.1

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.
- 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.

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.

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**:

> **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.

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*.
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.

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 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.

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

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 Oracle Clinical One Platform 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

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.

Besides creating users, user administrators can also edit Oracle Clinical One Platform 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 Oracle Clinical One Platform.
- 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.

4

Fixed issues in 25.1.1

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**)

Oracle Clinical One Analytics

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**)

Forms, visits, and rules

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**)

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 Oracle 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**)

Randomization and kits

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**)

Reports, archives, extracts, and notifications

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.

(Issue **37538595**)

Site users and subject data

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**)

5

Fixed issues in 25.1

All users

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**)

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 Oracle Clinical One Platform study. Previously, when a user associated with a study lacked permissions, one of the Oracle Clinical One Platform 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**)

Integrations

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 Oracle Clinical One Platform, 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**)

Reports, archives, extracts, and notifications

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 Oracle Clinical One Platform 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

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 Oracle Clinical One Platform if a dynamic form with duplicate records was subsequently hidden.

(Issue **36113979**)

6

Release impact on other applications

This document describes the known impact and limitations that new features and enhancements introduced in Oracle Clinical One Platform 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.

Oracle Clinical One Digital Gateway configured integrations

For this release, no impact over Oracle 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 Oracle Clinical One Platform 25.1.1 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:

- 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 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.

Oracle Clinical One Digital Gateway configured integrations

Some new features and enhancements in this release impact Oracle 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.
- 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.

7

Rest API updates

See the newly added, deprecated, and deleted endpoints in Oracle Clinical One Platform 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

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}

Change	Endpoint
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

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 Oracle Clinical One Platform 25.1.1.

Rest API patch updates

See the newly added, deprecated, and deleted endpoints in Oracle Clinical One Platform 25.1.1.

Services updates

The following services are updated:

- Codelist
- Data Collection
- Data Hub
- 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}

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

Designer

Change	Endpoint
New	• POST /v9.0/studies/{studyId}/studyDesign/paginated

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

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

8

Chat in real time with Oracle Support

Use Oracle Clinical One Platform chat for an easier way to contact the Oracle Support team.

1. On the homepage, click **Chat & Help**.
2. The following options are made available:

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. **Tip:** If you can't find what you need using the Knowledge Base, open the Life Sciences Help Center homepage and browse the application's documentation.

3. Click **Chat with Customer Support** then fill in the following fields:

Field	Description
Name	This field is populated by default with the name associated with your Oracle Clinical One Platform account.
Email	This field is populated by default with the email address associated with your Oracle Clinical One Platform account.
How can we help?	Enter the reason why you require real-time assistance from an Oracle Support employee. Use a maximum of 150 characters to describe your problem.

4. Click **Submit** to begin a live chat session. Or click **Cancel** to go back to the initial menu. After clicking **Submit**, a new chat window opens. The screen indicates your number in the queue and an estimated time of response.

5. Once a Support agent is available, type your message in the **Type a message** field, then click **Send**.
6. To attach a file and send it to the Support agent, use the **Attach icon** ().
7. To disconnect yourself from the chat and end it, click **End Chat** in the upper-left corner of the dialog.
8. Once disconected, click **Close** in the upper-left corner to close the chat dialog.

Tip:

- By default, the chat is unmuted. To mute the chat, click **Mute** in the upper-right corner.
- To print the conversation you have with a Support agent, click **Print**.

9

Get access to the Known Issues List

To protect the integrity and safety of our product and the improvements we make, we moved the list of known issues to the My Oracle Support (MOS) platform.

From now on, every newly introduced known issue, as well as the list of historical known issues introduced in both Oracle Clinical One Platform and Oracle Clinical One Digital Gateway will be available only in MOS.

Get an account in MOS

To get access to the Oracle Clinical One Platform knowledge base, you need two things: an account in MOS and your organization's customer support identifier (CSI). Whether you have those two things or not, the steps to get access in MOS are identical to those that you would follow to get access to the Product Verification Pack (PVP).

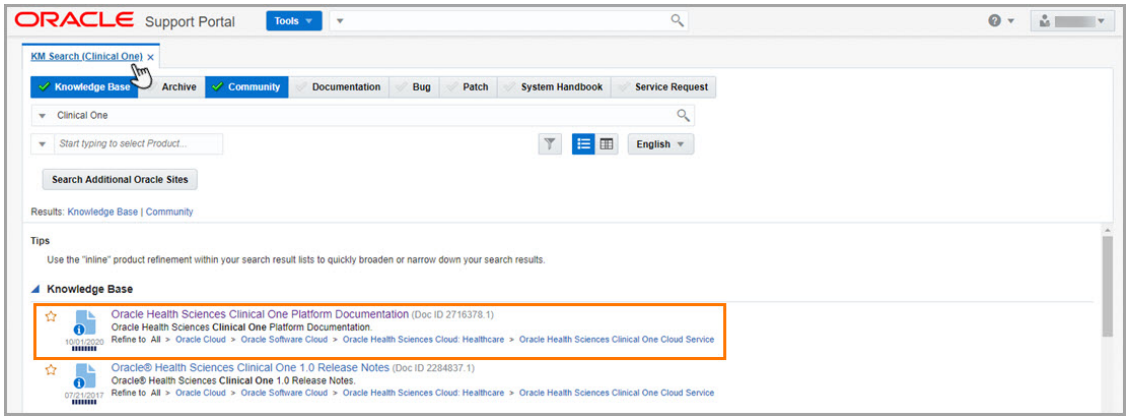
To make sure you get the right access in MOS, follow these two steps in the order listed below:

1. Step 1. Get an account for My Oracle Support (MOS)
2. Step 2. Associate your MOS account with your organization's customer support identifier (CSI)

Navigate in MOS

In MOS, you can either search for "Clinical One" or the Document 2716378.1. This article contains the Known Issues List attached in a PDF format.

Figure 9-1 How a user sees search results for "Clinical One" in MOS



Having trouble accessing known issues in MOS?

Reach out to us over email at *clinical_one_doc_feedback_us_grp@oracle.com*.

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Subscribe to product updates

- Receive and learn more about Life Sciences Support release notifications
- Subscribe to system maintenance page and status notifications
  Upon signing in, a new maintenance page displays when the Oracle Clinical One Platform, all studies for an organization, or a specific study is undergoing maintenance.

Receive and learn more about Life Sciences Support release notifications

Subscribe to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway notifications.

1. Log in to Oracle Life Sciences Support Cloud.
2. In the upper-right corner click the My Account icon (), then click **Account Settings**.
3. Enable **Send email notifications when new announcements are posted** at the bottom of the Account Settings page.

Anytime an Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release announcement is posted on Oracle Life Sciences Support Cloud, you receive an email from Oracle Life Sciences Support.

> **Note:**
>
> You will also receive notifications from other industry-specific applications developed by Oracle Life Sciences.

Announcement types, schedules, and other useful details

Several notifications are sent for each Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release.

Announcements posted on the Oracle Life Sciences Support Cloud follow a standard naming convention making them easy to locate. Example, **Clinical One - 2022 Q1 (22.1) Release Assessment Environment pre-release notice**.

The following notifications are sent for each type of release:

> **Note:**
>
> Upgrade dates are subject to change.

Type of release	Announcement	Details
Minor release	Pre-release themes announcement	Contains major themes planned for an upcoming release. This notification is posted approximately two months in advance of a minor release.
• *Minor release* (for example, 22.1) • *Patchset* (for example, 22.1.1)	Release Assessment Environment pre-release notice	***Note**: Approximately four weeks prior to major or minor releases only (for example, 22.1 or 22.2), Oracle releases the latest version of Oracle Clinical One Platform into a Release Assessment Environment.* • Posted two weeks before the planned Release Assessment Environment (RAE) upgrade. • Contains planned dates for the completion of the Release Assessment Environment (RAE) and Production upgrades. • May contain information on downtime, if it will occur during the upgrade of a release. • Draft Release Notes are available upon request. Reach out to your Oracle point of contact to get a draft copy of the Release Notes.
	Release Assessment Environment upgrade complete	• Posted upon the successful completion of the Release Assessment Environment upgrade. • Contains dates for the Production upgrade. • Release Notes and user guides are available on the Oracle Help Center. • The Product Verification Package (PVP) is available on My Oracle Support (MOS). For more information, see About the Product Verification Pack (PVP).
	Production upgrade complete	• Posted upon the successful completion of the Production upgrade. • Final Release Notes and user guides are posted on the Oracle Help Center if updates have been required since the last version. For more information, see the Revision History topic included in each publication.
Patch (for example, 22.1.1.1)	Pre-release notice	• Posted approximately one week before the planned Production upgrade. • Contains planned dates for the Production upgrade. • Contains general information about planned fixed issues. • Draft Release Notes are available upon request. Reach out to your Oracle point of contact to get a draft copy of the Release Notes.
	Production upgrade complete	• Posted upon the successful completion of the Production upgrade. • Final Release Notes and user guides are posted on the Oracle Help Center.

Subscribe to system maintenance page and status notifications

Upon signing in, a new maintenance page displays when the Oracle Clinical One Platform, all studies for an organization, or a specific study is undergoing maintenance.

The maintenance page includes a link to the Oracle Clinical One Platform status page which provides status information for the Oracle Clinical One Platform as well as the Oracle Clinical

One Digital Gateway, Oracle Clinical One Analytics, Oracle CRF Submit, and other Oracle Clinical One Platform systems and services.
The status page also includes information for the Oracle Clinical One Platform Release Assessment Environment. For more information about this environment, see the Release Assessment Environment Guide

On the status page, click **Subscribe to updates** to subscribe to Oracle Clinical One Platform status email notifications. Follow the steps below to subscribe to these email notifications.

1. Click the status page link on the maintenance page.

   You can also access the status page here Clinical One Status Page.
2. In the upper right corner, click **Subscribe to updates**.
3. Select your country, enter a valid email address, then click **Subscribe to updates**.

   A Subscription Successful message appears, and a confirmation email is sent.
4. Locate the Confirm your subscription email and click **Confirm Subscription**.

   The status page opens displaying the message Thank You! Your email subscription has been confirmed.
5. The status page includes options to cancel the subscription and update your notification preferences.

   If you cancel your subscription for any reason, you can follow the steps above to subscribe again.
6. (Optional) Make notification updates by removing check marks where applicable, then click **Update Subscription**.

The options to cancel and update will not be available the next time you visit the status page. If you need to cancel your subscription or update your notification preferences, you can do so by using links provided in any of the subsequent notifications that you receive. Simply click **Manage Subscriptions** or **Unsubscribe** in the footer of the email notification.

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Information about past releases

This book only has information for the latest release.

If you want to find details about the changes in previous releases, see the Change Log.

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System requirements

- Browser requirements
- Disaster recovery and Oracle Cloud Services backup strategy
  Learn more about disaster recovery, service availability, and the Oracle Cloud Services backup strategy.

Browser requirements

Browser and system requirements

Application	Device	Internet browser	Resolution
Oracle Clinical One Platform	Laptop or desktop	• **Google Chrome**: tested using version 127.0.6533.73 (Official Build) (64-bit). Version 119.0.6045.124 and later are supported. • **Microsoft Edge**: tested using version 126.0.2592.113 (Official build) (64-bit). Version 119.0.2151.58 and later are supported.	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers
Oracle Clinical One Analytics	Laptop or desktop	Oracle Analytics Serversupports Oracle Clinical One Analytics and it is supported in the following web browsers: • **Apple Safari** • **Google Chrome** • **Microsoft Edge** • **Mozilla Firefox** For more information see Certification - Supported Browsers.	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers

Disaster recovery and Oracle Cloud Services backup strategy

Learn more about disaster recovery, service availability, and the Oracle Cloud Services backup strategy.

Disaster Recovery and Service Availability

If you want to view information about disaster recovery and service availability for Oracle Cloud products, open the Oracle Life Sciences Clinical One Cloud Services—Service Descriptions and Metrics document, then search for disaster recovery.

Oracle Cloud Services Backup Strategy

Follow these steps to learn more about the Oracle Cloud Services backup strategy.

1. Start by going to Oracle Contracts.
2. Select **Cloud Services** from the top menu.
3. Apply the following filters, then select **View Documents**.
   - **Product**: Industry—Life Sciences
   - **Country**: Select the applicable country.
   - **Language**: Select the applicable language.
4. Scroll down to the *Delivery Policies* section and select **Download** or **View** for one of the following PDFs, which are displayed based on the language you selected.
   - *Oracle Cloud Hosting and Delivery Policies* (view section 2.2)
   - *Hosting and Delivery Policies—'Language'* (view section 2.2)
   - *Oracle Industries Cloud Services Pillar Document* (view section 12.1.5)

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About the Product Verification Pack (PVP)

> **Note:**
>
> A new PVP is made available for every release except patch releases.

The Product Verification Pack (PVP) is a collection of product release artifacts aimed at helping our customers with their validation efforts.

The documents in the PVP are used by Oracle for product certification purposes and Oracle makes the documents available to our customers at no charge ahead of the product release. You can use the PVP as a blueprint for acceptance testing.

You'll find the following documents in the Oracle Clinical One Platform PVP for both Oracle Clinical One Platform and Oracle Clinical One Digital Gateway:

- Verification Summary report
- Requirements document (combined for Oracle Clinical One Platform and Oracle Clinical One Digital Gateway)
- Requirements testing documentation with corresponding objective evidence
- Standard Control testing documentation with corresponding objective evidence

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Product Verification Pack (PVP) updates

The Oracle Clinical One Platform Product Development team is always working to update the Product Verification Package (PVP) documentation in response to feedback provided by our regulated customers.

Browse the historical updates we made to the Oracle Clinical One Platform Product Verification Pack (PVP).

- 22.4 release updates
  Starting with the 22.4 release, the Product Verification Pack (PVP) includes changes specific to certain folders in the pack.
- 23.3 release updates
  Starting with the 23.3 release, the Product Verification Pack (PVP) includes several changes to the documentation and how users can access the required files.
- 24.2 release updates
  Starting with the 24.2 release, the Production Verification Pack (PVP) includes a change to the documentation.

22.4 release updates

Starting with the 22.4 release, the Product Verification Pack (PVP) includes changes specific to certain folders in the pack.

A new Master Verification Plan is introduced

A standalone Master Verification Plan has been created to provide an overview of the Oracle Clinical One Platform and Oracle Clinical One Digital Gateway testing and documentation being generated for releases.

Updates to the ReadMe.txt file

When reviewing the PVP, the first document to reference will still be the ReadMe.txt file. This document has been updated to provide a comprehensive folder structure and documentation location for each release.

Updates in the Requirements document folder

Oracle is providing the following updates to this folder:

- Updated the **Verification Summary Report** (previously the Overview document). This document will detail the testing and retesting, results achieved, objective evidence and failures for the Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release.
- Updated the **Requirements Document**. Previously, a cumulative requirements document was generated and supplied in the PVP. With the 22.4 release, only those requirements tested for the current release will be provided in the PVP. The document will be smaller and more manageable for our regulated customers to review. The cumulative requirements document will still be available, on request, as a standalone static document which will have all release information through the current version.

- Introduced a new **21 CFR Part 11 Control Mapping Document**. We are providing a mapping document to help our regulated customers cross reference our 21 CFR Part 11 controls tested to GxP requirements listed in this document.

Updates in the Test Scenario folders

Under the Test Scenario folders, all Oracle Clinical One Platform and Oracle Clinical One Digital Gateway documentation has been combined. In previous releases, testing documentation was separated from the objective evidence. Starting with the 22.4 release, testing and objective evidence for Standard Control testing (regression testing) and requirements testing will be combined into respective folders. Under the Requirements folder, each requirement will be a standalone document and includes the objective evidence to help our regulated customers review those requirements pertinent to their own validation testing.

> **Note:**
>
> Oracle believes the upgrades to our documentation will help accelerate your review and evaluation prior to the Production release. If you have any feedback, reach out to your Oracle point of contact.

23.3 release updates

Starting with the 23.3 release, the Product Verification Pack (PVP) includes several changes to the documentation and how users can access the required files.

The Secure Sites platform is added as a secondary location for Oracle Clinical One Platform customers to download the PVP

Currently, the PVP is only published to the My Oracle Support (MOS) portal. To help facilitate access, Oracle will publish the PVP documentation to the Secure Sites platform, as well.

The Secure Sites location provides a PVP folder containing the zipped file

You won't be required to enter a password to access the ZIP file. The Secure Sites location will also provide the information separately if you choose to only donwload specific documentation relevant to your program.

The Secure Sites location will also include a Supporting Documentation folder

The Supporting Documentation folder contains the Master Verification Plan, the Cumulative Requirements document (up to but not including the current release), and the Standard Controls Mapping document.

> **Note:**
>
> For further instructions, see Step 4. Download the Product Verification Pack (PVP).

24.2 release updates

Starting with the 24.2 release, the Production Verification Pack (PVP) includes a change to the documentation.

Updates in the Requirements folder

The number of documents in the Requirements folder will now be three instead of four. The standalone Oracle Clinical One Digital Gateway 2X.x requirements document is merged with the Oracle Clinical One Platform 2X.x requirements document.

Clinical One Test Scenario – Standard Compliance Control (includes regression testing)

When it comes to the Standard Compliance documentation folder, there will be no changes. The DigitalGateway_2X.x_21CFRPart11_TestScenariosResults document continues to be a separate document from ClinicalOne_2X.x_21CFRPart11_TestScenariosResults.

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Download the PVP from MOS (on-prem customers)

Depending on the applications that you use in your work, you may have the following options for downloading the Product Verification Pack (PVP):

- If you have access and work with other Oracle on-premise applications, then you more than likely already have a MOS account and can successfully download the PVP from My Oracle Support (MOS). You can also choose to download the PVP from the Secure Sites website.
- If you have access and work with Oracle Clinical One Platform only, then we recommend you download the PVP from Secure Sites. If you want to download the PVP from MOS, your Oracle point of contact performs the required steps for you.
- Step 1. Get an account for My Oracle Support (MOS)
- Step 2. Associate your MOS account with your organization's customer support identifier (CSI)
- Step 3. Enter a ticket to obtain the password for the Product Verification Pack (PVP)
- Step 4. Download the Product Verification Pack (PVP)

Step 1. Get an account for My Oracle Support (MOS)

> **Note:**
>
> Unless you already have a My Oracle Support (MOS) account, you don't have to get another account. Getting an account takes just a couple of minutes and you only have to perform this task once.

1. If you think you might have a MOS account but aren't sure of your user name or password, follow these steps to retrieve your sign-in details. Typically, you already have a MOS account if:
   - You were identified as the primary contact from your organization for the deployment of Oracle Clinical One Platform when the environment was first provisioned. If you were the primary contact, you received the Welcome letter from Oracle and were provisioned with a My Oracle Support (MOS) account during the onboarding process. or
   - You've ever signed into Support Cloud. The two sites use the same account.

   a. Open My Oracle Support, and below the Login to My Oracle Support button, click **Forgot password?**.

   b. Follow the instructions on the page to retrieve your sign-in details.
2. If you don't have a MOS account, follow these steps to get one:

   a. Open My Oracle Support and below the Login to My Oracle Support button, click **Register as a new user**.

b. For step-by-step instructions for registering, see Creating a New User Account on My Oracle Support (Doc ID 1100133.1).

Next step: Step 2. Associate your MOS account with your organization's customer support identifier (CSI).

Step 2. Associate your MOS account with your organization's customer support identifier (CSI)

> **Note:**
>
> Even you have a MOS account, you must perform this task. Otherwise, you won't be able to download the Production Verification Pack (PVP) or see useful information until you associate your acount with your organization's customer support identifier (CSI). You only have to perform this task one time.

1. Obtain your organization's CSI using one of the following methods:
   - Find the CSI in the Welcome letter, if you received it.
     If you were identified as the primary contact from your organization for the deployment of Oracle Clinical One Platform when the environment was first provisioned, you received the Welcome letter from Oracle.
   - Consult the documents you received during the onboarding process.
   - Reach out to your Sales contact.
2. Sign in to My Oracle Support.
3. In the upper right, click the drop-down arrow to the right of your name, and select **My Account**.
4. Below Support Identifiers, click **Request Access**.
5. Fill in the fields:
   - **Note to Approver**: Include an optional note about why you need to be associated with the organization's CSI.
   - **Support Identifier**: Enter the numerical CSI for your organization.
6. Click **Request Access**.
7. Review these important guidelines so you understand how your request is approved, next steps, and future responsibilities:
   - If you are the first person from your organization to request to be associated with the CSI:
     - You can expect to hear back from Oracle within a couple business days, letting you know that the association has been set up.
     - As the first user at your organization to be associated with the CSI, you automatically become the Customer User Administrator (CUA) for your organization.
       * **As the CUA, you'll be responsible for approving all future requests for associations to your organization's CSI**.

    * You'll typically receive requests only when another person at your organization needs to download the PVP. After someone requests access, you'll receive an email, and all you have to do is return to MOS to approve their access.
    * You also have the ability to identify other users as CUAs. **We highly recommend setting up more than one CUA for your organization.** That way, if the current CUA is on vacation or leaves the company, your organization will still be able to approve requests. If your last CUA leaves your organization, reach out to Oracle Support for help in manually updating the CUA.

- If you aren't the first person from your organization to request to be associated with the CSI, the request for approval is emailed to the Customer User Administrators (CUAs) at your organization.
  One of them needs to sign in to My Oracle Support and approve your request and then you'll be able to see the PVP. They can also make you a CUA so that you'll have approval rights for future requests.

Next step: Step 3. Enter a ticket to obtain the password for the Product Verification Pack (PVP).

Step 3. Enter a ticket to obtain the password for the Product Verification Pack (PVP)

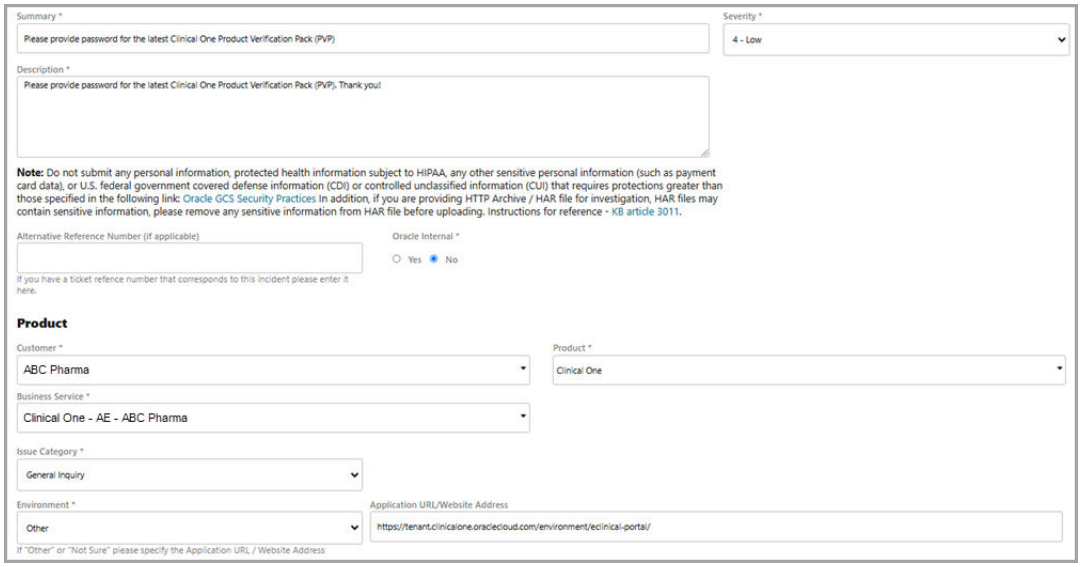
> **Note:**
>
> This task is mandatory. Due to security considerations, the PVP can be downloaded only if you have the current password. If you are responsible for validating, we think you'll find that the contents of the PVP are worth the extra step of getting the password. The password changes every 90 days, so you'll have to request a new password about four times per year.

1. Open Support Cloud.

   > **Tip:**
   >
   > Your Support Cloud account is the same as your My Oracle Support (MOS) account.

2. Select **Create Request**.
3. From the drop-down, select **Support Request**.
4. Enter a ticket and ask for the password for the product's PVP. For help filling in the fields, see the following sample ticket:

Figure 15-1 A sample ticket for requesting PVP access



5. Click **Submit**.

Next step: Step 4. Download the Product Verification Pack (PVP).

Step 4. Download the Product Verification Pack (PVP)

The URL for the PVP doesn't change.

1. Navigate to the following URL:

   https://support.oracle.com/epmos/faces/PatchDetail?requestId=22840173&_afrLoop=457623897492643&patchId=28825486

> **Note:**
>
> To find the PVP without using the URL, just paste **Patch 28825486** into the search box in the upper right on any page in My Oracle Support, and press **Enter** on your keyboard.

2. On the right, from the **Release** drop-down, choose the product release for which you need the PVP.
3. Below the drop-down, click **Download**.
4. In the File Download dialog, do the following:
   a. Check the download time for the PVP and make sure you'll be able to leave your computer on for the duration of the download.
   b. Enter the password you obtained from Support and click **Unlock**.

      The PVP downloads.

> **Tip:**
>
> Did a Password is invalid error appear? If so, the password has expired since you last obtained it. Enter a ticket to get the current password.

You're finished! Now all you have to do is save the PVP locally and unzip the file so you can view its contents.

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Download the PVP from Secure Sites (all customers)

> **Note:**
>
> Depending on the applications that you use in your work, you may have the following options for downloading the Product Verification Pack (PVP):
>
> - If you have access and work with other Oracle on-premise applications, then you more than likely already have a MOS account and can successfully download the PVP from My Oracle Support (MOS). You can also choose to download the PVP from the Secure Sites website.
> - If you have access and work with Oracle Clinical One Platform only, then we recommend you download the PVP from Secure Sites. If you want to download the PVP from MOS, your Oracle point of contact performs the required steps for you.

Prerequisites

To access and download your PVP from Secure Sites, you need to have an Oracle account and be granted access by Oracle to the specific Secure Sites folder.

Gain access to the Secure Sites platform

You can request access for multiple users on your team. To do that for each user, follow these steps:

1. Verify that the person on your team requiring access to Secure Sites has an Oracle account.
   - If they don't have an Oracle account or you're unsure of whether they have one, you must create an Oracle account them. For step-by-step instructions, see Create your Oracle account.
   - If they already have an Oracle account, then this step is complete.
2. After their Oracle account is set up, send an email to your study manager or your main Oracle point of contact. We recommend that you draft the email as follows:

   > **Note:**
   >
   > If you're requesting access for multiple people on your team, the email's body should contain details of all of the users you want to have access to Secure Sites.

   - **Subject line**: Request for access to PVPs in Secure Sites – (*your company name*)

- **Email text**: For each of the below users, please grant access to the PVP folder in Secure Sites:

User's first and last name	User's company email address	User's country
John Doe	john.doe@yourcompany.com	United States of America
Kari Lamare	kari.lamare@yourcompany.com	France

When Oracle has processed all access requests, each user receives an automated email containing a link to the PVP Secure Sites folder. If users do not receive an email, they should check their Junk or Spam email folder. We also recommend they contact their IT group about possible spam filtering.

Users have 24 hours to click the link they receive over email and access the site. If the link expires, or if the users do not receive an email, contact your Oracle point of contact to have a new email generated.

> **Note:**
>
> Once access to the customer's reading room is granted, it will remain active throughout the life of the contract and the Oracle point of contact does not need to request access each time a new PVP is uploaded. Please note, only two releases will be available in the reading room at one time. Once a new release is ready for upload, the oldest will be removed.

Download the PVP from Secure Sites

First, make sure you bookmark your Oracle Clinical One Platform Secure Sites link for future use. This same location will be used by Oracle to upload the Oracle Clinical One Platform PVP release information.

After that, download the PVP ZIP file, the individual PVP documents, or supporting documentation. For step-by-step instructions, go to the relevant release folder, and do one of the following:

To download the full PVP ZIP file:

1. Click **Download** ( ) to the right of the file or select the checkbox to the left of the file. Once selected, an Actions bar appears above the documents.
2. Click **Download Selected File** ( ).
   The download process starts. Depending on the bandwidth, this process might take a few minutes.

To download individual files:

1. Select the checxbox of one or multiple files.
   An Actions bar appears above the documents.
2. Click **Download Selected File** ( ).
   The download process starts and the files will be combined in a ZIP archive file.

> **Tip:**
>
> You can also click the Download icon () next to the file requiring download. This will download the individual files without grouping them into a ZIP archive.

Once the download process is complete, you can close the window.

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Revision history

Date	Part number	Description
26-March-2025	G16745-11	Made a structural change in the table of contents that doesn't affect the content or the described functionality changes.
24-March-2025	G16745-10	In this version: • Corrected information regarding what's new for the following enhancement: Manage subject event related data and visits better • Content was added for Disaster recovery and Oracle Cloud Services backup strategy.
19-March-2025	G16745-09	Corrected the release date on the Patch log page.
18-March-2025	G16745-08	For this release, we introduced new features, enhancements, and fixes. For more information, see the following: • What's new in 25.1 • Fixed issues in 25.1.1
03-March-2025	G16745-07	Documented a new fixed issue for the 25.1.0.2 patch release. For more information, see the Patch log.
26-February-2025	G16745-06	Enhanced language around the unavailability of blinded randomization numbers in datasets. For more information, see Blind subject randomization numbers.
25-February-2025	G16745-05	Documented new fixed issues for the 25.1.0.1 patch release. For more information, see the Patch log.
14-February-2025	G16745-04	Corrected details about impact to Oracle Clinical One Analytics for the Blinded randomization number enhancement. See Blind subject randomization numbers.
30-January-2025	G16745-03	Details about bug fixes for the Oracle CRF Submit shared server were added to Fixed issues for reports, archives, extracts, and notifications.

Date	Part number	Description
22-January-2025	G16745-02	Issue 36542136 was moved from (Fixed issues) *Sites, labs, depots, settings, and user management* to *Facilities, settings, and user management*.
17-January-2025	G16745-01	Original version of the document. • 20-December-2024: Original draft date. • 23-December-2024: Specified the setting's name (**Transferred Subjects in Current Site Only**) in Enhancements to Oracle CRF Submit archives and reports. • 17-January-2025: Temporarily removed descriptions of the Analytics-related improvements. These descriptions will be included in the Release Notes for a future release.