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

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Oracle Life Sciences Clinical One Platform and Oracle Life Sciences Clinical One Digital Gateway Release Notes, Release 24.2

G11332-08

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Preface

This preface contains the following sections:

- Documentation accessibility
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Documentation accessibility

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

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- 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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Patch log

This topic describes the history of patches and patchsets we have applied to the 24.2 release. None of these fixes affect the user work flow or the application's functionality.

No new features have been added to any of these patches and their upgrades do not affect users working with the Oracle Clinical One Digital Gateway application.

Table 1-1   Patch log

Release Number	Release Date	Notes
24.2.0.1	18-September-2024	For this release, we fixed one issue related to reports. For more information, see issue **37008259** in Reports, archives, extracts, and notifications.

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
- Integrations
- Notifications
- Randomization and trial supply management
- Reporting, archives and analytics
- Rules management
- User experience

Data collection

- Easily include lab normal updates in existing forms
  The process of updating lab normal ranges for existing lab forms is now more seamless.

- Design questions with an auto-lock
  Study designers can now restrict site users from editing subject data after subject screening, randomization, dispensation, or visit completion.

Easily include lab normal updates in existing forms

The process of updating lab normal ranges for existing lab forms is now more seamless.

> ✎ **Note:**
>
> Any automatic updates to lab normal ranges in lab forms do not impact a question's Signed or Verified status, while lab normal updates are still pushed to lab forms even when their data is locked.

Now that lab normal updates are more seamlessly included in existing lab forms, you can ensure that the most up-to-date normal range values are associated with all subject data without requiring visit-level interaction.

For example, if you identify data entry errors for a local lab's normal ranges during a peer review session, and you proceed to correct those errors in the application, those changes are automatically displayed in the existing lab forms included in a study, including forms that have already been completed or locked.

Details for all users

If you work with local labs, upon updating and saving a lab's normal ranges from the **Sites & Labs** tab, your updates are automatically refreshed in the existing lab forms associated with a live study version. To ensure that all of your updates are properly reflected in a form, it may take only a couple of minutes for the data to be refreshed.

> 💡 **Tip:**
>
> Want to view an audit trail of your lab normal updates? Either check the Answer & Visit History sidebar for a specific lab form row or run the new Lab Normal Range report. For more information on this new report, see New Lab Normal Range report.

Impact on reports, extracts, or data sets

Any lab normal updates that are automatically applied to existing lab forms are displayed as follows:

* In the following reports in the Oracle Clinical One Platform: the Subject Data report, the Subject Data Extract, and the Lab Normal Range report.

* In all of the expected datasets in Oracle Clinical One Analytics where lab normal updates are refreshed appropriately.

Already working in a live study?

Whether you're working in a live study or you're getting ready to set up a new study, you should know that this enhancement is available for new and existing studies and for new and existing labs, sites, and subjects.

For existing lab forms, any lab normal updates you made before this release (release 24.2) will not be applied retroactively. If you completed a lab form prior to this release, your lab normal updates are not automatically reflected in these past forms. Any updates you made to lab normals after this release (24.2) will be reflected in existing lab forms. For more information on how to enable your past lab forms to display your lab normal updates automatically, contact your Oracle point of contact.

Design questions with an auto-lock

Study designers can now restrict site users from editing subject data after subject screening, randomization, dispensation, or visit completion.

Study designers can now configure a new predefined rule when configuring a question's settings. The **Auto-lock** rule option restricts site users from modifying questions once a subject has completed a key event during the study, such as screening, randomization, drug dispensation, or when the visit has been completed.

Locking subject data during the study conduct period allows sponsor users to protect essential data used in system decision-making from updates made by the site users without sponsor intervention. A site user can request the unlocking of a question from a sponsor user for editing. The sponsor user must first manually unlock the item to edit, which will be modified, and then locked again.

Details for study designers

If you're assigned to a study role that includes the *Design Forms* permission, you can now add an **Auto-lock** rule to a question in a form's design.

Upon selecting the Auto-lock predefined rule, you can specify the condition of when the auto-lock of a question should occur. The following four options are available:

- **Subject Screened**: a question should be automatically locked after a subject is screened.
- **Subject Randomized**: a question should be automatically locked after a subject is randomized.
- **Subject Dispensed**: a question should be automatically locked after a subject is dispensed the kit.
- **Visit Completion**: a question should be automatically locked after a visit is completed.

In a live study, when the rule is applied, data related to the question with the auto-lock rule becomes read-only for site users after the defined condition is completed.

The auto-lock rule can be applied to all form types (one-section, two-sections, and lab forms) and all question types (including hidden questions), whether they're optional or required. However, instructional text items and clinical supplies forms do not support auto-lock rules.

You can add, delete or update an auto-lock rule as part of a study version change or when using the Advanced Study Versioning (ASV) feature. Only data where the precipitating event has not already occurred will be locked. Data where the precipitating event occurred before the ASV is applied will need to be manually locked.

Sponsor users will receive the Auto-lock failure notification if the rule locking is unsuccessful.

Details for site users

If you need to update a question that was automatically locked, this is what you should know:

> **Note:**
>
> The details listed below describe a workflow that occurs outside of the Oracle Clinical One Platform. You can contact your sponsor team through other means to request an approval for updating an automatically locked question.

- You need to request approval from a sponsor user, sponsor support representative, CRA, data manager, or medical monitor to indicate that you need to update a locked question.
- In the change request, you must follow the process defined by the sponsor user.

You can find additional information in the Frequently Asked Questions section from the *Site User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Impact to reporting and analytics

Updates to the following reports are introduced to support auto-lock rules:

- **Study Design Report** shows the auto-lock rule changes in the Action Rules column.
- **Annotated Case Report Form** shows the auto-lock rule changes in the Validations column as an Action item.
- **Subject Data Report** shows the auto-lock rule changes in the Type of Change column.

Chapter 2
Integrations

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

Integrations

- Configure Oracle Clinical One Digital Gateway integrations to integrate data as of a specific date
  A new Oracle Clinical One Digital Gateway setting lets you control what data gets integrated for your studies.

- Support for non-serialized inventory for integrations
  The supply and dispensation of non-serialized inventory is now supported for select Oracle Clinical One Digital Gateway integrations with Oracle Clinical One Platform studies.

Configure Oracle Clinical One Digital Gateway integrations to integrate data as of a specific date

A new Oracle Clinical One Digital Gateway setting lets you control what data gets integrated for your studies.

Details for integration managers

A new scheduling setting (**Only transfer data after specific date**), available in Oracle Clinical One Digital Gateway, lets you determine how far back an integration should look (in a study) when creating jobs for outbound data integrations. This enables you to control what data gets integrated for your studies.

By default, the setting is configured to send all data from the start of the study, which is the most common integration process. However, limiting the data you integrate can enhance the efficiency of your integrations.

The most common uses cases include:

Table 2-1   Use case details

Use case	Example
Limiting the test data being integrated	You created an integration for testing purposes. You did this two years ago and never deleted the test integration, as you may need it again.
	Today, you want to implement one change to the integration, and you need to test it. In this scenario, you'd set **Only transfer data after specific date** to a date that aligns with the day you changed the integration. This ensures your new testing does not include the older data.
After migrating a study to a new tenant	You wouldn't want to re-integrate data already integrated before the study migrated; you'd only want to integrate data since the day the study completed the migration process. In this scenario, you'd set **Only transfer data after specific date** to a date that aligns with the day the study completed migration.

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

Support for non-serialized inventory for integrations

The supply and dispensation of non-serialized inventory is now supported for select Oracle Clinical One Digital Gateway integrations with Oracle Clinical One Platform studies.

Details for integration managers

Non-serialized kits are tracked by lot number and quantity and not by the kit number. For more information about this new feature, see Distribute non-serialized inventory.

The following integrations now support the transmission of data related to non-serialized kits:

> **Note:**
>
> If your study is using an integration with Oracle Clinical One Digital Gateway which is not listed below, your study will not support the transmission of data related to non-serialized inventory.

- The integration with Almac Global Depot Network

  > **Note:**
  >
  > The integration with Almac Global Depot Network only supports a single kit type or description per lot. When using the Almac integration with non-serialized investigational product, a kit type must be mapped to an individual number.

- The integration with Oracle InForm
- The integration with Medidata Rave

How to update current integrations

Reach out to your Oracle point of contact if you would like to update the integration configuration to support non-serialized inventory.

Notifications

- New notification for report server limit exceeded
  This new notification informs users when a generated report exceeds the report storage server space.

New notification for report server limit exceeded

This new notification informs users when a generated report exceeds the report storage server space.

Each study mode is allocated 200 GB on the report storage server. When a report is generated that exceeds this limit, users are informed by the new **Report Space Limit Exceeded** notification.

When a report exceeds the limit, the report fails, and the person generating the report receives the notification. For scheduled reports, the person who scheduled the report gets the notification.

> **✎ Note:**
>
> The system does not notify users if one of the following global-level reports exceeds the limit:
>
> • Global Study Roles report
>
> • Life Sciences Learn Training Report
>
> • Study Roles Report by Study
>
> • User Assignment Across Studies report

More information can be found in the *Notifications and Permissions Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- Allow depot-to-depot shipments for staging kits
  Clinical supply managers can now allow depot-to-depot shipments to stage kits for a country prior to a blinded lot being approved in a study.

- Distribute non-serialized inventory
  Clinical supply managers can now provide sites with the ability to distribute non-serialized inventory to subjects and define a resupply process to ensure product availability when needed.

- Enhancements to sites and depots
  Sponsor users are now provided with user interface (UI) enhancements, as well as new options when updating contacts and organizations, and newly introduced notifications.

Allow depot-to-depot shipments for staging kits

Clinical supply managers can now allow depot-to-depot shipments to stage kits for a country prior to a blinded lot being approved in a study.

With the introduction of a new setting for blinded lots, you can better plan and control a study's supply strategy and configurations. By allowing depot-to-depot shipments before a lot is approved for release in a certain country, you give your team the possibility to ship the kits to the depot and stage them just in time for them to be shipped to the country-specific sites.

For example, a new blinded lot A is created for your study. Kits in lot A will be dispensed in three countries (Germany, France, and Spain) and each country has its own release process for these kits, as well as different intervals for releasing these new kits. Even though your study team cannot ship the kits to the sites in all three countries at once, they can now ship those kits to the depot (via a depot-to-depot shipment) to have them ready in due time for when the release of the kits can begin.

Details for clinical supply managers

> **✎ Note:**
>
> This feature doesn't impact any other components, such as study design, data collection, reports, integrations, or notifications.

Here's what's new in your workflow:

- On the **Study Inventory** tab, when you edit a blinded lot, a new toggle is displayed on the Edit Blinded Lot dialog. This new toggle is called **Release for Depot to Depot**.

- By default, the **Release for Depot to Depot** toggle is turned off. When you turn on the toggle, and a depot-to-depot shipment is created, this shipment will be delivered regardless of the DNS (Do Not Ship) settings specific for a lot or a country.

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

Distribute non-serialized inventory

Clinical supply managers can now provide sites with the ability to distribute non-serialized inventory to subjects and define a resupply process to ensure product availability when needed.

The use of non-serialized inventory can be helpful in numerous scenarios, especially in studies with a large number of subjects that require a larger supply. Because non-serialized inventory is not tracked, this leads to easier reconciliation, depending on the type of investigation product.

For example, if ten (10) kits are dispensed for a subject, but two (2) of the kits were damaged, all 10 kits are marked as *Damaged By Subject*. The eight (8) kits are still dispensed, but it is not specified which 2 kits are damaged because they are not tracked by kit number.

Details for clinical supply managers

When it comes to your workflow, here's what's new for you:

- On the **Study Inventory** tab, you can now manage both serialized and non-serialized kits. To easily identify any of these kit types, you can use the new Kit Type filter options: Serialized, Non-Serialized, or All.

- On the **Study Inventory** tab, you can now add kits to a lot by selecting the **Add to Lot** drop-down and entering the required information in the Add Non-Serialized Kit to Lot dialog.

- When specifying resupply settings, a min/max or predictive resupply strategy can be used for non-serialized kits.

- Non-serialized kits can be partially dispensed, locally sourced, and selected for a dose hold.

- Non-serialized kits *cannot* be individually ordered.

- Dispensation of reusable kits, site confirmation for dispensation, temperature excursion numbers, site and depot kit reconciliation are *not* available for non-serialized kits when both serialized and non-serialized kits are present in a study.

- On the **Depot Inventory** tab, non-serialized kits display by lot number and as unblinded.

- On the **Depot Inventory** tab, when a single lot is selected with the status of *Quarantined*, Quarantined Shipment Details appears in the side panel.

More information on non-serialized kit design and configuration can be found in the *Sponsor and CRO User Guide* and *Study Designer User Guide* after the Release Assessment Environment (RAE) upgrade.

Details for site users

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

- Details on non-serialized kits appear on the **Site Inventory** tab.
- Under **Kit Types**, you now have options to view **All**, **Serialized**, or **Non-Serialized** kits.
- For non-serialized kits, instead of a kit number, the lot number and quantity is displayed in the following user interface (UI) areas:
  - **Shipments** tab
  - **Site Inventory** tab
  - Add Shipment to Inventory dialog (when you register a shipment at a site)
  - Release Quarantined Kits dialog (when you quarantine kits at a site)
  - Dispense Kits dialog (after you dispense a non-serialized kit to a subject)
- When adding non-serialized kits to your inventory, you can enter an exact quantity of kits from the received lot you would like to add.

More information and step-by-step instructions on managing non-serialized inventory at the site level can be found in the *Site User Guide* after the RAE upgrade.

Impact on reports

Once the RAE upgrade is complete, additional details on non-serialized lots and counts of kits can be found in the following reports:

- Kit Inventory (Blinded) report
- Kit Inventory (Unblinded) report
- Kit Dispensation report
- Shipment Order Summary report
- Subject Events Report
- Study Design report
- Subject Visits (Blinded) report
- Subject Visits (Unblinded) report
- Titration Summary (Blinded) report
- Titration Summary (Unblinded) report

For more information, see the *Reporting Guide*.

> **✎ Note:**
>
> Kit numbers display as lot numbers for non-serialized inventory.

Individual barcodes and tracking are not available in Oracle Clinical One Analytics for non-serialized kits. Because all tracking is removed, Oracle Clinical One Analytics datasets display the most recent view of kits by groups and quantity based on their status. Updates to the Blinded and Unblinded Kits datasets can be found in the *Analytics User Guide* after the RAE upgrade.

Impact on notifications

The following notifications include additional details on non-serialized inventory when non-serialized kits are dispensed:

• **Unblinded dispensation notification**

• **Study inventory notification**

• **Kits quarantined notification**

• **Kits released from quarantine notification**

• **Kit status changed to "Misallocated" notification**

• **Kit status changed to "Not Dispensed to Subject" notification**

• **Subject dispensation notification**

For more information, see the *Notifications and Permissions Guide*.

Impact on integrations

To learn more about the impact of this new feature on your existing or future integrations, see Support for non-serialized inventory for integrations.

Already working in a live study?

When the upgrade for this release is complete, to start working with non-serialized kits you must update the study design adding a non-serialized kit type. Functions for non-serialized kits in existing studies will be available, such as new filter and field options, and kit status information on the **Study Inventory**,**Site Inventory**, and **Depot Inventory** tabs.

Enhancements to sites and depots

Sponsor users are now provided with user interface (UI) enhancements, as well as new options when updating contacts and organizations, and newly introduced notifications.

Enhancements to the sites now allow sponsor users to:

• Restrict a contact or organization without having to transfer or retire existing studies.

• Enter text when selecting a Reason for Change when deleting a contact.

• Add the date of retirement or death when marking an investigator as retired or deceased.

> **Note:**
>
> An investigator cannot be selected in a study once they have been marked as retired or deceased.

• Delete contact and organization addresses if they're not being used at the study level.

• Clear selected filters on the **Contacts** and **Organizations** tabs.

- Update one or all instances of addresses that have been copied from the main primary address when modifying an associated address.

More details can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Impact on notifications

Enhancements to sites also introduces the following notifications:

- **Study/Site has been transferred to a new Contact notification**: This notification is sent when a user transfers a study or site to a new contact.
- **Depot has been reassigned to a new Vendor Depot notification**: This notification is sent when a user reassigns a depot to a new vendor depot.
- **Contact status has been updated notification**: This notification is sent when a user updates the status of a contact at the global level.
- **Organization status has been updated notification**: This notification is sent when a user updates the status of an organization at the global level.

Further details can be found in the *Notifications and Permissions Guide* after the RAE upgrade.

Impact on reports

The **Sites and Depots report** now includes additional details, such as kit and address types.

More information on these reports can be found in the *Reporting Guide* after the RAE upgrade.

Reporting, archives and analytics

- New Lab Normal Range report
  The new Lab Normal Range report provides information about all the lab normal ranges entered for your studies.

- Report data gets automatically purged
  Reports are now automatically purged to optimize report storage.

- Enhancements to Oracle CRF Submit archives and reports

- Control authoring access in Oracle Clinical One Analytics
  New global roles are available to control authoring and read-only access to Oracle Clinical One Analytics. With these roles, you can control which users can create or edit reports and dashboards and which users are restricted to only viewing and running existing reports.

- Audit Trail dashboard in Oracle Clinical One Analytics
  Sponsor users can now use the Audit Trail Dashboard, available in Oracle Clinical One Analytics to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.

- Support for queries on visit dates in Oracle Clinical One Analytics
  Data related to queries raised on visit dates now populate in Oracle Clinical One Analytics in all applicable datasets.

- Oracle Clinical One Analytics supports replacing a subject number with a randomization number
  Replacing a subject number with a randomization number in an Oracle Clinical One Platform study is now supported in Oracle Clinical One Analytics datasets.

New Lab Normal Range report

The new Lab Normal Range report provides information about all the lab normal ranges entered for your studies.

By having all the existing data now available in one place within the **Lab Normal Range** report, you can regularly can verify the accuracy and completeness of the normal ranges entered for labs in the study, troubleshoot and minimize errors at a specific lab and across all labs in a study.

Before you work with this feature

- Users who are assigned to a study role that includes the *Add and Update Lab Normal Ranges* permission or are assigned to the View Only Unblinded Support template study role can run this report.

- As a user administrator, you can also assign the new permission *Run the Lab Normal Range Report* to a role, so that the user assigned to that role can generate the report.

- Users assigned to a study role that includes the *Run the Lab Normal Range Report* permission, who are not assigned the *Add and Update Lab Normal Ranges* permission, can only view normal ranges for the sites for which they have permission.

What data does this report show?

In a study, on the **Reports & Archives** page you will see a new report called **Lab Normal Range**.

When you select that report, you can use the **Settings** sidebar on the right to filter the data included in your report. Or you can schedule the report to run at a specific date and time.

This report will be available for new and existing studies as soon as the upgrade completes. The report contains the normal ranges for each lab, including:

- Low and high lab ranges

- Normal test results

- Fasting

- Effective date

- Entered, or last updated date information

- User identification details that performed the actions (first and last updated information)

- Action performed (created, modified or deleted)

- Associated sites to the lab

- Lab unit, test name, and ID

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

Report data gets automatically purged

Reports are now automatically purged to optimize report storage.

Details for all users

Starting with this release, each time you generate a standard report (study or global level) in any study mode, a system check runs to see if any previously generated reports are 120 days old or older; if found, the system automatically deletes them. This optimizes report storage and ensures smooth study export during the decommissioning process.

> ⚠️ **Caution:**
>
> The system check will be active after the Oracle Clinical One Platform Production upgrade is complete. The first time a user generates a report, the check will run, and reports will be purged.

Details for sponsor users

The system check includes the **Drug Order** and **Drug Reconciliation** forms, considered reports in Oracle Clinical One Platform studies. They are also automatically deleted when they are 120 days old.

Applicable shipment details for an auto-purged form are still available on the Shipment Details side panel in the UI (User Interface), even after the system deletes a form.

> ✏️ **Note:**
>
> You should not resend an auto-purged drug order or drug reconciliation form, as it will be resent to the depot, potentially causing confusion. This may trigger the depot to send shipments to sites that are not needed.

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

Enhancements to Oracle CRF Submit archives and reports

We've made it easier to locate RTSM data in the PDF output of an Archive

The PDF output for Submission, Archival (site and sponsor), and Custom Archive requests now include a new heading, Subject Randomization History. This was previously called Subject History.

The PDF output includes this section when you set the Advanced Setting, **Include RTSM Data**, to **Yes**.

For more information about this setting, see Available archive types and reports in the *Reporting Guide.*

In-product filters are now available for the Site Confirmation report

The Site Confirmation report now includes in-product filters. Before introducing these filters, site, and sponsor users were required to generate the report for all data, only then being able to filter data directly in the output file, which can be cumbersome for studies with many sites.

A new set of filters is available under the Settings side panel in the user interface, allowing users to apply filters before generating the report.

The new available filters are:

- **Request Name**
- **Request Type**
- **Published Date**
- **Site Name**
- **Confirmed By**
- **Confirmation Date**
- **Confirmation Status**

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

Control authoring access in Oracle Clinical One Analytics

New global roles are available to control authoring and read-only access to Oracle Clinical One Analytics. With these roles, you can control which users can create or edit reports and dashboards and which users are restricted to only viewing and running existing reports.

Details for user administrators and global user managers

The existing study-level permissions to run a specific dataset are still available, but now they provide read-only access to Oracle Clinical One Analytics for a given dataset. These dataset permissions allow a user to view and run existing reports and dashboards, viewing only data related to the given dataset. Without authoring access at the global level, a user cannot modify reports or create new ones.

To have authoring access, a user must be assigned any of the new Analytics global roles. The Analytics global user roles, now available on the Global Settings page in Oracle Clinical One Platform, are:

- *Analytics: Data Visualizer Authoring*: this role lets you create and modify reports and dashboards in the Oracle Clinical One Analytics Data Visualizer interface.
- *Analytics: BI Publisher Authoring*: this role provides access to the Oracle Business Intelligence (BI) Publisher functionality to create or customize pixel-perfect reports.

As a user administrator or global user manager, if you want a study team member to have authoring access to Oracle Clinical One Analytics, you must assign them the appropriate permissions at the study level and the appropriate new global user roles together. For example, if you only assign a user with any study-level dataset permission, like the *Run the Unblinded Kits Dataset* permission, they will only have read-only access to that specific dataset in Oracle Clinical One Analytics. If you assign a user with the *Run the Unblinded Kits Dataset* permission and the *Analytics: Data Visualizer Authoring* global role, they will have the ability to create, view, and update reports and dashboards that use this specific dataset.

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You can find additional information in the *Analytics User Guide* once the Release Assessment Environment (RAE) upgrade completes.

Details for users working with Oracle Clinical One Analytics

Given that not every user with access to Oracle Clinical One Analytics has authoring privileges, the landing page is changing. When you access Oracle Clinical One Analytics from Oracle Clinical One Platform, you are now redirected to the catalog page. On the catalog page, you can find all the reports available to you, and from here, you can open and run any report to work with it.

Browse the *Analytics User Guide* to learn how to navigate through Oracle Clinical One Analytics based on your permissions.

Already working in a live study?

As soon as this release is available, a current Oracle Clinical One Analytics user will only have read-only access. To provide authoring access to a study team user, make sure they are included in Oracle Clinical One Platform as a global user for your organization and that you assign them with the appropriate Analytics global roles.

Audit Trail dashboard in Oracle Clinical One Analytics

Sponsor users can now use the Audit Trail Dashboard, available in Oracle Clinical One Analytics to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.

> **✎ Note:**
>
> Whether you are working in a live study (and are already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle point of contact for more information about Oracle Clinical One Analytics training and mentoring.

With the new Audit Trail dashboard, the auditing process has become more efficient. You can now pick between several reports, each addressing a particular scenario, which makes it easier to obtain precise data for a specific part of the auditing process. To further improve the efficiency of your work, the visualizations available in each of these reports are specifically selected to best illustrate the data. Some visualizations you can also interact with, giving you the option to dynamically adjust them to better suit your needs.

The Audit Trail dashboard comes pre-packaged with a set of options, which facilitate your auditing process. This means you can save time on creating a dashboard from scratch. Nonetheless, you can still customize the Audit Trail dashboard to better meet your needs. You can find additional information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Before you work with this feature

> **✎ Note:**
>
> Even though this dashboard is intended to assist sponsor users, the Audit Trail dashboard is available to any user with the appropriate permissions.

The Audit Trail dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the **Subject Form Items Dataset** before viewing data in a corresponding dashboard.

Access to a dataset is based on the permission assigned in the Oracle Clinical One Platform. To access the Subject Form Items dataset and, consequently, the Audit Trail dashboard, make sure you have the *Run the Subject Form Items Dataset* permission assigned.

> **✎ Note:**
>
> New permissions have been introduced to manage read-only and authoring access to Oracle Clinical One Analytics. You can find additional information in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Details for sponsor users

As a sponsor user, you can have better control of how you view your study's data using the new Audit Trail dashboard. This new dashboard provides insights on data operations that have occurred in Oracle Clinical One Platform, structured around reports including initial data entry, updates to data, or the clearing and verifying of data. You can also track changes in your study's data on a form by form or a subject by subject basis, and adjust the granularity of these reports according to your needs.

Each of the reports features appropriate visualizations for your data. For instance, the volume of data transactions in your study is illustrated using a heat map, while data modifications on a form-by-form basis are represented using a pivot table.

In the new Audit Trail dashboard, you can switch between the following reports:

- Data Operations Summary: provides object-level summaries of all the data operations that have occurred.

- Data Operations Evolution: provides a view of trends in data operations at an item-level over time.

- Data Operations Analysis: provides summary views of data operations, pivoting and grouping them by properties such as **Country**, **Site**, **Role**, **Visit**, and **Form**.

- Data Modification Analysis: identifies the countries, sites, users, subjects, forms, and items that are most frequently modified.

- Form data Modifications Analysis: provides form-level visualizations of the volume of data modifications across a trial.

- Subject Audit Trail Data: consists of a listing table that provides all of the subject data operations that occurred in a study.

You can find additional information regarding this and other dashboards in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade completes.

Support for queries on visit dates in Oracle Clinical One Analytics

Data related to queries raised on visit dates now populate in Oracle Clinical One Analytics in all applicable datasets.

Given that raising queries on visit dates is possible in Oracle Clinical One Platform, you can now view and analyze this data in Oracle Clinical One Analytics. All datasets that include query data now include queries on visit dates, too. With this, you can also visualize the visit date alongside any queries raised against it.

> **Note:**
>
> Queries on visit dates appear assocaited to the form called "Visit Date".

To further support this data, new data elements are now available in the following datasets:

- Query dataset
- Study Design dataset

Similarly, new versions of the applicable Oracle DMW views and updates to the ODM-XML extracts are available to support queries on visit dates.

You can find additional information in the *Analytics User Guide* and the *REST API for Clinical One Platform* guide once the Release Assessment Environment (RAE) upgrade completes.

Oracle Clinical One Analytics supports replacing a subject number with a randomization number

Replacing a subject number with a randomization number in an Oracle Clinical One Platform study is now supported in Oracle Clinical One Analytics datasets.

Details for Oracle Clinical One Analytics users

The setting, **Replace Subject Number with Randomization Number**, was introduced in a previous Oracle Clinical One Platform release. When enabled, the randomization number replaces the subject number throughout the study after randomizing a subject.

More information about this setting is available in the *Sponsor and CRO User Guide* under *Specify study, enrollment, and visit settings*.

This enhancement impacts the following Oracle Clinical One Analytics datasets, starting with this release:

- Blinded Kits dataset
- Blinded Subject Event dataset
- Queries dataset
- Subject dataset
- Subject Form Items dataset
- Subject Forms dataset
- Unblinded Kits dataset
- Unblinded Subject Event dataset

Impact to datasets

A new column, SCREENING_NUMBER, is available in the Subject folder for each dataset.

For a new subject, the values displayed under SUBJECT_NUMBER and SCREENING_NUMBER match after you create a subject, as seen in the table below.

Table 2-2   Example dataset output before randomization

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_ NUMBER	SCREENING_NUMBER
001-001	Screened	*This cell is initially blank*	001-001

If the **Replace Subject Number with Randomization number** setting is enabled and you randomize a subject:

- SUBJECT_NUMBER displays the randomization number.

- PREVIOUS_SUBJECT_NUMBER displays the original subject number.

- SCREENING_NUMBER remains unchanged, as it always displays the original screening number for a subject.

Table 2-3   Example dataset output after randomization, where 123456 is the randomization number

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_ NUMBER	SCREENING_NUMBER
123456	Active	001-001	001-001

If you re-randomize a subject:

- SUBJECT_NUMBER displays the new randomization number.

- PREVIOUS_SUBJECT_NUMBER displays the initial randomization number.

- SCREENING_NUMBER remains unchanged, as it always displays the original screening number for a subject.

Table 2-4   Example dataset output after re randomization, where 789101 is the new randomization number

SUBJECT_NUMBER	SUBJECT_STATE	PREVIOUS_SUBJECT_ NUMBER	SCREENING_NUMBER
789101	Active	123456	001-001

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

Rules management

- Clear values on a form using custom rules
  With the new `clearValue()` helper function you can clear data in a target question for a calculation rule, whether it is a text, number, or choice question.

Clear values on a form using custom rules

With the new `clearValue()` helper function you can clear data in a target question for a calculation rule, whether it is a text, number, or choice question.

With the introduction of the `clearValue()` helper function, rule developers can now clear a form question using a custom calculation rule. This function can only be called as part of the return statement of a calculation rule, which means you can only use this helper function with question types that can be used as the target for a calculated value, such as:

- Text
- Number
- Choice-type controls (drop-down, checkboxes, or radio buttons)

The `clearValue()` helper function allows you to perform a "true clear", which is different from simply removing an item's data and replacing it with an empty string. Data clear is a more complex process that occurs in the backend, and by using this function you are actually returning an indicator to the rule process to start a data clear. When data is cleared, the given item state is as if it has never been answered. With all items in an unanswered state, a form can return to a status of *New*. This is important for site users so they can skip visits whenever necessary or avoid having false incomplete visits on a subject's record.

> **✎ Note:**
>
> Even if you clear a question's data, the whole answer history is preserved. All actions on a question are listed on the Answer & Visit History sidebar and in the audit trail. In there, you can also see which actions result from rule execution.

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

User experience

- Study roles and permissions are now translated
  Study roles with their assigned user permissions and data classifications are now localized when you operate theOracle Clinical One Platform in any of the available languages.

Study roles and permissions are now translated

Study roles with their assigned user permissions and data classifications are now localized when you operate theOracle Clinical One Platform in any of the available languages.

Whenever you set your language preference to a language other than English, you can now see study roles and permissions translated into the selected language. This localization is applicable to every task that involves study roles, permissions, and data classifications. This includes study role management (at the global and study levels), study user management, and reporting.

> **✎ Note:**
>
> While both template and custom study roles information is localized, user-entered data is never translated. This means that study role names and descriptions are only localized for template roles. For custom roles, this data is manually entered and always displayed as it was originally entered.

Impact on study role management

Study role management refers to the process of viewing, creating, and modifying study roles and their assigned data classifications. This can be either at the global level from the Global Settings page or at the study level from the study's settings. In both cases, if you are working on the **Study Roles** tab, the following UI areas display study role details, permissions, and data classification information, localized according to your language preference settings:

• On the main screen of the **Study Roles** tab, you can see the list of available study roles. The names for the template study roles are localized, as well as the role type (*Design*, *Sponsor*, or *Site*) for all study roles (template and custom).

• For each study role, upon selection, you can view the study role's localized permissions in the Permissions section on the sidebar. From this section, you can also view the study role's description, which gets localized but only for template study roles.

• Similarly, upon selection, you can view the localized data classifications assigned for each study role on the Data Classifications section of the sidebar.

• When you create a study role, in the Create Study Role dialog, you get localized options for the **Type** drop-down, and localized permissions to select and assign to the study role being created.

Additionally, the Study Role Name field now supports international characters, in the same way they were supported in the description field. With this, you can create or update custom study roles with a preferred name and language.

Impact on study user management

When working on the **Users** tab within a study's settings, the following UI areas display localized study roles, according to your language preference settings:

• Upon selection, you can view the assigned study roles for each study user in the corresponding section on the sidebar.

• When you create or edit a user, in the Create User or Edit User dialogs respectively, you get localized options for the template study roles on the **Study Roles** drop-downs available for each mode.

Impact on reports

Similarly, template study roles, study role types, and permissions included in reports are also localized. These reports include:

• User Assignment report

• User Assignment Across Studies report (global level)

• Study Roles Report by Study (global level)

• Global Study Roles Report (global level)

3
Fixed issues

All users

Users logged out while actively working in a study

Users no longer experience inactivity time-out issues while actively working in a study. Previously, users received inactivity timeout messages and were forcefully logged out when the defined inactivity time had not been reached.

(Issue **35900433**)

Facilities, settings, and user management

Only the first 20 sites are displayed on the Sites & Labs tab

For any study mode, if your study contains more than 20 sites, you can now view all sites on the Sites & Labs tab. Previously, if your study contained more than 20 studies, not all of them may have been visible in the UI, although you could still search for them.

(Issue **36484968**)

Filtering by a query creator's name isn't preserved

On the Query List page, when you filter queries by their creator's name and navigate to other sections of the Query List page, the filter you previously configured is preserved. Previously, the filter would get deselected once you viewed a specific query's details and then navigated back to the main page of the Query List.

(Issue **36836143**)

A study version is not deselected for all sites displayed in the UI

On the Sites & Labs tab, when you remove or update the study version associated with sites from the **Study Version** drop-down, your update is applied to all sites in your study, as expected.

(Issue **36730703**)

A source data verification checkbox appears for forms and questions when it should not

Source Data Verification (SDV) checkboxes no longer appear next to all forms and questions when you select **No** for the Source Data Verification setting, **Allow SDV Overrides**. Instead, checkboxes only appear next to questions that require SDV based on study settings.

For more information about the setting, see *Understanding source data verification* in the *Sponsor and CRO User Guide*.

Retracted recommended action:

1. Go to Study Settings and select the **Source Data Verification** tab.
2. Set **Allow SDV Overrides** to **Yes**.

(Issue **36766556**)

Unable to create new users using the bulk upload process when user names contain an underscore

Underscores are now permitted in user names when you create Oracle Life Sciences single sign-on (SSO) accounts in Oracle Life Sciences IAMS using the bulk upload process.

For more information about the template and the process, see *Manage Oracle Life Sciences single sign-ons in bulk* in the *Add Users Guide*.

(Issue **36676631**)

Forms, visits, and rules

Improved performance for Advanced Study Versioning (ASV) updates

When you apply changes to multiple forms through Advanced Study Versioning (ASV), you will notice an improvement in the performance of those updated forms. Previously, the system may have been slower when data was collected through forms that were modified or added through an ASV update.

(Issue **36771040**)

Oracle Clinical One Analytics

The Blinded Kits dataset does not include blinded kit records (former known issue)

The Blinded Kits dataset, used to analyze and visualize supply data, now includes details for both blinded and unblinded kit types. Previously, this dataset only displayed data for unblinded kits.

Retracted recommended action: None

(Issue **36131614**)

Randomization and kits

Kit status options aren't the same for individual kits and kit types

On the Study Inventory tab, when you alternate between selecting a specific kit type and selecting an individual kit of a specific type, you now see the same kit status options in the **Status** drop-down, on the **Kit Settings** sidebar. Previously, when you selected a type of kits (of the same status) and then selected a specific kit from that kit type, you may have noticed that the displayed statuses were different as you navigated from selecting a kit type to selecting an individual kit.

(Issue **36944615**)

Randomization lists are not automatically associated with a study version when moved from Draft to Test

When you move a study version from the Draft container to the Test container, randomization lists remain associated with it. Previously, they were not, and users encountered issues when attempting to associate a list manually after the move.

(Issue **36127185**)

The predictive resupply strategy only considers one-cycle visits for a branch defined with unlimited cycles

A predictive resupply strategy now considers all cyclic visits when you define a branch with unlimited cycles in designer. Previously, predictive resupply only considered the next cyclic visit instance.

(Issue **35476474**)

Reports, archives, extracts, and notifications

The Subject Data Extract fails to generate

The Subject Data Extract now generates successfully when generated by a blinded user, allowing blinded data to be extracted for review outside the system.

(Issue **37008259**)

No line breaks in the Life Sciences Learn Training Report

The CSV version of the Life Sciences Learn Training Report now contains proper line breaks between each record, ensuring that you can properly view your learning data.

(Issue **36442280**)

Some users might not be able to generate the Subject Visits (Unblinded) report

As long as you have the appropriate permission (*Run the Unblinded Subject Visit Schedule Report*), you can successfully generate the Subject Visits (Unblinded) report. Previously, running this report may have resulted in a failure due to an API issue.

(Issue **35528180**)

ORACLE

Some reports won't generate successfully for certain custom sponsor study roles

Users assigned to a custom study role that includes either the *View Sites* or *View Depots* permission can now successfully generate reports. Previously, report generation would fail if the study role did not also include either the *Create and Manage Sites* or *Create and Manage Depots* permissions.

Retracted recommended action: Update the custom study role by adding *Create and Manage Sites* or *Create and Manage Depots*, depending on which reports you need to generate.

Impacted reports:

- Subject Queries report
- Subject Events report
- Subject Visits (Blinded) report
- Subject Enrollment report
- Subject Data report
- Kit Chain of Custody (Blinded)
- Kit Inventory (Blinded) report
- Randomization List (Blinded) report

(Issue **36741692**)

Oracle CRF Submit Archives Settings, configured for Testing Mode, are incorrectly applied to Production Mode

The email notification settings initially defined under Testing Mode (on the Study Settings—Archives Settings tab) are no longer applied to Production Mode.

> ✏️ **Note:**
>
> For more information about Archives Settings, see Email and in-application notifications.

(Issue **35987053**)

Oracle CRF Submit Archives Blank Form PDF displays an incorrect question option

The Blank Form PDF displays the correct options associated with each question.

The issue occurred because two questions on different forms were designed with the same refname (SAS Label) value. This led to a conflict when Oracle CRF Submit pulled the questions into the archive, as it could not determine the correct options due to the duplicate question refnames. As a result, options associated with the other question were displayed.

(Issue **36395284**)

Oracle CRF Submit Archives display the incorrect form status for the Date of Visit form

After clearing all data on forms in a dynamic visit and untriggering the dynamic visit, the correct form status, Not Started, displays instead of Completed in Oracle CRF Submit archives for the Date of Visit form.

(Issue **36393008**)

The Oracle CRF Submit Kit Chain of Custody report Table of Contents is empty

When you generate the Kit Chain of Custody (Blinded) report on the Archives tab, the Table of Contents (TOC) includes the expected details instead of being blank.

(Issue **36380339**)

Oracle CRF Submit Archives status shows Created when, in fact, they fail due to exceeding the storage server limit

When you generate any Oracle CRF Submit Archive, and the request exceeds the storage server limit, the system presents you with the failure message, Failed Out of storage.

Previously, the status in the Download Archives side panel incorrectly indicated it was generated successfully by displaying the status Created.

> **Note:**
>
> In a previous release, the storage server allocation per customer was increased from 100 GB to 1000 GB to minimize issues with storage server errors.

Retracted recommended action: Manually delete old archives to free up space on the storage server, then regenerate the failed request.

(Issue **36110325**)

The Oracle CRF Submit Storage limit has exceeded notification is being sent every 30 Minutes

The **Storage limit has exceeded** notification, which is used to notify sponsor users when a request generated for a study exceeds the allocated storage server limit for a tenant, is no longer sent every 30 minutes when the email list exceeds 255 characters, and the notification status is successfully updated to *Processed*.

For more information about Oracle CRF Submit notifications, see *Email and in-application notifications* in the *Reporting Guide*.

(Issue **36744636**)

The Kit Chain of Custody (Blinded) report contains empty rows

The Kit Chain of Custody (Blinded) report output file no longer contains additional empty rows when you select **All** under the **Location** filter. This occurred because some sites (Locations) included in the report had no kit-related data entered. The report now ignores these sites (Locations) when generating.

> **Note:**
>
> This issue concerns the Kit Chain of Custody (Blinded) report, available under the **Archives tab** after clicking **Reports & Archives**.

Retracted recommended action: Generate the report by selecting only those sites (Locations) with kit-related data.

(Issue **36367831**)

Site users and subject data

The status of Queries closed in an unscheduled visit are not reflected in the Answer & Visit History side panel

The Answer & Visit History side panel now displays the status Closed for queries closed on the All Subjects page and at the form level (for unscheduled visits).

Previously, the status was displayed correctly in other areas of the user interface and in the Subject Queries report, but was not reflected in the side panel. An incorrect data element ID in the database caused this issue.

(Issue **36847101**)

Data does not save when using the right-click-paste function of a mouse

Data successfully saves when you use a mouse's right-click-paste function.

Retracted recommended action: Use Ctrl + V to paste the text into the text field.

(Issue **36455509**)

Users are unable to skip a visit after clearing all data

The visit status gets updated to New, allowing users to skip the visit. The issue occurred because the visit's status remained as In Progress after clearing the Visit Date field, which triggered rules to clear all other visit data.

Retracted recommended action:

1. Go to the All Subjects page and navigate to the visit that cannot be skipped.

2. Answer any question in the visit and save, but do not answer a question that triggers rules to populate other questions.

3. Select the **Clear** option from the menu to remove the data entered in step 2, then save. **Result:** The visit status gets recalculated to NEW, allowing you to skip it.

(Issue **36459552**)

Visit Data Verification forces users back to the All Subjects page

Selecting the **Ready to Verify** or **Verified** filters under the **All reviews** drop-down on the All Subjects page, followed by clicking **Verify Visit Data** on the subject visit details page, no longer results in undesirable behaviors such as infinite loops between the subject visit details page and the All Subjects page.

Retracted recommended action: Do not set the **Ready to Verify** or **Verified** filters on the All Subjects page.

(Issue **36129949**)

4

Rest API updates

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

Permissions

- The *ec-designer-ors-svc* permission has been added to access some APIs of the Designer category.

Services updates

The following new service has been added:

- Designer ORS

The following services are updated:

- Data Action
- Data Capture
- Data Hub
- Data Integration
- Designer
- Designer EDC
- Randomization and Supplies
- Reporting
- Sites and Depots

Designer ORS

> **✐ Note:**
>
> Designer ORS endpoints are listed under the Designer category.

Change	Endpoint
New	• `POST` /v10.0/studies/{studyId}/versions/{version}/kits
	• `GET` /v10.0/studies/{studyId}/versions/{version}/kits
	• `GET` /v10.0/studies/{studyId}/versions/{version}/kits/{kitId}
	• `PUT` /v10.0/studies/{studyId}/versions/{version}/kits/{kitId}
	• `DELETE` /v10.0/studies/{studyId}/versions/{version}/kits/{kitId}
	• `GET` /v6.0/studies/{studyId}/kits

Data Action

Change	Endpoint
New	• POST /v1.0/studies/{studyId}/{mode}/subjects/visits/lock

Data Capture

Change	Endpoint
New	• GET /v1/studies/{studyId}/{mode}/subjects/{subjectId}/{studyVersion}/demographicstatus • GET /v7.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements

Data Hub

Change	Endpoint
New	• POST /v2.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits • POST /v4.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • POST /v5.0/tenant/{tenantId}/studies/{studyId}/dataCollection • GET /v6.0/studies/{studyId}/{mode}/odm/metadata • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v7.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisitsPOST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits/formItems • POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v9.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

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

Designer

Change	Endpoint
New	• POST /v2.0/studies/{studyId}/versions/{version}/forms/copyForms

Designer EDC

> **Note:**
>
> Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	• `POST` /v1.0/studies/{studyId}/visitsforms/actionitems

Randomization and Supplies

Change	Endpoint
New	• `PUT` /v1.0/studies/{studyId}/{mode}/nsinventory
	• `POST` /v1.0/studies/{studyId}/{mode}/nsinventory/audit
	• `GET` /v1.0/studies/{studyId}/{mode}/nsinventory/kit-types/{kitTypeId}/kits
	• `POST` /v1.0/studies/{studyId}/{mode}/nsinventory/lots/{lotId}
	• `GET` /v1.0/studies/{studyId}/{mode}/nsinventory/lots/{lotId}/quantity
	• `PUT` /v1.0/studies/{studyId}/{mode}/nsinventory/{nsinventoryId}
	• `GET` /v1.0/studies/{studyId}/{mode}/nsinventorystatuses/allowed/{fromInventoryStatusId}
	• `GET` /v1.0/studies/{studyId}/{mode}/orders-nsinventory
	• `POST` /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/replaceRand
	• `GET` /v10.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	• `GET` /v16.0/studies/{studyId}/{mode}/visits/subjectvisit
	• `GET` /v2.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits
	• `PUT` /v2.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits
	• `GET` /v2.0/studies/{studyId}/{mode}/events/kitreplacement/{eventId}
	• `GET` /v2.0/studies/{studyId}/{mode}/orders-inventory/audit
	• `POST` /v2.0/studies/{studyId}/{mode}/reports/blinded-titration-summary
	• `POST` /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits
	• `POST` /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/receive-quarantined
	• `POST` /v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/removeKits
	• `GET` /v2.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/unblinded-disp-history
	• `GET` /v3.0/studies/{studyId}/{mode}/events/codebreak/{eventId}
	• `POST` /v3.0/studies/{studyId}/{mode}/shipments/{shipmentId}/received
	• `POST` /v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codebreak
	• `POST` /v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/codeview
	• `GET` /v4.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits
	• `GET` /v4.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits
	• `POST` /v4.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits
	• `POST` /v5.0/studies/{studyId}/{mode}/reports/subjects
	• `GET` /v5.0/studies/{studyId}/{mode}/shipments/{shipmentId}/kits
	• `PUT` /v5.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits
	• `GET` /v5.0/studies/{studyId}/{mode}/unblinded-disp-history
	• `GET` /v7.0/studies/{studyId}/{mode}/inventory/kit-types
	• `GET` /v8.0/studies/{studyId}/{mode}/orders
	• `GET` /v8.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• `GET` /v8.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits

Change	Endpoint
Deprecated	• GET /v1.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	• GET /v1.0/studies/{studyId}/{mode}/inventory/kitDetailsPOST /v1.0/studies/{studyId}/{mode}/inventory/kits/audit
	• GET /v1.0/studies/{studyId}/{mode}/orders
	• GET /v1.0/studies/{studyId}/{mode}/orders-inventory/audit
	• GET /v1.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• POST /v10.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v10.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v11.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v11.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v12.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v12.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v13.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v13.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v15.0/studies/{studyId}/{mode}/visits/subjectvisit
	• POST /v16.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v2.0/studies/{studyId}/{mode}/inventory/kit-types
	• GET /v2.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	• POST /v2.0/studies/{studyId}/{mode}/inventory/kits/audit
	• GET /v2.0/studies/{studyId}/{mode}/orders
	• GET /v2.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• GET /v3.0/studies/{studyId}/{mode}/inventory/kit-types
	• GET /v3.0/studies/{studyId}/{mode}/orders
	• GET /v3.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• GET /v4.0/studies/{studyId}/{mode}/inventory/kit-types
	• GET /v4.0/studies/{studyId}/{mode}/orders
	• GET /v4.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• GET /v5.0/studies/{studyId}/{mode}/inventory/kit-types
	• GET /v5.0/studies/{studyId}/{mode}/orders
	• GET /v5.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• GET /v6.0/studies/{studyId}/{mode}/orders
	• GET /v6.0/studies/{studyId}/{mode}/orders/{shipmentId}
	• GET /v6.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	• GET /v7.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	• GET /v8.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	• POST /v9.0/studies/{studyId}/{mode}/visits/subjectvisit
	• GET /v9.0/studies/{studyId}/{mode}/visits/subjectvisit

Reporting

Change	Endpoint
Deleted	• `GET` /v1.0/reportmetadata/downloadList
	• `GET` /v1.0/reportmetadata/reportId/{id}
	• `GET` /v1.0/reports/download
	• `POST` /v1.0/reports/page
	• `GET` /v1.0/studies/{studyId}/{mode}/reportmetadata
	• `GET` /v1.0/studies/{studyId}/{mode}/reportmetadata/reportId/{id}
	• `POST` /v1.0/studies/{studyId}/{mode}/reports
	• `DELETE` /v1.0/studies/{studyId}/{mode}/reports
	• `GET` /v1.0/studies/{studyId}/{mode}/reports/download
	• `POST` /v2.0/reports/page
	• `GET` /v2.0/studies/{studyId}/{mode}/reports/download

Sites and Depots

Change	Endpoint
New	• `POST` /v1.0/studies/{studyId}/{mode}/labs/{labId}/labnormals/bulkLookUp
	• `GET` /v2.0/contacts
	• `GET` /v2.0/organizations
	• `GET` /v2.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}
	• `GET` /v3.0/studies/{studyId}/{mode}/labs

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.

Oracle Life Sciences Data Management Workbench

- Data specific to non-serialized inventory is not currently supported in Oracle DMW. For more information on the new feature, see Distribute non-serialized inventory.

- Questions with the new auto-lock rule are not currently supported in Oracle DMW. Questions which have self-locked still behave as regular locked items, but this is not reflected in Oracle DMW. For more information on the new feature, see Design questions with an auto-lock.

- While now supported in Oracle Clinical One Analytics, queries created to validate the Visit Date are not available in Oracle DMW. For more information, see Support for queries on visit dates in Oracle Clinical One Analytics.

- For Oracle DMW, the following details apply when a subject number is replaced by a randomization number:

    – If the **Replace Subject Number with Randomization number** setting is enabled and a subject is randomized, clinical data extracts loaded into Oracle DMW display the randomization number as the subject number. A subject's initial number, assigned during their screening in Oracle Clinical One Platform, is always displayed in the new SCREENING_NUMBER column. For more information about this behavior, see Oracle Clinical One Analytics supports replacing a subject number with a randomization number.

    – This update occurs for both new and pre-existing clinical data extract records, with existing records being updated with a new DHTIMESTAMP value to reflect this subject number change. The update to the DHTIMESTAMP value for all existing clinical data records can be viewed in other DHVW views loaded into Oracle DMW aside from clinical data extracts. Use the DHVW_SUBJECTS_DATASET_V extract view to inspect a subject's number change.

Oracle Clinical One Analytics also known as Data Hub

- While the auto-lock validation rule type is supported in Oracle Clinical One Analytics, with data related to it being displayed in the Study Design dataset, data on locked questions, forms, or visits is not yet supported in any datasets. This will be available in a future release. For more information on the new feature, see Design questions with an auto-lock.

Oracle Clinical One Digital Gateway configured integrations

- The following are the only Oracle Clinical One Digital Gateway integrations which support non-serialized kits:

    – Oracle Clinical One Platform and Almac Global Depot Network.

    – Oracle Clinical One Platform and Oracle InForm.

    – Oracle Clinical One Platform and Medidata Rave integrations.

For more information on the integrations which support this feature, see Support for non-serialized inventory for integrations. Alternatively, you can reach out to your Oracle point of contact.

6

Chat in real time with Oracle Support

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

1. On the homepage, click **Chat & Help**.

2. The following options are made available:

Option	Description
Urgent Issue?	Opens the Oracle Life Sciences Support Cloud portal where you can submit a Service Request (SR).
Chat with Customer Support	Opens a new chat window and adds you to the queue to engage with a support agent in real time.
Call Technical Support	Opens the Life Sciences Support page where you can find out the details about where to call depending on your location.
Check the Knowledge Base	Opens FAQs and other documentation from the Oracle Life Sciences Support Cloud Knowledge Base.

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

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

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

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

5. Once a Support agent is available, type your message in the **Type a message** field, then click **Send**.

6. To attach a file and send it to the Support agent, use the **Attach icon** ( ).

7. To disconnect yourself from the chat and end it, click **End Chat** in the upper-left corner of the dialog.

8. Once disconected, click **Close** in the upper-left corner to close the chat dialog.

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

7

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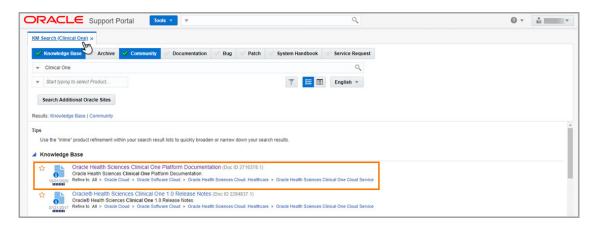
To make sure you get the right access in MOS, follow these two steps in the order listed below:

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 7-1   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*.

8

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

Subscribe to system maintenance page and status notifications

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

The maintenance page includes a link to the Oracle Clinical One Platform status page which provides status information for the Oracle Clinical One Platform as well as the Oracle Clinical One Digital Gateway, Oracle Clinical One Analytics, Oracle CRF Submit, and other Oracle Clinical One Platform systems and services.

The status page also includes information for the Oracle Clinical One Platform Release Assessment Environment. For more information about this environment, see the Release Assessment Environment Guide

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

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

   You can also access the status page here Clinical One Status Page.

2. In the upper right corner, click **Subscribe to updates**.

3. Select your country, enter a valid email address, then click **Subscribe to updates**.

   A Subscription Successful message appears, and a confirmation email is sent.

4. Locate the Confirm your subscription email and click **Confirm Subscription**.

   The status page opens displaying the message Thank You! Your email subscription has been confirmed.

5. The status page includes options to cancel the subscription and update your notification preferences.

   If you cancel your subscription for any reason, you can follow the steps above to subscribe again.

6. (Optional) Make notification updates by removing check marks where applicable, then click **Update Subscription**.

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

9
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.

10

Browser requirements

System requirements

Computer	Internet browser	Resolution
Laptop or desktop	**Google Chrome**: • Version 119.0.6045.124 and later are supported. • **Oracle Clinical One Platform 24.2** was tested using version 127.0.6533.73 (Official Build) (64-bit). **Microsoft Edge:** • Version 119.0.2151.58 and later are supported. • **Oracle Clinical One Platform 24.2** was tested using version 126.0.2592.113 (Official build) (64-bit).	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers

11

About the Product Verification Pack (PVP)

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

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

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

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

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

12

Product Verification Pack (PVP) updates

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

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

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

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

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

22.4 release updates

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

A new Master Verification Plan is introduced

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

Updates to the ReadMe.txt file

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

Updates in the Requirements document folder

Oracle is providing the following updates to this folder:

- Updated the **Verification Summary Report** (previously the Overview document). This document will detail the testing and retesting, results achieved, objective evidence and failures for the Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release.

- Updated the **Requirements Document**. Previously, a cumulative requirements document was generated and supplied in the PVP. With the 22.4 release, only those requirements tested for the current release will be provided in the PVP. The document will be smaller and more manageable for our regulated customers to review. The cumulative requirements document will still be available, on request, as a standalone static document which will have all release information through the current version.

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

Updates in the Test Scenario folders

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

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

The Secure Sites location will also include a Supporting Documentation folder

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

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

24.2 release updates 12-3

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

Updates in the Requirements folder

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

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

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

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Download the PVP from MOS (on-prem customers)

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

- If you have access and work with other Oracle on-premise applications, then you more than likely already have a MOS account and can successfully download the PVP from My Oracle Support (MOS). You can also choose to download the PVP from the Secure Sites website.

- If you have access and work with Oracle Clinical One Platform only, then we recommend you download the PVP from Secure Sites. If you want to download the PVP from MOS, your Oracle point of contact performs the required steps for you.

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

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

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

- Step 4. Download the Product Verification Pack (PVP)

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

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

1. If you think you might have a MOS account but aren't sure of your user name or password, follow these steps to retrieve your sign-in details. Typically, you already have a MOS account if:

   - You were identified as the primary contact from your organization for the deployment of Oracle Clinical One Platform when the environment was first provisioned. If you were the primary contact, you received the Welcome letter from Oracle and were provisioned with a My Oracle Support (MOS) account during the onboarding process. or

   - You've ever signed into Support Cloud. The two sites use the same account.

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

   b. Follow the instructions on the page to retrieve your sign-in details.

2. If you don't have a MOS account, follow these steps to get one:

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

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

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

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

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

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

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       *   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)

> **✎ 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.
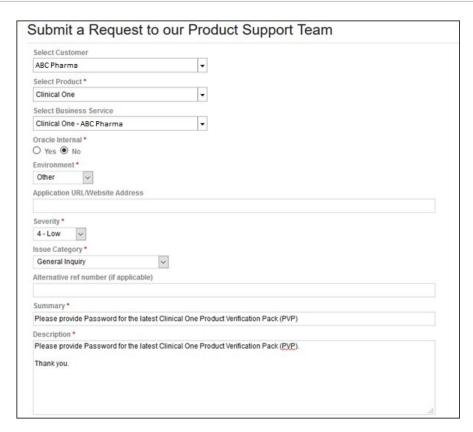
1. Open Support Cloud.

> **💡 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.

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

Step 4. Download the Product Verification Pack (PVP)

The URL for the PVP doesn't change.

1. Navigate to the following URL:

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

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

2. On the right, from the **Release** drop-down, choose the product release for which you need the PVP.

3. Below the drop-down, click **Download**.

4. In the File Download dialog, do the following:

   a. Check the download time for the PVP and make sure you'll be able to leave your computer on for the duration of the download.

   b. Enter the password you obtained from Support and click **Unlock**.

   The PVP downloads.

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

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

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Download the PVP from Secure Sites (all customers)

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

Prerequisites

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

Gain access to the Secure Sites platform

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

1. Verify that the person on your team requiring access to Secure Sites has an Oracle account.
   - If they don't have an Oracle account or you're unsure of whether they have one, you must create an Oracle account them. For step-by-step instructions, see Create your Oracle account.
   - If they already have an Oracle account, then this step is complete.

2. After their Oracle account is set up, send an email to your 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 Oracle Clinical One Platform point of contact) to have a new email generated.

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

Download the PVP from Secure Sites

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

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

To download the full PVP ZIP file:

1. Click **Download** (⬇) to the right of the file or select the checkbox to the left of the file. Once selected, an Actions bar appears above the documents.

2. Click **Download Selected File** (⬇).
   The download process starts. Depending on the bandwidth, this process might take a few minutes.

To download individual files:

1. Select the checxbox of one or multiple files.
   An Actions bar appears above the documents.

2. Click **Download Selected File** (⬇).
   The download process starts and the files will be combined in a ZIP archive file.

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

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

15
Revision history

Date	Part number	Description
07-October-2024	G11332-08	A bug that was incorrectly documented under "Fixed Issues, Randomization and Kits" was removed.
27-September-2024	G11332-07	Included a new note about a customer's access to the PVP document provided through Secure Sites. For more information, see the **Gain access to the Secure Sites platform** section in the Download the PVP from Secure Sites (all customers) topic.
25-September-2024	G11332-06	Revised the publication and removed the locking subject data entered at site permission. For more information, see the Design questions with an auto-lock.
19-September-2024	G11332-05	Performed the following updates: • Documented new details about the impact of the Replace Subject Number with Randomization number setting on Oracle DMW integrations. See Release impact for other applications. • Included a note indicating that the patches we apply on top of this release do not include new features. See the Patch log. • Highlighted the note about the PVP being made available for a major or minor release only. See About the Product Verification Pack (PVP). • Specified that Oracle releases the latest version of the Oracle Clinical One Platform into a Release Assessment Environment 4 weeks prior to the Production upgrade. See Subscribe to Life Sciences Support release announcements.
18-September-2024	G11332-04	For this release, we fixed one issue related to reports. For more information, see the Patch log.

Date	Part number	Description
02-September-2024	G11332-03	Documented updates to the chapter related to the Product Verification Pack (PVP). For more information, see the following: • 24.2 release updates • About the Product Verification Pack (PVP) Enhancement 35942859, related to locating RTSM data, was moved from Fixed issues to Enhancements to Oracle CRF Submit archives and reports under What's new.
30-August-2024	G11332-02	Re-published the publication due to a system error. No changes were made in the publication for this revision.
30-August-2024	G11332-01	Original version of the document