

# Oracle® Life Sciences Clinical One Platform and Oracle® Life Sciences Clinical One Digital Gateway Release Notes



Release 24.1.1

F91489-11

July 2024

The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

ORACLE®

Oracle Life Sciences Clinical One Platform and Oracle Life Sciences Clinical One Digital Gateway Release Notes, Release 24.1.1

F91489-11

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# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

## Documentation accessibility

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## Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

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

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

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# 1

## Patch log

This topic describes the history of patches and patchsets we have applied to the 24.1 release.

**Table 1-1 Patch log**

| Release Number | Release Date | Notes  |
|----------------|--------------|--|
| 24.1.1         | 03-July-2024 | <p>For this release we made the following changes:</p> <ul style="list-style-type: none"><li>• Included the following new features and enhancements:<ul style="list-style-type: none"><li>– <a href="#">Manage all queries in one place</a></li><li>– <a href="#">New Subject Randomization Data Extract</a></li><li>– <a href="#">Quickly identify forms that require your attention</a></li><li>– <a href="#">Other enhancements</a></li></ul></li><li>• Fixed the following issues:<ul style="list-style-type: none"><li>– Issue <b>36774406</b> was fixed for <a href="#">Facilities, settings, and user management</a>.</li><li>– Issue <b>36695050</b> was fixed for integrations.</li><li>– Issues <b>36312970</b>, <b>36710994</b>, <b>36308776</b>, <b>36391622</b>, and <b>35981904</b> were fixed for reports, archives, extracts, and notifications.</li></ul></li></ul> |



Table 1-1 (Cont.) Patch log

| Release Number | Release Date | Notes  |
|----------------|--------------|--|
| 24.1.0.1       | 14-June-2024 | <p>For this release we made the following changes:</p> <ul style="list-style-type: none"><li>• Fixed multiple issues related to Oracle Clinical One Analytics, reports, data extracts, integrations, visits, and permissions.<ul style="list-style-type: none"><li>– For issues <b>36453777</b>, <b>36453959</b>, and <b>36457894</b>, see <a href="#">Oracle Clinical One Analytics</a>.</li><li>– For issues <b>36528076</b> and <b>36275528</b>, see <a href="#">Reports, archives, extracts, and notifications</a>.</li><li>– For issue <b>36176038</b>, see <a href="#">Integrations</a>.</li><li>– For issue <b>36292294</b> <a href="#">Forms, visits, and rules</a>.</li><li>– For issue <b>36488514</b>, see <a href="#">All users</a>.</li></ul></li><li>• Included an enhancement for the Oracle Siebel Clinical Trial Management System (CTMS) - Site integration. For more information, see Site time zone defaults to UTC.</li></ul> |

# 2

## What's new

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

- [Data collection](#)
- [Data review](#)
- [Integrations](#)
- [Randomization and trial supply management](#)
- [Reporting, archives, and analytics](#)
- [Rules management](#)
- [User experience](#)
- [Other enhancements](#)

### Data collection

- [Allow a future date in forms](#)  
Study designers can choose to allow a future date for a Date/Time question by turning the **Allow Future Date** toggle on or off.
- [Add instructional text](#)  
Study designers can now add instructional text to certain forms to provide users with additional information about how to complete a form and its questions.
- [Create Drug Reconciliation forms](#)  
As part of the drug reconciliation process, site users can now generate purpose-built drug reconciliation forms, which can be designed with a new self-populating type of field.
- [Enhancements to local labs](#)  
Study designers can now let site users enter more than one instance of a lab form at a visit.

### Allow a future date in forms

Study designers can choose to allow a future date for a Date/Time question by turning the **Allow Future Date** toggle on or off.

In some cases, you may be required to define a validation rule check for site users when collecting future dates in which they receive a system validation error. For example, if a site user collects the date of Informed Consent. The **Allow Future Date** control allows you to create this kind of validation rule check in these types of scenarios.

#### Details for study designers

Here is what's new in your workflow when adding Date/Time questions:

- The Details side panel now includes the **Allow Future Date** toggle for every Date/Time question type.

 **Note:**

This feature is not available for time-only questions.

- Turning the toggle **On** allows future dates while **Off** does not.

 **Note:**

The user can enter and save a future date while the toggle is set to **Off**, however, the system will alert the user of a validation error.

- The toggle is set to **On** by default.
- Future dates are determined against the date and timezone of the respective site. For example, when a site user answers a Date/Time question, the application compares the date of the site's timezone with the time that they entered.

 **Note:**

A timezone must be specified for your site in order for future date validations to function properly.

- Only one validation rule is triggered at a time if there is more than one configured for a question. If the **Allow Future Date** is set to **Off** and a future date is entered, the system error message appears. Once this is resolved, validation rules that failed appear next.
- When it comes to partial dates, only the present information is compared to the current date.
- The **Allow Future Date** toggle is not visible for Age Smart objects and is defaulted to off, resulting in a validation error if a future birth date is entered.

 **Note:**

You are required to move the study version for the Approved container to implement this option for live studies.

More information on allowing future dates can be found in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

### Impact on reports

More details on **Allow Future Date** settings in the Annotated Case Report Forms and Study Design report can be found in the *Reporting Guide* after the RAE upgrade.

 **Note:**

The **Allow Future Date** toggle settings appear blank in the Study Design Dataset for existing studies in Oracle Clinical One Analytics until a new study version is moved to the container.

**Already working in a live study?**

When the upgrade for this release is complete, this function will be set to **On** by default for existing studies to keep functionality consistent. If you would like to disallow future dates, then you are required to move your study to Production in order to activate this feature.

You are required to perform an Advanced Study Version update to date questions in your study in order to set the **Allow Future Date** toggle to **Off** for existing studies.

 **Note:**

When the **Allow Future Date** toggle is changed from **On** to **Off** for a question as an Advanced Study Version change, the validation is applied to existing dates that were in the future at the time the date was entered, based on the audit trail

## Add instructional text

Study designers can now add instructional text to certain forms to provide users with additional information about how to complete a form and its questions.

**Details for study designers**

When it comes to creating forms, here's what's been enhanced in your workflow:

- Instructional text *cannot* be used in question groups, repeating forms, or repeating tables, including lab forms.

 **Note:**

Instructional text can only be added to the top section of a two-section form.

- When you click **Add** in an appropriate form, the option to include a new question as instructional text is available for forms and can be added anywhere within a form.
- The added text can be formatted for further clarity, if desired. External links and email addresses can also be included.
- Once your study version is approved, the added instructional text can be modified or deleted.
- If the form only contains questions added as instructional text, it cannot be listed for signature configurations.

More information and step-by-step instructions on adding instructional text can be found in the *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

For information about how instructional text gets displayed in Archives requests, see Enhancements to Oracle CRF Submit archives and reports.

### Details for site users

As a site user, there is no change to your workflow. However, be aware that forms may now include read-only instructional text inserted by sponsor users at the time they created a form.

### Impact on reports

The Study Design report and Annotated Case Report Forms now include instructional text that has been added to any forms.

## Create Drug Reconciliation forms

As part of the drug reconciliation process, site users can now generate purpose-built drug reconciliation forms, which can be designed with a new self-populating type of field.

### Before you work with this feature

As part of drug reconciliation, the new purpose-built drug reconciliation forms aim to replace drug order forms. Introduced in conjunction with the new instructional text field, drug reconciliation forms are more customizable and can be designed as part of the standard form design process. For more information on the new instructional text field, see [Add instructional text](#).

To design drug reconciliation forms, study designers must have the *Design Supplies and Dispensation* permission assigned.

### Details for study designers

As a study designer, you can now add a new question type to your Drug Reconciliation form called Existing Data. This new type of question uses existing study data to reduce the number of fields a Clinical Research Associate (CRA) needs to complete when using the form to perform drug reconciliation. Existing data fields are only available to drug reconciliation forms.

Drug reconciliation forms have a three-section structure by default, which you can customize according to your needs. These are:

- A flat section, containing study, depot, site, and user details.
- A repeating section, containing self-populating fields related to kit information.
- Another flat section, with target depot and form information fields.

### Details for sponsor users

As part of the drug reconciliation process, CRAs can now access the drug reconciliation form in the **Shipments** tab in the study's Supplies panel. Once kits are marked for destruction, CRAs can select which kits to perform reconciliation for in the site inventory, generate and complete the form, and use it according to the workflow of the study.

You can find additional information in the *Information for CRO and Sponsor Users* guide after the Release Assessment Environment (RAE) upgrade.

### Impact on reports

- Drug reconciliation forms are reflected in the Study Design report through a three-section layout:
  1. Questions before the table
  2. Questions inside the table

3. Questions after the table
- Drug reconciliation forms are also reflected in the Annotated CRF report.

**Note:**

drug reconciliation forms will not be included in Oracle Clinical One Analytics.

**Already working in a live study?**

To start working with drug reconciliation forms, you must update and go through the entire study versioning process, since Advanced Study Versioning (ASV) is not supported. To apply your changes, update in a draft study version, approve it and assign it to the impacted sites in the appropriate modes.

**Note:**

existing drug order forms which have been used for drug reconciliation will not be affected should a study designer create a drug reconciliation form.

## Enhancements to local labs

Study designers can now let site users enter more than one instance of a lab form at a visit.

**Note:**

This enhancement only applies to lab forms.


**Details for study designers**

If you're a study designer, here's what's new in your workflow:

- In a lab form, the Details side panel now displays a new toggle called **Allow for Multiple Instances**. By default, this toggle is turned off.
- When you turn the **Allow for Multiple Instances** toggle on, you let a site user enter more than one instance of the same lab form during a visit.
- From now on, you can also hide all questions in the **Questions Before the Table** section, configure, associate lab results to other forms using **Link & Show** rules, and only configure the following predefined rules: **Show Question** and **Show Section**.
- Moreover, for a lab form the **Repeating Form** toggle is turned on by default and inactive, while the **Allow Additional Rows** toggle is turned off by default and active.

**Details for site users**

If you're a site user collecting lab data, here's what's new in your workflow:

- If you're allowed to add additional instances of a lab form to a subject's visit, you can click **Add** (  ) next to the title of a lab form to include a new instance of the same lab form. Or you can click **Add** next to the lab form's title.
- For each lab form instance you add, you must do the following:

- Select a lab from the **Select Lab** drop-down so you can collect data associated with the appropriate lab.
- Collect data for the Sample Collection Date and Fasting questions.

### Impact on reports

The following reports and extracts are impacted:

- The Annotated Case Report Forms includes the text **Allow for Multiple Instances** in the header of each lab form that is configured this way.
- The Study Design report includes a new column called **Allow for Multiple Instances** for each lab form. The column displays No or Yes, depending on whether that toggle is turned on or off in a lab form.
- When additional instances of a lab form are included in a study, the following **REPEATNUMBER** column in the Subject Data Extract will display a lab form's instance number.
- In Oracle Clinical One Analytics, the Study Design dataset will display the **Allow for Multiple Instances** design setting. The Subject Form Items dataset will display additional instances of a lab form.

### Impact on custom rules

You can use custom rules to compare data between instances of a lab form in the same visit. Moreover, because a lab form now works as a two-section form, you can also start using the same rule helper functions that are available for two-section forms.

### Impact on integrations

When it comes to Oracle CRF Submit, you can learn more about the impact on this integration type in our Release Notes. For more information, see [Enhancements to Oracle CRF Submit archives and reports](#).

### Already working in a live study?

As a study designer, you can update existing lab forms to let a site user enter additional instances of a lab form at a visit through a study version change. This update is not supported through Advanced Study Versioning (ASV).

More information about this feature can be found in the following user guides, after the Release Assessment Environment (RAE) upgrade:

- *Study Designer User Guide*
- *Site User Guide*
- *Reporting Guide*

## Data review


- [Manage all queries in one place](#)  
Using the new Query List page, site and sponsor users can now prioritize and manage queries more efficiently by viewing, filtering, and working on the queries of a study, all in one place.

## Manage all queries in one place

Using the new Query List page, site and sponsor users can now prioritize and manage queries more efficiently by viewing, filtering, and working on the queries of a study, all in one place.

The Query List page shortens the time spent by users on tasks such as responding to queries, finding queries raised by users with a specific role, subject data cleanup, query cleanup where queries have been opened erroneously, or other work related to queries.

### Details for all users

You can access the new Query List page by selecting the **Queries** icon (  ), on the Home page. You can also access the Query List by selecting the **Query List** button on the Subjects page.

While the queries you can see vary depending on your permissions, the queries are grouped as follows:

- **To Do**: queries that you need to perform actions on. This includes open queries, assigned open queries, answered queries, and candidate queries.
- **Unresolved**: queries that you have permission to see and that do not have a status of **Closed** or **Deleted**. This view includes queries that are pending the action of other users, meaning you may only have permission to see some of these queries.
- **Closed**: all the queries with a **Closed** or **Deleted** status that you have permission to see.



#### Note:

While this new feature doesn't introduce any new permissions, refer to Descriptions of permissions in Clinical One for more information on the existing permissions required to view, create, and manage queries.

To help you quickly find the queries you need to work on, you can filter your list of queries based on criteria such as **Subject Number**, **Status**, **Query Age**, or **Assigned to Role**. The queries you are working on can also be sorted in ascending or descending order based on age.

### Improved view of a query's history

In order to swiftly gain a detailed understanding of a query, you can now navigate from the list of queries to a page dedicated to the query's detailed, consolidated history. This new page lists all the events related to the query in a reverse-chronological order, along with other fine-grain administrative details.

To further shorten the time spent working with queries, you can either jump to a query's source in a form or, provided you have the necessary permissions, update the value of an answer in a form. Once you're in a form, you can click **Return to Query Details** to easily return to the query management view.

### Details for site users

As a site user, your responsibilities on the Query List page revolve around viewing queries and working with their source form questions. Within the dashboard, queries with the following statuses are visible to you: **Opened**, **Answered**, **Closed**.



Using the new feature to directly access the source of a query, you can quickly edit the answers of questions for which queries have been raised. You can also answer a query from its query details page, provided that no update is required for its associated question.

### Details for sponsor users

As a sponsor user, your responsibilities on the Query List page are focused around processing the queries associated with a study. You can view questions with all statuses and depending on each status, you can perform the following actions:

- View queries
- Re-open queries
- Close queries
- Delete queries

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

## Integrations

- [Site time zone defaults to UTC when not defined in the source CTMS system](#)

### Site time zone defaults to UTC when not defined in the source CTMS system

The Oracle Siebel Clinical Trial Management System (CTMS) - Site Integration runs on a schedule to retrieve a list of sites in a source CTMS system. The integration then creates the sites in Oracle Clinical One Platform, where a time zone is required.

If the source CTMS system does not have a time zone defined by the time the integration runs, the Oracle Clinical One Platform will default the time zone setting to UTC. This ensures system errors do not occur when calculations run for things like future date validation or dispensation when using titration or when trying to prevent out-of-window dispensation.

For more information, see [Site Integration](#)

## Randomization and trial supply management

- [Set exceptions to kits with the Do Not Dispense dispensation logic](#)  
Additional options are available to sponsor users, allowing them to control kit dispensation based on protocol requirements and to ensure patient safety.
- [Duplicate a randomization list](#)  
Sponsor users can now reproduce an existing randomization list on request for regulatory inspection purposes. After you first generated the randomization list for a study, you can re-run an exact duplicate on demand.

### Set exceptions to kits with the Do Not Dispense dispensation logic

Additional options are available to sponsor users, allowing them to control kit dispensation based on protocol requirements and to ensure patient safety.

Clinical supply managers now have the ability to set an exception for kits with the Do Not Dispense (DND) dispensation logic at both the country and site level to adhere to protocol requirements and preserve patient safety.

This feature supports sponsor users in scenarios such as a country or a site that requires a longer expiration timeframe for distributing the investigational product to subjects. Similarly, this can be helpful in emergency situations when there is a shortage in supply at the site and an override of the initial distribution setting is necessary.

### Details for sponsor users

When it comes to configuring dispensation schedules for kits, here's what has been enhanced in your workflow:

- You must be assigned the *View Dispensation Exceptions* permission in order to view dispensation exceptions that have been created.
- You must be assigned the *Create and Manage Dispensation Exceptions* permission in order to add, edit, copy, and delete DND dispensation logic exceptions.
- Study designers can still configure the DND (Days) in a study's visit schedule, while a clinical supply manager (or a sponsor user) can configure exceptions to the DND dispensation during the study conduct period, as well.  
For more information on specifying DND dispensation in study design, see *Define the dispensation schedule*.
- Exceptions to the DND logic are created on the Study Supplies page and can be defined by country, which are included at the time of depot or site creation. Exceptions can be further defined by site within the country, and updated at the site or country level by visit.
- Exceptions can be made for all visits where dispensation occurs.
- The DND logic considers the limit or exceptions at the time of dispensation for a subject's country or site when the subject completes a partial dispensation or removing the subject from a dose hold visit.
- When removing an exception from a site, the site defaults to the country's DND settings. If you remove an exception from a country, the country returns to the study design's default DND settings.

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

### Impact on reports

The Study Design report now includes exceptions set for kits with the DND dispensation logic.

## Duplicate a randomization list

Sponsor users can now reproduce an existing randomization list on request for regulatory inspection purposes. After you first generated the randomization list for a study, you can re-run an exact duplicate on demand.

### Before you work with this feature

Reproduce a randomization list by copying the same design parameters and adding the same randomization seed number when randomizing multiple lists to ensure the resulting list will be the same as the first.

When reproducing a randomization list with a seed, it's crucial to know that Oracle Clinical One Platform will use and maintain the latest active randomization list to re-shuffle the treatment

arms in the study. To revert to any previous randomization lists you need to manually unassign the current active list from the study version.

### Details for sponsor users

If you need to duplicate a randomization list for auditing purposes, this is what you should know:

When re-generating a randomization list, on the **Randomization** tab, a new field called **Randomization Seed** is available in the Randomization List dialog.

When adding the same seed number and maintaining the same design parameters as the original randomization list, an algorithm can produce a second list as a duplicate of the first. This approach ensures both lists follow the same randomization sequence, maintaining consistency between them.

The process provides proof for regulatory agencies that the study is randomized properly and that the list can be regenerated on request.

### Impact on reports

The following reports will show the randomization seed lists generated under the field of **Randomization List**:

- Study Design report
- Randomization List (Blinded) report
- Randomization List (Unblinded) report

## Reporting, archives, and analytics

- [Enhancements to Oracle CRF Submit archives and reports](#)
- [Hide randomization details in the Study Design Report](#)  
Sponsor users can now hide randomization details in the Study Design Report.
- [New Subject Randomization Data Extract](#)  
Sponsor users can now extract cumulative data including randomization details, such as the subject ID along with its randomization number and associated treatment.

## Enhancements to Oracle CRF Submit archives and reports

### We've increased the storage server space allocated for each customer

To accommodate the increasing usage of Oracle CRF Submit and to minimize the possibility of encountering issues when generating archives and history reports for large studies, we increased the storage server space allocated for each customer from 100 GB to 1000 GB.



#### Note:

Storage server space is allocated per customer and shared across all your studies.

### PDF output supports Instructional Text questions

Study designers can add instructional text to any form to provide users with instructions to complete a form or the questions on it.

The text appears in Submission PDF, Archival PDF (sponsor and site), Blank Form PDF, and Custom PDF request output.

- The PDF reflects the question's location on the form and the instructional text's font format (size, type, and color), as displayed in the user interface, but the PDF does not include a row number.
- Email addresses and hyperlinks in the instructional text appear as plain text in the PDF.

For more information, see Instructional text.

### **A new pop-up reminds site users to confirm a request after download**

After downloading an Archival PDF request, a Custom PDF request, or the Kit Chain of Custody (Blinded) report, a site confirmation required pop-up reminder is presented to site users when the sponsor who generated and shared the request requires confirmation.

The reminder appears for site users assigned to a study role that includes the permission *Confirm download of Archival PDFs and content (Site)*.

After the Release Assessment Environment (RAE) upgrade, you can find additional information in Download an archive or report in the *Reporting Guide*.

### **The Site Confirmation report is available for site users**

Sponsor users can share Archival PDF, Custom PDF, and the Kit Chain of Custody (Blinded) report with site users and require site confirmation after download; confirmation actions get tracked in the Site Confirmation report. For more information about the confirmation process, see Confirm an archive or report after download.

Site users assigned to a study role that includes the permission, *Confirm download of Archival PDFs and content (Site)*, can generate the **Site Confirmation report** for associated sites.

After the Release Assessment Environment (RAE) upgrade, you can find additional information about this report (for site users) in the Site Confirmation report.

### **New lab forms now render as two-section forms in PDF output**

The PDF layout for lab forms created before this release remains unchanged.

Archives generated after this release render newly created lab forms as two-section forms.



#### **Note:**

This change impacts the Submission PDF, Archival PDF (sponsor and site), and Custom PDF requests PDF output. There is no impact on Blank PDFs, as lab forms already display as two-section forms.

This change is to support an enhancement in this release that allows multiple instances of a lab form to be associated with the same visit. For more information about this enhancement, see Enhancements to local labs.

## Hide randomization details in the Study Design Report

Sponsor users can now hide randomization details in the Study Design Report.

*Study Design Report Suppress Randomization* is a new permission that conceals critical information from the randomization list such as the **Multiplier for Blocks** that can unblind a blinded user if revealed.

If you are a blinded user who has been assigned this new permission, you can still run the report and you can still use the report filters as intended, but the **Randomization list** details are hidden to you. Specifically, the **Generated Randomization List** section in a **Study Design Report** shows empty for users assigned this new permission, even if they select the **Generated Randomization List** check box option when running the report.

Find additional information in the *Add Users Guide* after the Release Assessment environment (RAE) upgrade.

Updates to the Study Design report can be found in the *Reporting Guide* after the RAE upgrade.

### Related Topics

- Edit a study role that is already assigned to users

## New Subject Randomization Data Extract

Sponsor users can now extract cumulative data including randomization details, such as the subject ID along with its randomization number and associated treatment.

### Details for sponsor users

A new data extract, Subject Randomization Data Extract, is available under **Reports & Archives** for Oracle Clinical One Platform studies in any mode. This report contains randomization-related information, including the following:

- Subject metadata
- Visit information for the visit when randomization occurred
- Details about the users who last updated a subject's randomization visit or stratification factors
- Randomization details
- Assigned treatment
- Stratification data

The stratification data included in this report corresponds to any form question defined as a stratum factor in the randomization design. Only records for randomized subjects are included, and only values that were used for a given subject as stratification factors at the time of randomization are populated for the subject. This means that, even if the site updates this data for a subject after randomization, the values that were actually used to determine randomization are retrieved. Conversely, if stratification factors are not specified, no stratification factors are listed.

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

### Details for user administrators

To support the creation of this new data extract, a new permission is introduced. Any user that's assigned the new *Run the Subject Randomization Data Extract Report* permission can generate this report. However, users can only see the data that they're allowed to, based on their access to classified data.

Similarly, the Subject Randomization Data Extract can contain blinded or unblinded data, depending on the user's permissions within the study. Having at least one of the following permissions makes unblinded data available in the generated extract:

 **WARNING:**

Extracts generated by unblinded users must be managed carefully when sharing to protect other users blinding.

- *Receive the Unblinded Dose Hold Notification*
- *Upload and Generate Inventory Lists*
- *View Dispensation Exceptions*
- *Create and Manage Dispensation Exceptions*
- *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies*
- *Manage Study Inventory for Unblinded Users*
- *Manage Randomization Lists*
- *Create and Manage Lots*
- *Create Shipments to Depots*
- *Upload and Generate Randomization Lists*
- *Receive the Unblinded Kit Misallocation Notification*
- *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies*
- *Run the Unblinded Randomization Report*

You can find additional information in the *Add Users Guide* after the RAE upgrade.

## Rules management

- [Access data not collected in forms](#)  
Rule developers can now access subject information and other data not collected directly in a forms and include it in the rule processing or as a return value.

## Access data not collected in forms

Rule developers can now access subject information and other data not collected directly in a forms and include it in the rule processing or as a return value.

In some scenarios, a custom rule's logic requires you to reference data not collected in a form, such as the subject number and status or site related information. With the introduction of the Subject Object you can now access different attributes for data that is not included in any form.

The Subject Object has the following attributes:

- SubjectNumber
- SubjectStatus
- ScreeningDate
- ScreenFailureDate

- CompletionDate
- WithdrawalDate
- RandomizationDate
- TreatmentArm
- CohortName
- SiteNumber
- SiteName
- Country (of the site)
- Region (of the site)

All these attributes are available with their descriptions, using the predictive text feature in the Rule Editor and can be used for rule processing or as a result for a calculated value. This last scenario can be suitable to drive **Show Visit**, **Show Form**, and **Show Question** predefined rules or as a form question base for branching.

 **Caution:**

Some of these attributes allow access to potentially unblinding information, so use them with caution and with assigned queries to limit access to this information.

Remember that you can lessen the burden on site and sponsor users, and increase overall efficiency by using Oracle Clinical One Platform's custom JavaScript rules and query management functionality. Leverage these core features using subject-related data in your custom rules' logic, and gain better control over a subject's visit schedule, country-specific privacy regulations, and many other protocol requirements.

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

## User experience

- [Quickly identify forms that require your attention](#)  
Simple repeating forms, two-section forms (including lab forms) now display improved status icons in a visit.

### Quickly identify forms that require your attention

Simple repeating forms, two-section forms (including lab forms) now display improved status icons in a visit.

Whether you're a site or sponsor user, you can better identify the status of a simple repeating form, a two-section form, or a lab form when you look at the **Forms** sidebar or in the repeating form table. With the newly improved form status icons, you can quickly visualize whether your form is complete or if there might be issues with the data included in it.

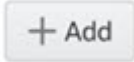
Here's what's new in the User Interface (UI) depending on the type of form that is included in a visit:




## Form status icons and their descriptions

The following form status icon descriptions **apply to all of the above-mentioned form types: simple repeating forms, two-section forms, and lab forms**. This includes forms that contain a Label item.

### Note:


To accommodate the consistent display of form status icons across all form types, you can now add a new repeating form row or a new two-section form instance by

clicking **Add**  next to a form's title within the visit.

| Form status icon  | Description   |
|---|---|
|    | <p>Appears when a form's required questions are completed successfully without any validation errors.</p> <ul style="list-style-type: none"> <li>For a simple repeating form, this icon appears when all required questions in the form are completed or when all required questions in a repeating form row are completed.</li> <li>For a two-section form, this icon appears when all required questions (in both sections) are completed.</li> </ul> |
|  | <p>Appears when at least one of the form's required questions are incomplete.</p> <ul style="list-style-type: none"> <li>For a simple repeating form, this icon appears when at least one required cell in the repeating form table is left unanswered.</li> <li>For a two-section form, this icon appears when at least one required question is left unanswered in any of the two-sections.</li> </ul>  |
|  | <p>Appears when at least one field in a form contains a validation error.</p>   |

## Details for simple repeating forms

The following notes apply when a form status icon is displayed in a simple repeating form:


- For a **simple repeating form**, each form status icon is displayed both on the **Forms** sidebar and on the **Number #** column next to a repeating form row.
- The icon displayed on the **Forms** sidebar indicates a cumulative status of all started repeating form instances. For example, if a Demography form (designed as a simple repeating form) contains three completed rows and one repeating form row whose data collection was started, but not complete, the **Incomplete form icon**  is displayed. You can click the form's title to then navigate to the form and fill-in the empty required fields.
- When a site user hasn't started filling in repeating form yet, the **Forms** sidebar doesn't display any status icons. The **Number #** column next to a repeating form row doesn't display a form status icon either. The same behavior applies when a repeating form's data is cleared.



### Details for two-section forms and lab forms

The following notes apply when a form status icon is displayed in a two-section form or a lab form:

- For a **two-section form** (including a lab form), each form status icon is displayed on the **Forms** sidebar, next to the form's title and next to each two-section form instance, as well.
- When a site user hasn't started filling in a two-section form or a lab form yet, the **Forms** sidebar doesn't display any status icons either next to the form's title or next to any of the two-section or lab form instances. The same behavior applies when data is cleared.
- On the **Forms** sidebar, if you notice a form icon that indicates incomplete fields or validation errors, you can expand the list of two-section form instances and click the instance number to navigate directly to it.
- The icon displayed on the **Forms** sidebar indicates a cumulative status of all started two-section form instances. For example, if a form instance of a Hematology form (designed as

a two-section form) has any incomplete required fields, the **Incomplete form icon**  is displayed next to the original form's title and the form instance number.

**Figure 2-1** How you may see the Forms sidebar



## Other enhancements

### Improved readability of the Cycle Number text label

To ensure that all users have a comfortable user experience in the application, the following visual changes are introduced on the Subjects page:

- The font size for a visit cycle's number is increased.
- The word "cycle" is appended to the front of the cycle.
- The cycle indicator is left aligned to the separator bar between the cycles of a visit.

### **Oracle Clinical One Digital Gateway User Interface (UI) enhancements**

For this release, the following enhancements are introduced in the Oracle Clinical One Digital Gateway UI:

- The **Integration Start Date** field is now renamed as **Job Start Date**.
- The **Subject Data for CTMS Report** label is now displayed in the UI to be consistent with other Oracle Clinical One Platform report titles.

No functionality changes are introduced with these UI changes. For more information, reach out to your Oracle point of contact.

### **Additional data points are now included in the User Assignment reports**

As a user administrator, these new data points let you easily manage users, as well as review, and audit their data. The User Assignment report report and the User Assignment by Site report report now include the following changes:

- New columns now include the user's first name and last name to the right of their user name.
- The user's permissions now reflect the overall permission names in the application.
- In the User Assignment report, the site ID assigned to the user appears in the Organization column. For example, you see data populated as: SiteID-OrgName.
- In the User Assignment by Site report, the report's header includes the site ID associated with a user.

# 3

## Fixed issues

- [All users](#)
- [Facilities, settings, and user management](#)
- [Forms, visits, and rules](#)
- [Integrations](#)
- [Oracle Clinical One Analytics](#)
- [Randomization and Kits](#)
- [Reports, archives, extracts, and notifications](#)
- [Site users and subject data](#)

### All users

#### **Users with view only permissions cannot see form and visit data in newly created visits**

Now, any user assigned permissions to view can see form and visit data for newly created visits. Previously, when a user assigned view only permissions attempted to open certain visits, the visit would open to a blank screen and no form for visit data was visible.

**Retracted recommended action:** After a user with permissions to edit accesses the visit and views the visit data, a user with view only permissions can open the visit and view its data normally.

(Issue **36726515**)

#### **Sponsor and site users are unable to view sites under the Sites & Labs tab**

Now, for impacted custom roles, sponsor and site users can see sites on the Sites & Labs tab when they are assigned the *View Sites* permission, as expected.

(Issue **36488514**)

#### **Chat & Help does not display the hours of operation**

Now, after logging in, when you click Chat & Help in the upper right corner of Oracle Clinical One Platform, you are presented with the hours of operation. For more information about Chat & Help, see [Chat in real time with Oracle Support](#).

(Issue **36332772**)

### Facilities, settings, and user management

#### **The Order Forms button is inactive for a resupply shipment**

On the **Shipments** tab, when you select a resupply shipment, you can now view and click the **Order Forms** button successfully. Previously, this button was inactive, preventing you from downloading the Kit Order Form for a resupply shipment. (Issue **36774406**)

**You cannot remove a study role after selecting one from the drop-down (former known issue)**

Now, when creating a new user or editing an existing one, it is possible to remove a role after selecting it. Previously, you could not remove a role as the default option, Select Study Role, was unavailable after making a selection.

**Retracted recommended action:** If you need to remove a study role from a user, reverting the drop-down to the default option, Select Study Role on either the Create User or Edit User windows, do the following.

1. Use the tab key to navigate to the mode where you want to remove the study role.
2. Once on the correct cell, click Delete, then click the tab key again to move away from that cell.
3. Do this for each study mode if applicable.
4. Click Save to close the window or Next, if you need to make additional updates on the Sites & Depots tab.

(Issue **34999892**)

## Forms, visits, and rules

**All visits display under the Previous Visits section**

Now, on the Subjects tab, the Previous Visits and Next Visits columns display visits appropriately, whether there is an Adverse Event visit type or not. Previously, all visits were displaying under the Previous Visits section when there was no Adverse Event visit type present in the study design.

(Issue **36292294**)

**A user can select a lab even though the triggering condition for the lab form was not met**

Now, when a user changes the answer from No to Yes for a question where Yes triggers a dynamic lab form but does not submit the Reason for Change first, they are presented with a validation error and cannot select the lab from the drop-down until they save the Reason for Change.

Previously, the user was permitted to select a lab even though the triggering condition, which includes submitting the Reason for Change, was not fully satisfied.

(Issue **36524481**)

**A query shows as Answered in the Subject Queries report but Open in the user interface**

Now, when a user raises a query on an empty question and subsequently adds and immediately removes a comment, the query's status in the user interface and the Subject Queries report display Answered.

(Issue **36477797**)

**Cannot verify a blank field on a lab form (former known issue)**

Now, when you select an empty field and attempt to verify it, you are no longer presented with a message stating that an error occurred in the system.

**Retracted recommended action:** If you cannot enter data into the blank field, confirm that the lab form has a local lab selected and that a data flag marks the blank field.

(Issue **33498920**)

**Cannot verify blank two-section forms (former known issue)**

Now, when you attempt to verify a blank two-section form in an incomplete visit, the verification check boxes are present.

**Retracted recommended action:** Try completing fields in the Questions Before the Table section and mark at least one question in the Questions in the Table section with a data flag to be able to verify the blank two-section form.

(Issue **33498896**)

**Performance is slow when starting a skipped visit**

Now, when a user returns to a skipped visit to enter data, they will see an improvement in the time it takes for a skipped visit and its forms to load.

(Issue **35654352**)

**Unscheduled visits shown out of order**

Now, when a study includes unscheduled visits with visit start dates set between scheduled visits, the unscheduled visits are displayed correctly between the appropriate scheduled visits based on the visit start date instead of displaying scheduled and unscheduled visits grouped based on type.

(Issue **36048993**)

**An error occurs on the rule variable when the rule calls the clearChoice( ) helper function**

Now, a user no longer encounters the following error (also displayed in the Answer History side panel), resulting in a red box around the parent question.

**Error:** DCS-030 Item in the request body does not match with existing Data Element Item.

**Example:** In the following example, the rule target populates only when the rule variable is No.

If the user initially selects Yes, the rule calls the clearChoice( ) helper function to clear the target question, which is blank, resulting in the error.

The screenshot shows a form with two sections. The first section, labeled "Rule variable", contains a question: "Did Blinded Independent Central Reviewer confirm disease progression?" with two radio button options: "No" and "Yes". The second section, labeled "Rule target", contains a question: "Please indicate subject status following end of blinded treatment:" with three radio button options: "Proceed to End of Treatment/Safety Follow-up", "Proceed to Open Label Treatment", and "Yes and proceed to open label treatment". Below this, there is a question: "Trigger for Blinded Treatment assignment" with one radio button option: "Yes and proceed to open label treatment". At the bottom, there is a question: "Trigger for EOT1 FU form" with one radio button option: "No - Is the subject continuing?".

(Issue **36059717**)

**Visit hover text does not match the edited Adverse Event visit title**

Now, when hovering over the Adverse Event visit tile for a subject, the edited visit title is displayed instead of the previously hard-coded default value, Adverse Event, ensuring the hover text matches the column header's name.

(Issue **36364602**)

## Integrations

**Form data fails to load in Oracle DMW**

Now, for an integration between the Oracle Clinical One Platform and Oracle DMW, data for repeating form records loads completely without timing out.

(Issue **36176038**)

**Standard reports fail to generate when initiated during an Oracle Clinical One Platform upgrade**

(Details for bug 35239014) Standard reports such as Subject Visits, Subject Data, and Subject Events now generate successfully when initiated during an Oracle Clinical One Platform upgrade.

The reports previously failed during an upgrade because a particular file was updated before the metadata in the database, resulting in incompatible files and report failures. In future upgrades, the file and metadata will be updated together, ensuring the file is always compatible.

 **Note:**

The fix for bug 35239014 also resolved bug 35237829 related to CTMS report integration failures.

(Details for bug 35237829) The CTMS report integration initiates a call to the reporting service to generate the Subject Data for CTMS standard report. The integration then places the output file on the Oracle sFTP server for customer consumption. Bug 35239014 caused report failures for reports generated manually in the user interface and when initiated by the CTMS report integration.

(Issues: Fixing the base bug **35239014** (incompatible file issue) also resolved bug **35237829** (CMTS report integration failure).

**The lab integration fails if the study version in the request body does not match the production version**

The request body for the lab data intake integration now contains the correct study version, ensuring the job completes successfully.

Previously, the job would fail if a new study version was created and applied to a site while subjects were still active in the visit where the study version change was applied. A study version mismatch between Oracle Clinical One Platform and the integration request body caused the integration failure.

(Issue **36695050**)

## Oracle Clinical One Analytics

### **Dynamic forms in baseline visits are not showing as missing forms in the Forms dataset**

Now, a form that is dynamically displayed in an associated visit, but not displayed in other associated visits in the same study, is correctly displayed as missing in datasets such as the Forms or Form Items datasets.

(Issue **36453777**)

### **Study roles in the Queries dataset are not displayed correctly**

Now, details for current study roles display correctly in the Queries dataset. Previously, details in some study role columns appeared incorrectly as NULL.

(Issue **36453959**)

### **Shipments with more than 1000 kits appear as *Deferred* in Oracle Clinical One Analytics reports**

Now, a shipment with 1000 kits or more appears as the appropriate state in Oracle Clinical One Analytics reports. Previously, shipments that were created and sent to a site through Oracle Clinical One Platform with more than 1000 kits were appearing in a state of *Deferred* in Oracle Clinical One Analytics reports.

(Issue **36457894**)

### **The Unblinded Kits dataset may not contain data for replaced kits (former known issue)**

Now, when you generate a custom report based on the Unblinded Kits dataset, subject details for randomization, visits, and events are included for a replaced, damaged dispensed kit.

(Issue **33543337**)

### **Null value stored, resulting in data missing in Oracle Clinical One Analytics**

Now, complete GUID strings are stored without null values, ensuring data catchup in Oracle Clinical One Analytics picks up all data and completes processing it successfully.

(Issue **36419269** for storing a null value and **36420106** for missing data in Oracle Clinical One Analytics.)

## Randomization and Kits

### **Need to refresh to see the notification for unmapped treatment arms (former known issue)**

Now, when you add a new treatment arm to the first randomization design in a study, a notification appears on the Map Treatment Arms button (in Visits & Events) under the following circumstances.

- You design a study with two randomization designs and map subjects to treatment arms in the second randomization design.
- You add a new treatment arm to the study and associate it only with the first randomization design.

**Retracted recommended action:** Refresh the page, then the red notification appears.

(Issue **29910314**)

## Reports, archives, extracts, and notifications

### **Record of removed and hidden dynamic forms appear in the Subject Data Extract**

Now, any record of hidden dynamic forms that were removed does not appear in the Subject Data Extract when it is generated in any format. Previously, a record of dynamic forms that were removed and hidden with no form data showed in the Subject Data Extract.

(Issue **36528076**)

### **Oracle CRF Submit archive requests fail with no saved data and open queries (former Known Issue)**

Now, a Submission PDF, Archival PDF (site and sponsor), and Custom PDF request generate properly. Previously, the requests would fail to generate if a request included a subject with no data, but an open query, saved in any form at any visit.

**Retracted recommended action:** Use the FailureReport.txt, included with a failed request, to identify the subjects, then lock or freeze them. After a subject is Locked or Frozen, a subject PDF is generated successfully.

(Issue **36275528**)

### **The Subject Events report displays a different label for kit numbers**

Now, the Replaced Kit ID column is renamed to Replaced Kit Number in order to match the data displayed in the Subject Events report for that specific column.

For more information, see the Subject Events Report in the *Reporting Guide*.

(Issue **35864763**)

### **Duplicate randomization events displayed in the Subject Events report**

Now, in the Subject Events report, the randomization event is displayed a single time for every subject. Previously, the randomization event was displayed multiple times for the same subject, making you think the system randomized a subject multiple times.

(Issue **33545211**)

### **The Reason audit column in Archives PDFs is blank for transferred subjects**

Now, when you select Other as the reason for transfer, the manually entered reason is displayed under the Reason audit column in the Subject Record Transfer History (prth.pdf) file, included with the subject PDFs for transferred subjects. For more information about Archives, see About archives and reports.

(Issue **36113596**)

### **The User Assignment report contains incorrect organization data**

The Organizations column in the User Assignment report correctly displays the organizations (sites and depots) assigned to a user instead of displaying N/A.

Previously, N/A was displayed when the system encountered an unexpected time-out before retrieving all data.

(Issue **35764367**)



### Oracle CRF Submit email notifications are not always received (former Known Issue)

Oracle Clinical One Platform now sends Oracle CRF Submit email notifications to all eligible users.



#### Note:

Eligible users are defined under each notification and include the following options: Sponsor Users, Site Users, and Default Email.

Previously, some users were not receiving email notifications due to a system limitation on the number of eligible users.

For more information, see Email and in-application notifications.

(Issues **35981904**, related to the Storage limit has exceeded notification, and **36391622**, related to notifications for the Sponsor and Site and the success and failure of requests, were addressed.

### In the Rules report, the Visit Name column has a leading space

When generating the Rules report in CSV format, the Visit Name column header no longer contains a leading space.

**Retracted recommended action:** Manually remove the space in the output file.

(Issue **36710994**)

### The Kit Reconciliation report fails when site names include quotation marks

The Kit Reconciliation report now generates successfully even when site names include quotation marks.

**Retracted recommended action:** Remove the quotation marks from the site name, then re-run the report.

(Issue **36312970**)

### Oracle CRF Submit Archives Custom PDF requests fail when a misallocated kit is not associated with a visit

The Oracle CRF Submit Archives Custom PDF now generates successfully even if a visit is not selected when updating a kit's status to misallocated for a kit dispensed in error.



#### Note:

If you do not select a visit, the Subject History section of the PDF includes details about the misallocated kit.

For more information about RTSM data in archives, see the Submission PDF, Archival PDF (sponsor), Archival PDF (site), and Custom PDF requests.

(Issue **36308776**)

## Site users and subject data

### **Unable to save data for a question group after clearing data**

Now, when a user enters data for a question that is part of a question group after clearing data using the Clear option, data is successfully saved.

**Retracted recommended action:** Refresh the page and continue entering data.

Issue (35883879)

# 4

## Rest API updates

See the newly added, deprecated, and deleted endpoints of the Oracle Clinical One Platform APIs.

### Services updates

The following services are updated:

- [Data Hub](#)
- [Data Integration](#)
- [Data Capture](#)
- [Designer](#)
- [Designer EDC](#)
- [Randomization and Supplies](#)
- [Query](#)
- [Rules](#)
- [Rule Designer](#)
- [Sites and Depots](#)

### Data Hub

| Change     | Endpoint  |
|------------|---|
| <b>New</b> | <ul style="list-style-type: none"><li>• POST /v4.0/tenant/{tenantId}/studies/{studyId}/dataCollection</li><li>• GET /v5.0/studies/{studyId}/{mode}/odm/metadata</li></ul> |

### Data Integration

| Change     | Endpoint   |
|------------|--|
| <b>New</b> | <ul style="list-style-type: none"><li>• POST /v1.0/studies/{studyId}/{mode}/report/rtsmdataextract</li></ul> |

### Data Capture

| Change         | Endpoint  |
|----------------|---|
| <b>New</b>     | <ul style="list-style-type: none"><li>• PUT /v1.0/studies/{studyId}/{mode}/properties/{type}/{subjectId}/{id}</li><li>• POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisitsinfo</li><li>• PUT /v12.0/studies/{studyId}/{mode}/dataelements/{dataElementId}</li><li>• POST /v13.0/studies/{studyId}/{mode}/visitstatus/subjects</li><li>• GET /v2.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata</li><li>• PUT /v3.0/studies/{studyId}/{mode}/dataelements/clear/{scope}</li></ul> |
| <b>Deleted</b> | <ul style="list-style-type: none"><li>• GET /v8.0/studies/{studyId}/{mode}/visitstatus</li><li>• PUT /v9.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}</li></ul>   |

## Designer

| Change         | Endpoint   |
|----------------|--|
| <b>New</b>     | <ul style="list-style-type: none"> <li>• POST /v1.0/studies/{studyId}/versions/{version}/forms/associateForms</li> <li>• POST /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/previewFormNotification</li> <li>• POST /v17.0/studies/{studyId}/versions/{version}/forms</li> <li>• GET /v17.0/studies/{studyId}/versions/{version}/forms</li> <li>• GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded</li> <li>• GET /v17.0/studies/{studyId}/versions/{version}/forms/unblinded/{formId}</li> <li>• GET /v17.0/studies/{studyId}/versions/{version}/forms/{formId}</li> <li>• PUT /v17.0/studies/{studyId}/versions/{version}/forms/{formId}</li> <li>• DELETE /v17.0/studies/{studyId}/versions/{version}/forms/{formId}</li> <li>• GET /v17.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms</li> <li>• POST /v2.0/studies/{sourceStudyId}/copy</li> <li>• GET /v2.0/studies/{studyId}/studyversionobjects/formitems</li> <li>• POST /v2.0/studies/{studyId}/updateCopyStudyStatus</li> <li>• POST /v2.0/studies/{studyId}/versions/{version}/branches/{branchId}/copyBranch</li> <li>• GET /v2.0/studies/{studyId}/visits</li> <li>• POST /v2.0/studies/{targetId}/copystudyobjects</li> <li>• POST /v2.0/studies/{targetStudyId}/retryCopyStudy</li> <li>• POST /v3.0/studies/{studyId}/versions/{version}/design/visits/{visitId}/validate/assign/randomization/{randomizationId}</li> <li>• POST /v8.0/studies/{studyId}/versions/{version}/visits</li> <li>• GET /v8.0/studies/{studyId}/versions/{version}/visits</li> <li>• GET /v8.0/studies/{studyId}/versions/{version}/visits/{visitId}</li> <li>• PUT /v8.0/studies/{studyId}/versions/{version}/visits/{visitId}</li> <li>• DELETE /v8.0/studies/{studyId}/versions/{version}/visits/{visitId}</li> </ul> |
| <b>Deleted</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/studies/{studyId}/integrationreport</li> <li>• GET /v1.0/studies/{studyId}/versions/{versionId}/cohorts</li> <li>• GET /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/formLogo</li> </ul>  |

## Designer EDC



### Note:

Designer EDC endpoints are listed under the Designer category.

| Change     | Endpoint  |
|------------|---|
| <b>New</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/studies/{studyId}/{mode}/forms/formitems</li> <li>• GET /v1.0/studies/{studyId}/{mode}/forms/latest</li> </ul> |

## Randomization and Supplies

| Change         | Endpoint  |
|----------------|---|
| <b>New</b>     | <ul style="list-style-type: none"> <li>• POST /v1.0/studies/{studyId}/{mode}/dndexception</li> <li>• GET /v1.0/studies/{studyId}/{mode}/dndexception</li> <li>• GET /v1.0/studies/{studyId}/{mode}/dndexception/{id}</li> <li>• PUT /v1.0/studies/{studyId}/{mode}/dndexception/{id}</li> <li>• DELETE /v1.0/studies/{studyId}/{mode}/dndexception/{id}</li> <li>• POST /v1.0/studies/{studyId}/{mode}/kits/existingdata</li> <li>• POST /v1.0/studies/{studyId}/{mode}/reports/dndexceptions</li> <li>• GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/visits/{visitId}/status</li> <li>• PUT /v2.0/studies/{studyId}/{mode}/orders/{shipmentId}</li> <li>• GET /v2.0/studies/{studyId}/{mode}/randlistdesigns</li> <li>• POST /v2.0/studies/{studyId}/{mode}/sites/{siteId}/recon/shipments</li> <li>• POST /v2.0/studies/{studyId}/{mode}/{studyVersion}/randlist/generate</li> <li>• POST /v3.0/studies/{studyId}/{mode}/lots/blinded-lots</li> <li>• GET /v3.0/studies/{studyId}/{mode}/lots/blinded-lots</li> <li>• GET /v3.0/studies/{studyId}/{mode}/lots/blinded-lots/{blindedLotId}</li> <li>• PUT /v3.0/studies/{studyId}/{mode}/lots/blinded-lots/{blindedLotId}</li> <li>• GET /v3.0/studies/{studyId}/{mode}/sites/{siteId}/shipments</li> <li>• PUT /v4.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits</li> <li>• PUT /v5.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId}</li> <li>• GET /v6.0/studies/{studyId}/{mode}/shipments</li> </ul> |
| <b>Deleted</b> | <ul style="list-style-type: none"> <li>• POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisits2s</li> </ul>  |

### Query

| Change            | Endpoint   |
|-------------------|--|
| <b>New</b>        | <ul style="list-style-type: none"> <li>• GET /v3.0/studies/{studyId}/{mode}/queries/queryTable</li> </ul>  |
| <b>Deprecated</b> | <ul style="list-style-type: none"> <li>• GET /v2.0/studies/{studyId}/{mode}/queries/queryTable</li> <li>• POST /v8.0/studies/{studyId}/{mode}/report/{reportName}</li> </ul> |

### Rules

| Change     | Endpoint   |
|------------|--|
| <b>New</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/studies/{studyId}/{mode}/rerunhistory/{ruleId}</li> </ul> |

### Rule Designer



#### Note:

Rule Designer endpoints are listed under the Rules category.

| Change            | Endpoint   |
|-------------------|--|
| <b>Deprecated</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/rule/studies/{studyId}/{mode}/simple</li> </ul> |

## Sites and Depots

| Change     | Endpoint  |
|------------|---|
| <b>New</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/studies/{studyId}/{mode}/regions/countries/history</li> <li>• GET /v1.0/studies/{studyId}/{mode}/regions/history</li> <li>• GET /v1.0/studies/{studyId}/{mode}/sdfs/allSdf/{sdfType}</li> <li>• GET /v1.0/studies/{studyId}/{mode}/sdfs/allstudyversions/{sdfType}</li> <li>• POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/sdfDetails</li> <li>• GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/countries</li> <li>• POST /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/validateFields</li> <li>• PUT /v2.0/contacts/deleteContact/{id}</li> <li>• PUT /v2.0/organizations/deleteOrganization/{id}</li> </ul> |

- [Rest API patch updates](#)  
See the updates to the Oracle Clinical One Platform APIs for 24.1.1.

## Rest API patch updates

See the updates to the Oracle Clinical One Platform APIs for 24.1.1.

The following services have been updated:

- [Designer EDC](#)
- [Query](#)
- [Users, Permissions and Roles](#)

### Designer EDC



#### Note:

Designer EDC endpoints are listed under the Designer category.

| Change     | Endpoint   |
|------------|--|
| <b>New</b> | <ul style="list-style-type: none"> <li>• POST /v1.0/studies/{studyId}/forms/labNormalItems</li> <li>• POST /v1.0/studies/{studyId}/visitsforms/formitems</li> <li>• POST /v1.0/studies/{studyId}/visitsforms/strata</li> </ul> |

### Query

| Change     | Endpoint  |
|------------|---|
| <b>New</b> | <ul style="list-style-type: none"> <li>• GET /v1.0/studies/{studyId}/{mode}/querymgmt/filteredList</li> <li>• GET /v10.0/studies/{studyId}/{mode}/openQueryDetails</li> <li>• GET /v10.0/studies/{studyId}/{mode}/queryDetails</li> <li>• POST /v10.0/studies/{studyId}/{mode}/report/{reportName}</li> </ul> |

## Users, Permissions and Roles

| Change | Endpoint   |
|--------|--|
| New    | <ul style="list-style-type: none"><li>• POST /v1.0/authstudies/{studyId}/users</li></ul> |

# 5

## Release impact for other applications

This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

- Instructional text items are not currently supported in downstream applications, such as Oracle DMW, Oracle Clinical One Digital Gateway, or Oracle Clinical One Analytics. For more information about instructional text, see Add instructional text.
- Drug reconciliation forms are not currently supported in downstream applications, such as Oracle DMW, Oracle Clinical One Digital Gateway, or Oracle Clinical One Analytics. For more information on this type of forms, see Drug Reconciliation forms.

### Impact specific to Oracle DMW only

The length of the following columns is increased and this impacts your integrations with Oracle DMW. For more information, reach out to your Oracle point of contact.

The following columns are updated:

| Data Hub table               | Data Hub column        | Current data length | New data length |
|------------------------------|------------------------|---------------------|-----------------|
| DH_SITE_DEPOT_ADD<br>RESS    | FAX                    | 200                 | 2000            |
| DH_SITE_DEPOT_ADD<br>RESS    | PHONE                  | 200                 | 2000            |
| DH_SITE_DEPOT_ADD<br>RESS    | EMAIL                  | 1020                | 2000            |
| DH_SITE_DEPOT_ADD<br>RESS    | ADDRESS_POSTALCO<br>DE | 20                  | 80              |
| DH_SUBJECTS_VISITS           | ADDRESS_POSTALCO<br>DE | 20                  | 80              |
| DH_SUBJECT_FORMIT<br>EMS     | LAB_NAME               | 800                 | 2000            |
| DH_SITE_DEPOTS               | SDF_NAME               | 800                 | 2000            |
| DH_SITE_DEPOT_ADD<br>RESS    | SDF_NAME               | 800                 | 2000            |
| DH_SITE_DEPOT_ATT<br>RIBUTES | SDF_NAME               | 800                 | 2000            |
| DH_SITE_DEPOT_COU<br>NTRIES  | SDF_NAME               | 800                 | 2000            |
| DH_OR_S_RND_NUMBE<br>RS      | SITE_NAME              | 800                 | 2000            |
| DH_OR_S_KIT_TYPES            | SITE_NAME              | 800                 | 2000            |
| DH_SUBJECT_SITE_S<br>UMMARY  | SITE_NAME              | 800                 | 2000            |
| DH_SUBJECTS                  | SITE_NAME              | 800                 | 2000            |
| DH_SUBJECT_VISIT_S<br>UMMARY | SITE_NAME              | 800                 | 2000            |
| DH_QUERY                     | SITE_NAME              | 800                 | 2000            |
| DH_SUBJECTS_VISITS           | SITE_NAME              | 800                 | 2000            |



| <b>Data Hub table</b>           | <b>Data Hub column</b> | <b>Current data length</b> | <b>New data length</b> |
|---------------------------------|------------------------|----------------------------|------------------------|
| DH_INVENTORIES                  | SITE_NAME              | 800                        | 2000                   |
| DH_ORDERS                       | SITE_NAME              | 800                        | 2000                   |
| DH_SUBJECT_FORMIT<br>EMS        | SITE_NAME              | 800                        | 2000                   |
| DH_FORMS_ASSOCIAT<br>IONS       | SITE_NAME              | 800                        | 2000                   |
| DH_SUBJECTS_MISSI<br>NG_VISITS  | SITE_NAME              | 800                        | 2000                   |
| DH_SUBJECT_FORMS                | SITE_NAME              | 800                        | 2000                   |
| DH_ORDERS                       | DEPOT_NAME             | 800                        | 2000                   |
| DH_USER_SITEDEPOT<br>_ACCESS    | SITE_DEPOT_NAME        | 800                        | 2000                   |
| DH_SUBJECT_TRANSF<br>ERS        | FROM_SITE_NAME         | 800                        | 2000                   |
| DH_SUBJECT_TRANSF<br>ERS        | TO_SITE_NAME           | 800                        | 2000                   |
| DH_SITE_DEPOT_ADD<br>RESS       | ADDRESS_COUNTRY        | 400                        | 16000                  |
| All Data extract form<br>tables | SITE                   | 800                        | 2000                   |

# 6

## Be a part of the Oracle Clinical One Platform community

Whether you're looking to get expert advice or just learn more about Oracle Clinical One Platform, you'll find answers in our community. Participate in discussions, provide feedback, connect with Support, and learn more about the Oracle Clinical One Platform. Join the Clinical One community to get the help that you need!

To access the community straight from the URL, go to the [Clinical One community](#) and bookmark it. Alternatively, you can access the community from your Oracle Clinical One Platform Home page. On the Home page, under your user name, there is now a new link called **My Community**. Click it and it will take you to the community landing page where you need to sign in. This link is only available to users at a sponsor.

### **Note:**

Keep in mind that you must be logged into your Oracle SSO account to be able to access the Oracle Community General FAQs page.

### Get access to the Oracle Clinical One Platform community

This community can only be accessed by sponsor user roles who have an Oracle Single Sign-On (SSO) account. To get an Oracle SSO account to log into your Oracle Clinical One Platform community, you must perform the following tasks:

1. Go to <https://community.oracle.com/industries/life-sciences/>.
2. On the landing page, click **Register**.
3. On the new page, fill-in the fields, and click **Create Account**.  
For step-by-step instructions on how to create and confirm an Oracle SSO account, see [Get an Oracle.com Account](#).
4. After confirming your account, return to <https://community.oracle.com/industries/life-sciences/> and click **Log In**.

### Related Topics

- [Clinical communities](#)

# 7

## 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   |
|-----------------------------------|---|
| <b>Urgent Issue?</b>              | Opens the Oracle Life Sciences Support Cloud portal where you can submit a Service Request (SR).                        |
| <b>Chat with Customer Support</b> | Opens a new chat window and adds you to the queue to engage with a support agent in real time.                          |
| <b>Call Technical Support</b>     | Opens the Life Sciences Support page where you can find out the details about where to call depending on your location. |
| <b>Check the Knowledge Base</b>   | 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.<br>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 disconnected, 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**.

# 8

## 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).

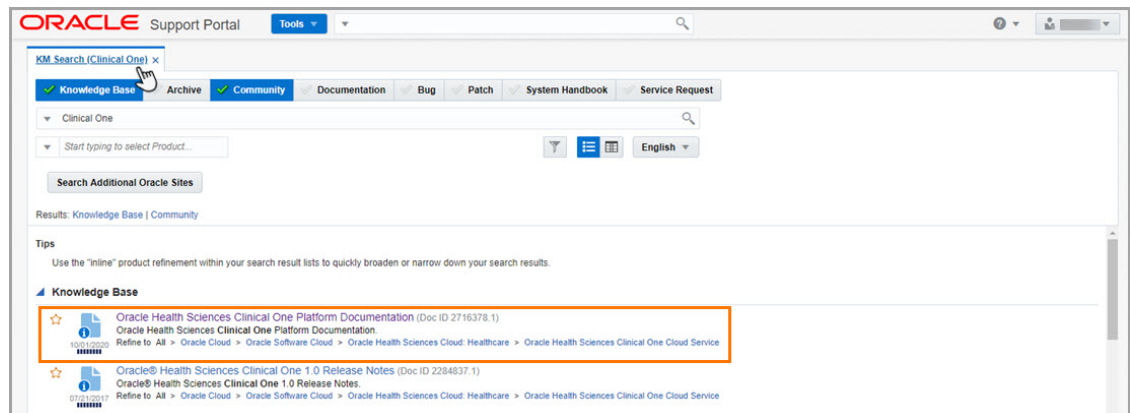
To make sure you get the right access in MOS, follow these two steps in the order listed below:

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 8-1 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](mailto:clinical_one_doc_feedback_us_grp@oracle.com).


# 9

## Subscribe to product updates

- [Subscribe to Life Sciences Support release announcements](#)
- [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.

### Subscribe to Life Sciences Support release announcements

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

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 HSGBU Support.

#### **Note:**

You will also receive announcements from other industry-specific applications developed by Oracle Health Sciences.

#### **Announcement types, schedules, and other useful details**

Several announcements 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**.

The following announcements are sent for each type of release:

#### **Note:**

Upgrade dates are subject to change.

| Type of release   | Announcement                                    | Details  |
|---|---|--|
| <ul style="list-style-type: none"> <li>• <i>Minor release</i> (for example, 22.1)</li> <li>• <i>Patchset</i> (for example, 22.1.1)</li> </ul> | Release Assessment Environment Pre-release      | <ul style="list-style-type: none"> <li>• Posted two weeks before the planned Release Assessment Environment (RAE) upgrade.</li> <li>• Contains planned dates for the completion of the Release Assessment Environment (RAE) and Production upgrades.</li> <li>• May contain information on downtime, if it will occur during the upgrade of a release.</li> <li>• Draft Release Notes are available upon request. Reach out to your Oracle Point of Contact to get a draft copy of the Release Notes.</li> </ul> |
|   | Release Assessment Environment Upgrade Complete | <ul style="list-style-type: none"> <li>• Posted upon the successful completion of the Release Assessment Environment upgrade.</li> <li>• Contains dates for the Production Cloud upgrade.</li> <li>• Release Notes and user guides are available on the <a href="#">Oracle Help Center</a>.</li> <li>• The Product Verification Package (PVP) is available on My Oracle Support (MOS). For more information, see About the Product Verification Pack (PVP).</li> </ul>   |
|   | Production Cloud Upgrade Complete               | <ul style="list-style-type: none"> <li>• Posted upon the successful completion of the Production Cloud upgrade.</li> <li>• Final Release Notes and user guides are posted on the <a href="#">Oracle Help Center</a> if updates have been required since the last version. For more information, see the Revision History topic included in each publication.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• <i>Patch</i> (for example, 22.1.1.1)</li> </ul>  | Production Cloud Pre-release                    | <ul style="list-style-type: none"> <li>• Posted approximately one week before the planned Production Cloud upgrade.</li> <li>• Contains planned dates for the Production and Release Assessment Environment (RAE) upgrades.</li> <li>• Contains general information about planned fixed issues.</li> <li>• Draft Release Notes are available upon request. Reach out to your Oracle Point of Contact to get a draft copy of the Release Notes.</li> </ul>  |
|   | Production Cloud Upgrade Complete               | <ul style="list-style-type: none"> <li>• Posted upon the successful completion of the Production Cloud upgrade.</li> <li>• Final Release Notes and user guides are posted on the <a href="#">Oracle Help Center</a>.</li> </ul>  |

## 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.



# 10

## 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.

# 11

## Browser requirements

### System requirements

| Computer          | Internet browser   | Resolution  |
|-------------------|--|---|
| Laptop or desktop | <ul style="list-style-type: none"><li>Google Chrome version 119.0.6045.124 <b>(recommended)</b></li><li>Microsoft Edge version 119.0.2151.58</li></ul> | <p>Make sure the resolution display of your computer is configured using the following values</p> <ul style="list-style-type: none"><li>1920x1080 (recommended) for a full High Definition (HD) monitor</li><li>1366x768 px or higher (standard resolution) for most non-HD computers</li></ul> |

# 12

## About the Product Verification Pack (PVP)

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:

- Verification Summary report
- Requirements document
- Requirements testing documentation with corresponding objective evidence
- Standard Control testing documentation with corresponding objective evidence

A new PVP is made available for every release except patch releases.

## 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.

### 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 Project Manager or Customer Success Manager.

## 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 download 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 \(PVP\)](#).

# 14

## 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 account 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 the **Support Requests** tab.
3. Click **Create a new Support Request**.
4. Enter a ticket and ask for the password for the product PVP. For help filling in the fields, see the following sample ticket.



### Submit a Request to our Product Support Team

Select Customer

Select Product \*

Select Business Service

Oracle Internal \*  
 Yes  No

Environment \*

Application URL/Website Address

Severity \*

Issue Category \*

Alternative ref number (if applicable)

Summary \*

Description \*

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&\\_afLoop=457623897492643&patchId=28825486](https://support.oracle.com/epmos/faces/PatchDetail?requestId=22840173&_afLoop=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.

# 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 Oracle Clinical One Platform Project Manager (or your main Oracle Clinical One Platform 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 Clinical One Platform Project Manager (or your main Oracle Clinical One Platform point of contact) to have a new email generated.

### 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 checkbox 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   |
|--------------|-------------|---|
| 10-July-2024 | F91489-11   | Fixed the formatting for the <b>Queries</b> icon in <a href="#">Manage all queries in one place</a> .   |
| 05-July-2024 | F91489-10   | Documented a new fixed issue 36774406.<br>For more information, see the <a href="#">Patch log</a> .   |
| 03-July-2024 | F91489-09   | For this release we made the following changes: <ul style="list-style-type: none"><li>• Documented new fixed issues for release 24.1.1.</li><li>• Documented new features introduced in the 24.1.1 release.</li></ul> For more information, see the <a href="#">Patch log</a> .<br>Additionally, the following topics were included: <ul style="list-style-type: none"><li>• <a href="#">Rest API patch updates</a></li></ul> |
| 14-June-2024 | F91489-08   | For this release we: <ul style="list-style-type: none"><li>• Documented new fixed issues for release 24.1.0.1.</li><li>• Documented an enhancement for the Oracle Siebel Clinical Trial Management System (CTMS) - Site integration.</li></ul> For more information, see the <a href="#">Patch log</a> .  |
| 31-May-2024  | F91489-07   | Documented a new fixed issue <b>35864763</b> . For more information, see <a href="#">Reports, archives, extracts, and notifications</a> .   |
| 30-May-2024  | F91489-06   | Information was updated in <a href="#">Allow a future date in forms</a> .   |
| 19-May-2024  | F91489-05   | Information was corrected in <a href="#">Allow a future date in forms</a> .   |
| 08-May-2024  | F91489-04   | The following updates were included: <ul style="list-style-type: none"><li>• More information related to the announcement strategy for releases. See <a href="#">Subscribe to Life Sciences Support release announcements</a>.</li><li>• More information related to impact on downstream integrations. See <a href="#">Release impact for other applications</a>.</li></ul>  |

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| <b>Date</b> | <b>Part number</b> | <b>Description</b>   |
|-------------|--------------------|--|
| 07-May-2024 | F91489-03          | <a href="#">Subscribe to Life Sciences Support release announcements</a> was updated to include new information on the announcement strategy for releases. |
| 06-May-2024 | F91489-02          | Enhancements to Oracle CRF Submit archives and reports was updated with details about the increase in the storage space allocated to each customer.        |
| 02-May-2024 | F91489-01          | Original version of the document   |

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