

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



Release 22.2.1

F56714-06

August 2022

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

ORACLE®

Oracle Health Sciences Clinical One Platform and Oracle Health Sciences Clinical One Digital Gateway
Release Notes, Release 22.2.1

F56714-06

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
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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>.

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 of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> 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 briefly describes the history of small fixes we have applied to the 22.2 release. None of these fixes affect the user work flow or the application's functionality.

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

Table 1-1 Patch log

Release Number	Release Date	Notes
Release 22.2.1	08-August-2022	<p>For this release, we fixed issues related to notifications and data collection.</p> <p>For more information, see:</p> <ul style="list-style-type: none">• Fixed issues for reports, archives, extracts, and notifications to review details for bugs 34307434 and 34399461.• Fixed issues for forms visits, and rules to review details for bug 34287424 and 34314729.• Fixed issues for site users and subject data to review details for bug 34376688. <p>A new enhancement has been added for this release, as well.</p> <p>To learn more, see:</p> <ul style="list-style-type: none">• Hide the visit window projection

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What's new

- [Data collection](#)
- [Randomization and trial management](#)
- [Reporting and analytics](#)
- [Rules management](#)
- [Other enhancements](#)
- [Documentation updates](#)
Learn more about the updates to our documentation.

Data collection

- [Enhanced queries management experience](#)
You can now manage queries directly on the **Queries** sidebar, on the right side of the page.
- [Hide the visit window projection](#)
Sponsor users can now hide the visit window information using the Hide the Visit Window Projection option on the Study Settings page.

Enhanced queries management experience

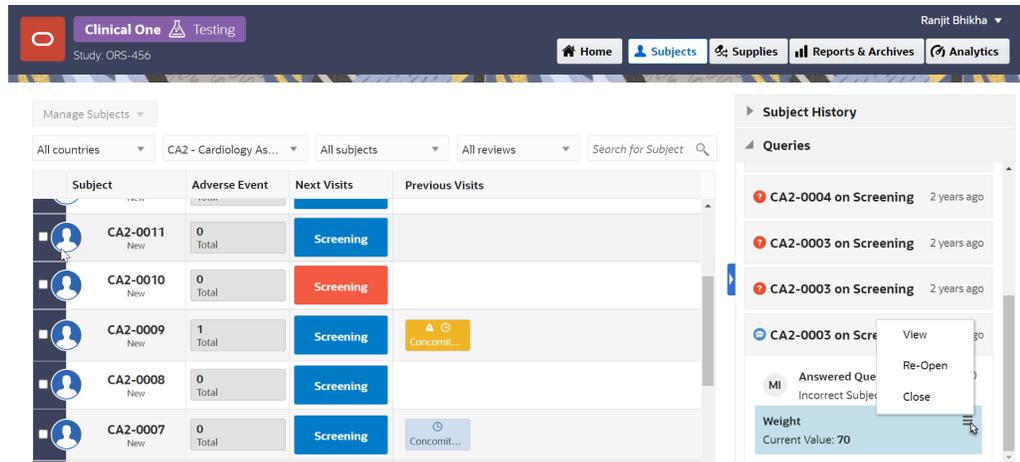
You can now manage queries directly on the **Queries** sidebar, on the right side of the page.

Details for sponsor and site users

Queries are used to question clinical data correctness and to ensure data quality by promoting conversations between sponsor and site users. Previously, queries could only be managed by directly interacting with the question on the form. This could lead to situations where queries became inaccessible through the User Interface (UI), such as when a question is hidden due to a design change or a user's action.

With this new feature, you can now manage queries directly on the **Queries** sidebar. There are several menu options available for each query item. Menu options are displayed depending on your user role and permissions, the type of query, and the status of the query you want to manage. With each query, you may be able to perform the following actions:

- **View** a query in a visit form.
- **Answer** an opened query.
- **Open** a candidate query.
- **Close** a query.
- **Re-Open** an answered query.
- **Delete** a candidate query.



Already working in a live study?

As soon as this release is available, you can use this menu to manage any new and existing queries on the sidebar. Details on how to manage queries from the **Queries** sidebar will be featured in the *Sponsor and CRO User Guide* and the *Site User Guide*.

Hide the visit window projection

Sponsor users can now hide the visit window information using the Hide the Visit Window Projection option on the Study Settings page.

Currently, projected visit dates and time frames for upcoming scheduled visits are displayed on the Subjects page. Now, the new **Hide the Visit Window Projection** setting allows sponsor users to hide the time frame for scheduled visits for an active subject.

Details for sponsor users

A new field, **Hide the Visit Window Projection**, has been added to the Study Settings page. Selecting **Yes** for the **Hide the Visit Window Projection** configuration hides the date and date range for scheduled visits under the visit title. If **No** is selected, the system displays the projected visit date, or date range, for upcoming scheduled visits.

This configuration can be updated during the study conduct period, and there is no restriction to edit it once a study version is promoted to the Approved container.

Already working in a live study?

Once the upgrade for this release is complete, the **Hide the Visit Window Projection** configuration will be available for all studies. This setting will be set to **No** by default for all existing and newly created studies. For step-by-step instructions on how to update this setting, see Specify study, enrollment, and visits settings.

Randomization and trial management

- [Notification and report enhancements for shipment receipts](#)
Sponsor users can now get notified about individual kits and shipments being quarantined and released.

- [Organize kits by block numbers](#)
Now, when they define their kit lists, clinical supply managers can now organize kits by block numbers.

Notification and report enhancements for shipment receipts

Sponsor users can now get notified about individual kits and shipments being quarantined and released.

Details for user administrators and global user managers

Users assigned the *Receive the Quarantined Shipment Notification* permission will be able to receive both the Shipment Quarantined and Kits Quarantined notifications, while users assigned the *Receive the Released from Quarantine Notification* permission will be able to receive both the Shipment Released from Quarantine and Kits Released from Quarantine notifications.



Note:

These permissions are differentiated between site and depot users with corresponding notifications.

About the new shipment receipt notifications

The Shipment Quarantined and Shipment Released from Quarantined notifications provide details regarding the:

- Study Name and Study ID
- Study Mode
- Shipment ID
- Origin and Origin ID
- Destination and Destination ID
- Shipping Address and Date Performed
- User who performed the status update

The Kits Quarantined and Kits Released from Quarantine notifications include details identical to the Shipment Quarantined and Shipment Released from Quarantine notifications, but features additional information on the number of kits quarantined and their IDs.

Additional information on these notifications and permissions will be featured in the *Notifications and Permissions Guide*.

Details for other sponsor users

The Shipment Order Summary report now includes a new column indicating the shipments temperature monitor status with one of the following displayed in the column:

- **Yes:** Indicates a temperature monitor went off
- **No:** Indicates a temperature monitor did not go off
- **Missing:** Indicates there was no temperature monitor present in the shipment



Note:

If the study's supply settings are configured to disallow temperature excursions, data in the column displays N/A.

The shipment status column displays a value of Quarantined if the entire shipment has been quarantined and Received if the shipment has been partially quarantined.

More information will be featured in the Shipment Order Summary report.

Already working in a live study?

Once the upgrade for this release is complete, users assigned the *Receive the Quarantined Shipment Notification* and *Receive the Shipment Released from Quarantine Notification* permissions will be able to receive the associated notifications, and temperature monitor status will be visible in the Shipment Order Summary report.

Organize kits by block numbers

Now, when they define their kit lists, clinical supply managers can now organize kits by block numbers.

Organizing kits by block numbers allows you to protect your kits that are prone to breakage and need to be packaged together. With the new option for block numbers, you can meet the distribution vendors' needs by sending kit data as a whole unit, not for each individual kit.

Details for clinical supply managers

Here's what's new for you:

- On the Kits tab, when you upload a kit list, you can now map the Block Number imported header to the appropriate value, whether it's Don't Import or Block Number.
- On the Shipments tab, when you create a shipment, a kit type may describe its block size. For example, a placebo kit type may indicate that the block size for this kit type is 4 units.
- When you create a new shipment, if you add a number of kits that is lower than its block size, the system adds additional kits to complete the block. For example, if you include 2 placebo kits in a shipment, the system includes 2 additional kits to complete the block of 4 units.
- On the Study Inventory page, there is a new column called Block. On this column, the system indicates how many units are included in a block for each kit.

Already working in a live study?

As soon as the upgrade is complete for this release, you can begin uploading kit lists and organize your kits by block numbers. More information on how to set up block numbers when uploading a kit list can be found in the *Sponsor and CRO User Guide*.

Reporting and analytics

- [Future and skipped visits and forms data included in Oracle Clinical One Analytics datasets](#)

Data of not-yet-started (future) visits and forms is now included in Oracle Clinical One Analytics datasets, allowing data managers to view future and skipped visits alongside completed visits, as well as to perform analysis of not-yet-started visits and data to be collected in a subject's journey.

Future and skipped visits and forms data included in Oracle Clinical One Analytics datasets

Data of not-yet-started (future) visits and forms is now included in Oracle Clinical One Analytics datasets, allowing data managers to view future and skipped visits alongside completed visits, as well as to perform analysis of not-yet-started visits and data to be collected in a subject's journey.

Data managers can now build custom reports including not-yet-started visits and forms data. This includes skipped and scheduled future visits, all forms attached to them, and any other not-started form. With this enhancement you are now able to:

- Build a report that displays all skipped visits for a subject.
- Build a report to view all missing forms and pending data to be collected for a subject.
- Project how much data will be collected at a site over a fixed period of time.
- Create a schedule of when forms should be started for a subject.



Note:

Dynamic visits and forms, as well as cycle visits, are not included until an event happens that causes the visit or form creation as part of a subject's schedule. This may cause variations between any projected data and real data.

The following datasets have been updated to include missing visits data:

- Blinded Subject Events Data Set
- Unblinded Subject Event Data Set
- Subject Forms Dataset

This enhancement represents the addition of not-yet-started visits data to the data already available through each of these datasets. No new folders or data elements were added. Also, all previous reports and visualizations you have created using these datasets will still be available and possible to recreate and maintain. To differentiate between data associated with completed visits and data associated with future or skipped visits, you can filter visits by status. For more information, see the *Analytics User Guide*.

Rules management

- [Helper functions for two-section forms](#)
Additional helper functions have been created to support rules on two-section forms.

Helper functions for two-section forms

Additional helper functions have been created to support rules on two-section forms.

Details for rule designers

Rule designers can use new helper functions to simplify their workflow when working in two-section forms. The following helper functions have been created to support custom rules on repeating sections of two-section forms:

- `findMinIn2SForms()`
- `findMaxIn2SForms()`
- `findMinDateIn2SForm()`
- `findMaxDateIn2SForm()`
- `findMatching2SFormWithinRange()`
- `findDuplicate2SFormWithinRange()`
- `find2SFormInstance()`
- `getMatching2SFormsCount()`

These helper functions mirror the functionality of existing helper functions for repeating forms.

Already working in a live study?

As soon as this release is available, these helper functions can be used in any existing or newly created rules and two-section forms. More information about new and existing helper functions will be featured in the Two section form functions section in the *Rules Developer Guide*.

Other enhancements

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. To subscribe to status notifications, see System maintenance page and status notifications.

User study access expires at the end of the day for the date defined

The value you enter in the To field of an Effective Date Range, either populated using **Create/Assign User** through the user interface or if included in the User Upload Template, now allows users to access a study through the end of the day for the date defined. For example, if the date 11-May has been defined as the end date, the user can access the study until 11:59 PM UTC of that day. Previously, user access would expire at 12:01 AM UTC of the date defined.

Study roles populate the User Upload Template upon download

Study roles, including template roles, now populate the Study Roles tab of the User Upload Template upon download. For additional details, see *Create user accounts using the upload template*.

Recommission a study

Your organization can now request the recommissioning of a study that was previously decommissioned by Oracle in Oracle Clinical One Platform. More information about this enhancement will be featured in the *Recommission a Study* section of the *Sponsor and CRO User Guide*.

Format question hint text using rich text HTML tags

Study designers can now format question hint text using the following rich text HTML options, making it easier to communicate data collection requirements to your users.

- **Styles:** header, footer, and paragraph.
- **Font:** bold, underline, italics, and six color options.
- **Links:** Email and external links can be embedded in the text.

More information about this enhancement will be featured in the *Create Question Hint text* section of the *Study Designer User Guide*.

Define regions for your study in Oracle Clinical One Platform

Clinical supply managers can now define regions by subsets of states of a country or a geographical area, allowing study designers to stratify in a more granular manner, based on region. A single country can be included in multiple regions, however, states can only be included in one region.

When study designers select the option to stratify based on region, the randomization algorithm works with randomization designs blocked by region and using minimization by region.

Step-by-step instructions on how to define regions will be featured in the *Sponsor and CRO User Guide*.

Edit scheduled reports

If you work with scheduled reports, you can now edit an existing schedule directly from the **Schedule reports** section on the Reports sidebar.



Note:

To access a given report and to schedule reports, you must have the required permissions. For more information, see the *Add Users Guide*.

More information about this feature will be included in Schedule a report within the *Sponsor and CRO User Guide*.

Documentation updates

Learn more about the updates to our documentation.

New in this release

The new *Notifications and Permissions Guide* allows users to easily locate descriptions for the different notifications and their required permissions in Oracle Clinical One Platform.

Changes to user guide titles

- The *Information for Depot Users* guide has been changed to the *Depot User Guide*.
- The *Information for Site Users* guide has been changed to the *Site User Guide*.
- The *Information for Sponsor and CRO Users* guide has been changed to the *Sponsor and CRO User Guide*.

3

Fixed issues

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

Facilities, settings, and user management

An issue with a full SDV strategy occurs (former known issue)

Study managers: Now, when you work with a full SDV strategy, subject statuses are displayed as expected, in the API response and in the system. Previously, even though the SDV strategy was meant for a full verification of subjects' data, certain subjects seemed to not be selected for verification by the strategy's algorithm. For example, a subject's status appeared as NULL, even though they should've been selected for verification. In particular, this issue occurred when settings of the strategy were modified during the course of the study. The cause of this issue was due to certain values not being automatically updated in the application's database. (Issue **34053138**)

A user's access to the study expires at the end of the specified date

User administrators: Now, the date that you specify in the To field of an Effective Date Range allows users access to a study through the end of that day. For example, if the date 11-May is defined as the end date, the user can access the study until 11:59 PM UTC of that day. Previously, a user's access would expire at 12:01 AM UTC of that day. For more details, see [Other enhancements](#). (Issue **25475146**)

Japanese characters cannot be used in naming an SDV strategy

Study managers: Now, when your language preference is set to Japanese, you can add a Japanese title for your Source Data Verification strategy. Previously, when you attempted to complete the Title field, an error message was displayed stating that only letters and numbers are allowed. (Issue **32705148**)

Forms, visits, and rules

Subject visit shows as incomplete or unsaved when parent-child form rule applied

Site users: Now, the form saves the data and the visit is complete when creating a parent-child rule form. Previously, the subject visit showed incomplete or unsaved data, even when the subject already completed the screening or did not select the question that triggered the child form. (Issue **34314729**)

Frozen, dynamic child questions, do not update when unfreeze action applied.

Site Users: Now, child questions unfreeze successfully allowing the site user to edit the question. The appropriate icon is also displayed. Previously, the child question was not successfully unfrozen limiting the users ability to edit the question. The appropriate icon was also not displayed.

Retracted Workaround: None. (Issue **34287424**)

A visit's status is not updated a subject fails screening

Site users: Now, when a subject fails screening during a screening visit that contains both screening and randomization events, the status of that screening visit is marked as Complete with Errors, as expected. Previously, the screening visit's status was not updated and remained as In Progress. This caused several issues in the system, particularly with signing the data for a visit like this.

Inconsistent rule behavior for automated queries

Rule designers: When an automated query rule is configured for unscheduled or study completion visits, you may notice that queries are not displayed, as expected. This issue can be reproduced when the operand and target items are configured in the Questions Before the Table section of a two-section form. (Issue **34183025**)

Duplicate emails might be sent out based on a custom rule (former known issue)

Rule designers: Now, when you create a rule to send an e-mail notification, if the email address of a user is specified twice as a testing email address or both as a Testing and Production email address, one single email is sent out to that specific email address. Previously, duplicate e-mail messages were sent out to that specific user.

Retracted workaround: Although the email is now sent only once for the same email address, you should still make sure that you only specify each email address once, when you create a custom rule for an email notification. (Issue **33987346**)

Large code lists take longer time to save (former known issue)

Study designers: Now, when a code list contains over 200, you can save that code list without any interruptions or delays. Previously, with larger code lists, you may have noticed that the application was taking longer than usual to save any of your changes, such as applying it to a question in a form.

Retracted workaround: None. (Issue **33948251**)

Long questions are not properly displayed in a notification email (former known issue)

Study designers and other sponsor users: Now, you can use longer question titles and they will be displayed appropriately in a notification email. Previously, when the questions included in a form were too long, the users receiving any notifications related to changes for those questions were not able to properly view the entire list of questions that generated a notification.

Retracted workaround: You no longer have to avoid using question titles that are longer than usual (typically over 200 characters). (Issue **33938985**)

Skipped visit is marked as In Progress after being frozen (former known issue)

Data managers: Now, when you freeze data in a skipped visit and do not create a new study version that you assign to a site, that visit's status remains Skipped, as expected. Previously, when you froze data in a skipped visit, that visit's status was updated to In Progress. This issue occurred when several settings and actions were previously performed:

- The settings Site Enters Visit Dates, Site Edits Visit Dates, and Visit Can Be Skipped were configured for a Dispensation, Option, and Non-Dispensation visits.
- A new study version was generated and moved to Testing or Production.

Retracted workaround: None. (Issue **34122179**)

Clearing a custom rule error message leads to clearing a coding item target (former known issue)

Site users and rule designers: Now, after a custom rule's error message is no longer displayed on the screen, the associated coding target items aren't cleared, as expected. Previously, after a custom rule's error message was cleared from the User Interface (UI), the system also cleared any verbatim terms from the forms. This interfered with the way terms were coded in a form.

This issue was reproduced in an Adverse Event.

Retracted workaround: None. (Issue **34111603**)

Cannot enter lab result in a lab form's row (former known issue)

Site users: Now, in a lab form, when you open a row in a new dialog (to fill in fields), you can enter data straight into the lab form table. Previously, you may have noticed that you were no longer allowed to enter data straight into the lab form table. Instead, you could only fill in fields in the form by opening each row in a separate dialog.

Retracted workaround: You no longer have to return to the Subject page and then re-open the visit that contains your lab form. (Issue **33905908**)

A designer must refresh the page to see a lock icon (former known issue)

Study designers: Now, when working along multiple study designers, you no longer need to constantly refresh your browser's page to make sure that the lock icon is displayed or not (depending on whether other designers are working in the study or not). Previously, you had to refresh your browser page when working with multiple study designers.

This was caused by a backend issue that determined the system to not display the appropriate lock icons after data was refreshed.

Retracted workaround: You no longer have to constantly refresh your browser's page to make sure that the lock icon is either displayed or not, or that newly created forms by other designers are displayed. (Issue **33665785**)

Data flags in dynamic lab forms not displayed when user changes the parent question values (former known issue)

Study designers: Now, when testing forms in Testing mode, you will see that data flags are properly displayed in a dynamic lab form. Previously, after modifying the answer to a determining question, you may have noticed that the data flags that were previously applied in a lab form were no longer displayed.

Retracted workaround: None. (Issue **32723537**)

Target field in two-section form is not updated (former known issue)

Rule designers and testers: Now, after you define a custom rule with a read-only target field located in a two-section form, you may notice that the target field is updated after that rule is run, as expected.

Retracted workaround: After the rule runs, you no longer have to refresh your browser's page. The system automatically refreshes the data and the updated value appears in the target read-only field. (Issue **33047748**)

The Rules Editor dialog title is now translated to Japanese

Rule designers: When the application's language preference is set to Japanese, you may notice that the Rule Editor dialog title is properly translated to Japanese. Previously, this title was not translated and was displayed in English. (Issue **32914076**)

The Rules sidebar does not display data from the current form (former known issue)

Rule designers and testers: Now, when navigating between forms, the Rules sidebar displays data related to the form that you are currently accessing. Previously, the Rules sidebar displayed rules-related data from the previous form you just accessed.

Retracted workaround: None. (Issue **33635407**)

Schedule Above First section is properly formatted in Japanese

Study designers: On the Data Collection page, the Schedule Above First section (displayed in-between unscheduled visits in a branch) is now properly displayed on the user interface. Previously, the words did not fit and looked misaligned. This issue only occurred when the application's language preference was set to Japanese. (Issue **32903499**)

Advanced study versioning updates do not work during multiple study updates (former known issue)

Study designers: Now, when you perform an advanced study versioning update and then attempt to move the study version from Testing to Approved (in one type of browser) and then create a new study version (in another type of browser), an error message is displayed. The error message states that the creation of a new draft study version has failed, as expected. Previously, after performing these two simultaneous study updates, you may have noticed that your advanced study versioning updates were no longer reflected in the updated study version.

Retracted workaround: None. (Issue **33416734**)

The lock icon disappears from a locked form (former known issue)

Study designers: Now, the lock icon continues to be displayed on a form while you (as a study designer) are deleting another form in the study. Previously, when you attempted to delete a form (for example, Form A) and another study designer was editing another form (for example, Form B), you may have noticed that the lock icon disappeared from Form B.

Retracted workaround: You no longer have to refresh your browser's page to have the lock icon reappear. (Issue **34058105**)

Integrations

Oracle Central Coding system timeout when attempting to process duplicate records

Now, duplicate source ID entries are not being entered in the CODING_AUDIT table when a GET request job retry fails. Previously, duplicate entries were made in the CODING_AUDIT table when the Get Request job failed and a retry was attempted. Subsequent GET requests would attempt to process the duplicates resulting in a system timeout. (Issue **34087438**)

Oracle Clinical One Analytics

Site records not properly displayed in datasets (former known issue)

From now on, data related to a site's start date or end date will be properly reflected in the Oracle Clinical One Analytics application and its datasets.

Retracted workaround: You no longer need to reach out specifically to your Oracle Project Manager to refresh data in the Analytics application. (Issue **33940889**)

Audit data is not displayed in Oracle Clinical One Analytics (former known issue)

Now, a subject's kit data also display audit data, as expected. Here is what you will be able to see when it comes to a subject's kit audit data:

- For a replaced kit (with a reason of Not dispensed to subject), subject and visit details are also displayed until the kit is updated as Available in the system. For a new kit, only a subject's details are displayed, without any associated visit details.
- For a replaced kit (with a reason of Lost/Damaged), subject and visit details are displayed until the kit is updated as Available in the system. For a new kit, only a subject's details are displayed, without any associated visit details.
- For a reused kit, details of the associated visit before the kit's reuse are displayed. After the kit is reused, the latest visit details are displayed.
- For a misallocated kit, details of the newly assigned subject are displayed.

Retracted workaround: None. (Issue **33563978**)

Shipment records are not properly updated in the Unblinded Kits dataset (former known issue)

Now, when you attempt to include historic records of kit shipment details in your custom report, the data is displayed as expected. Previously, data was not properly updated. For example, if the status of a kit was updated from **Pending Destruction** to **Destroyed**, this update was not reflected in your report.

Retracted workaround: None. (Issue **33485267**)

Kits' data is not properly displayed in datasets (former known issue)

Now, in the Unblinded Kits dataset, when you attempt to display a kit with an updated shipment date, you may notice that the element DH_TIMESTAMP is updated, as expected. Previously, this element was not displayed accordingly.

Retracted workaround: None. (Issue **33448065**)

Randomization and kits

Cannot move study version after removing a treatment arm (former known issue)

Study designers: Now, after you remove a treatment arm from a live study version, you can successfully move that study version from Draft to Testing. Previously, a confusing error message was displayed indicating that moving this study version to Testing failed.

Retracted workaround: None. (Issue **33520150**)

Kit type titration assigned to visit in branch can still be edited (former known issue)

Study designers: Now, you can no longer remove kits from a kit type titration that was already assigned to a visit in a branch. Previously, after assigning a kit type titration to a visit in a branch, you may have noticed that you were still able to remove kits from the kit type titration.

Retracted workaround: None. (Issue **32101959**)

Reports, archives, extracts, and notifications

The Subject Events report experienced longer than normal runtime

Site and sponsor users: Now, when you run the Subject Events report you will no longer encounter above normal runtime. Previously, you could encounter a longer than normal runtime due to invalid number entries in the Kibana staging table. Going forward the staging table will be cleared to remove the potential of encountering this issue. (Issue **34399461**)

Shipment creation notification not consistently sent to customer depot when new shipment created.

Customer depot vendor: Now, receives shipment creation notification when a new shipment is created. Previously, the email associated with a customer depot did not receive shipment creation notifications when a new shipment was created.

Retracted Workaround: None. (Issue **34307434**)

The Archival PDF takes a long time to generate

Sponsor users: Now, when you run the Archival PDF in a study that contains a larger volume of data, you will notice that the archive is generated in the expected amount of time. Previously, the system may have been slow and your Archival PDF took too long to generate.

This issue was due to the queryDetails API endpoint. The API did not properly retrieve the study version associated with the Archival PDF and this affected the system's performance. (Issue **34161625**)

Kit Dispensation report displays data from all sites

Site and sponsor users: When you run the Kit Dispensation report, and select a specific site for the Location setting, you may notice that the report displays data from all sites in a study. Instead, the report should only display data for the specific site you previously selected. (Issue **34294108**)

The Subject Query report must not display data on candidate or deleted queries

Site users: Now, as a site user, when you're running the Subject Query report you will notice that you can no longer see data on candidate queries or deleted queries. That is the expected behavior, since only sponsor users should be able to view data on candidate or deleted queries. (Issue **34091418**)

The Subject Events report displays data discrepancies (former known issue)

Sponsor and site users: Now, when you generate the Subject Events report, you will notice that data related to event instance numbers is properly displayed, even if you run this report at the same time with other reports in the system. Previously, you may have noticed certain data discrepancies in this report. This issue was caused by the use of multiple data columns (in the application's backend) for multiple reports at the same time.

Retracted workaround: You no longer have to actively avoid running multiple reports at the same time. For example, you can now run the Subject Data report and the Subject Events report at the same time. (Issue **34060530**)

Values in the Subject Query report are not properly displayed in Japanese

Sponsor and site users: In the Japanese version of the Subject Query report, all values in the Query State column are now displayed in Japanese, as expected. Previously, values in the Query State column were displayed in English. (Issue **33130514**)

Subject Data Extract in a CSV format is empty

Data managers and statisticians: You will no longer run the risk of generating a Subject Data Extract (in a CSV format) that is completely empty. This issue was caused by a database limitation, where data records that exceeded a certain character limit were not displayed in the extract at all. (Issue **34135585**)

Deleted columns displayed with an incorrect status in extracts (former known issue)

Data managers and statisticians: Now, in a Subject Data Extract, modified data records are no longer displayed as deleted. Instead, when a data record is modified by a site user, its status is properly reflected in the extract. Previously, you may have noticed that certain data records were displayed as deleted, even though they were still present in the application. This issue could be observed when a site user opened the application in multiple browser sessions and updated the same data record in different ways (for example, they removed the data record in one session and then modified the same data record in another session).

Retracted workaround: None. (Issue **33743917**)

The CPORT format is now clearly displayed for SAS extracts

Data managers and statisticians: Now, when you extract subject data in a CPORT format, the extract displays the .CPT extension that is needed to differentiate between extract formats. Previously, this extension was not displayed. (Issue **34227314**)

Tool tips for reports are not displayed in the preferred language

Sponsor and site users: Now, when you change your application's preferred language after having generated reports in your study, you may notice that the report-related tool tips appear in the preferred language, as expected. Previously, if you switched between preferred languages during the generation of a report, you may have noticed that the tool tip texts were displayed using a mix of English and Japanese. (Issue **33103591**)

Japanese characters are not displayed in a SAS dataset (former known issue)

Data managers and statisticians: Now, Japanese characters are displayed correctly in a Subject Data Extract generated in a sas7bdat format. Previously, Japanese characters were not properly displayed in this type of data extract. This issue was encountered when you opened the SAS dataset with SAS Universal Viewer, version 1.5.

Retracted workaround: None. (Issue **33279322**)

Column name in the Subject Queries report might be confusing (former known issue)

Sponsor users: Now, both the Subject Queries report and the Subject Data report display a column called Repeating Section Number, as expected. Previously, the column was called Repeating Form Number without taking into account the number of repeating form instances in a two-section form.

Retracted workaround: None. (Issue **33508078**)

The User Assignment and User Assignment by Site reports do not display correct data for removed users (former known issue)

User administrators: Now, after a user is removed from a study, the Status column is updated with a new status of "Removed" for that specific user, as expected. Moreover, when you add a new user to a study, its status is displayed as "New" in the report. After the newly added user signs in the application for the first time, their status is displayed as "Active" in the report. Previously, a user that was removed from the study was still displayed with a status of "New/Active" in the User Assignment reports. This issue occurred when you included historical data in your reports.

Retracted workaround: None. (Issue: **34018392**)

Candidate or deleted queries should not be displayed in the Subject Queries report for site users

Site users: Now, when you run the Subject Queries report, you can only see the queries that you are also allowed to see on the user interface (typically queries with a status of Opened, Answered, or Closed - depending on your permissions). Previously, as a site user, you could also see queries with a status of Candidate or Deleted, even though you did not have the permission to view or manage those types of queries on the user interface. (Issue **34091418**)

Site users and subject data

API fails to add subjects

Site users: Now, the API can add subjects. Previously, when site users selected the option, **Prevent Site Users from Manually Adding Subjects**, the study setting would also apply to the API. Hence, preventing the API to add subjects even when site users cannot. (Issue **34376688**)

Coded terms are not properly formatted to be send to Oracle Central Coding (former known issue)

Site users: Now, you can no longer copy and paste coded terms into a repeating form table cell, to avoid any potential errors in the coding process. Previously, not only did the application not remove any extra spaces that you added into the form, but it also did not prevent you from copying and pasting data that must have been integrated with another system. Because extra spaces were not cleared or avoided, the integration of those coded terms with Oracle Central Coding may have failed.

Retracted workaround: Although this issue is now fixed, we recommend you avoid adding coded terms straight into the repeating form table. Instead, open a repeating form instance in a separate dialog and enter your coded terms. (Issue **34027154**)

New validation error message for exceeding a text field's character limit

Site users: Now, when you exceed the character limit of a text field in a form, an appropriate validation error message is displayed. The new validation message states that the value cannot exceed a specified number of characters in length. Previously, the validation message stated that the value in that field must be less than a specified number of characters. (Issue **34151882**)

Cannot update kit status from Expired to Misallocated (former known issue)

Site users and sponsor users: Now, on the Site Inventory tab, you can update an expired kit's status to Misallocated. Previously, you did not have that option. When clicking **Update Kit**, the Misallocated option was not displayed. (Issue **33920822**)

Frozen icon is missing from a frozen adverse event

Data managers: In Oracle Clinical One Platform, on the Subjects page, every adverse that contains frozen data is marked with the Frozen icon, as expected. Previously, even though data was frozen in an adverse event (and this status was reflected in reports in both the Oracle Clinical One Platform and the Oracle Clinical One Analytics), the Oracle Clinical One Platform UI did not display the expected icon on the visit card. (Issue **34217709**)

Manually entering a date does not work in a repeating form table (former known issue)

Site users: Now, when Japanese is set as your preferred language in the application, and you attempt to manually enter a date in the repeating form table view, the date remains the way you set it. Previously, you may have noticed that the date was automatically set to the current date.

Retracted workaround: You can always update a date field either by using the calendar widget or opening the repeating form instance in a new pop-up window. (Issue **33698622**)

Dynamic form not displayed when multiple answers are selected (former known issue)

Site users: Now, when a one-section form contains multiple questions with a Show Form dynamic rule that is supposed to display the same dynamic form, this configuration works, as expected. The same dynamic form can be dynamically displayed when multiple determining questions are answered. Previously, this was not possible.

Retracted workaround: None. (Issue **33282026**)

Field incorrectly displaying as frozen

Site users: Now, fields not frozen by a user do not appear as frozen in the Oracle Clinical One Platform user interface and audit trail. Previously, a field could appear as frozen in the user interface even when the field was not frozen by a user.

Retracted workaround: You no longer have to manually freeze the field again, and then unfreeze it. (Issue **34086892**)

4

Be a part of the Oracle Clinical One Platform community

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

Get access to the Oracle Clinical One Platform community

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

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

More information

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

Note:

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

5

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).

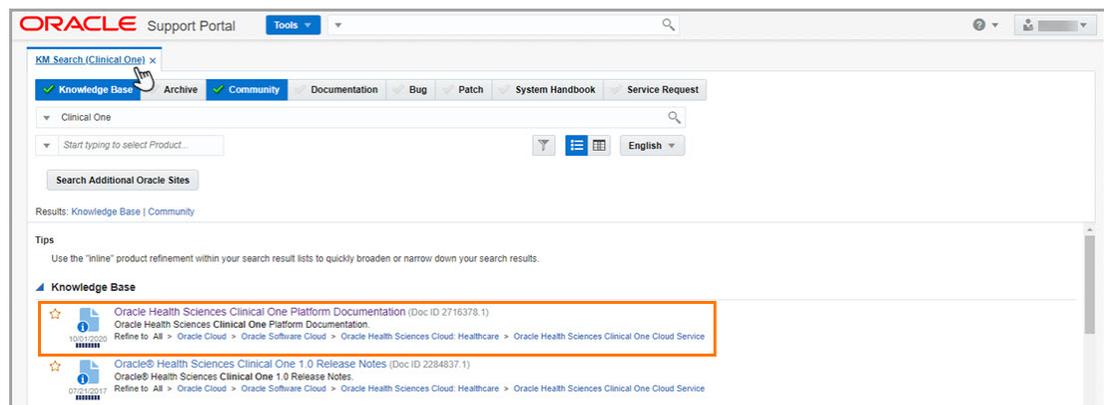
To make sure you get the right access in MOS, follow these two steps in the order listed below:

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 5-1 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.

6

Subscribe to product updates

- [Health Sciences Support release announcements](#)
- [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.

Health Sciences Support release announcements

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

1. Sign into Health Sciences Support.
2. On the Home page, in the upper-right corner, click [My Account](#).
3. On the left, click **Subscriptions**.
4. Click **Select interests**.
5. In the new window, type in your email address.
6. Go to your inbox and look for an email from Oracle Communications. Open the email, and click **Subscribe**.
7. Select your country and your job role.
8. From the section **Recommended for you**, select **Industry-specific Applications**. Additionally, select any other topics that you're interested in.
9. Click **Subscribe**.

After you subscribe, every time an Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release announcement is posted in the Health Sciences Support platform, you receive an email containing the following details:

- **Title of the email:** New announcement posted to hsgbu.custhelp.com
- **Sender of the email:** Oracle HSGBU Support
- **Title of the release announcement:** Typically contains the name of the product, the year and quarter of the upcoming release, as well as the release number.
- **Date Published:** The date when the announcement is posted on Health Sciences Support.
- **Section:** HSGBU Updates

 **Note:**

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

How often do we send out these release announcements?

We send out several notifications for each Oracle Clinical One Platform and Oracle Clinical One Digital Gateway release:

Type of release	Announcements
Quarterly releases (that contain new features)	<ul style="list-style-type: none"> <li data-bbox="881 417 1377 617">• Pre-Assessment Environment Notice: This is the first announcement posted two weeks before the date of the planned Assessment Environment (AE) upgrade. This notification contains general information about the new features in the upcoming release. <li data-bbox="881 625 1377 846">• Assessment Environment (AE) Notice: This is the second announcement posted upon the successful completion of the Assessment Environment (AE) upgrade to the new release. This notification contains general information about the new features, as well as the Production release date. <li data-bbox="881 854 1377 968">• Production Notice: This is the third announcement posted upon the successful completion of the Production upgrade to the new release.
Patches (that only contain fixes applied to the current release)	<ul style="list-style-type: none"> <li data-bbox="881 982 1377 1150">• Cloud Upgrade Notice: This is the first announcement posted sometime before the date of the planned upgrade. This notification contains the approximate date of the Production upgrade and a general description of the fixes in that release. <li data-bbox="881 1159 1377 1270">• Cloud Upgrade Complete: This is the second announcement sent on the day of the Production release, announcing to you that the upgrade is complete.

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 status information for the Oracle Clinical One Platform Assessment Environment (AE). For more information about the Assessment Environment (AE), see the [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 and enter a valid email address.

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.

7

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.

8

Computer and browser requirements

System requirements

Computer	Internet browser	Resolution
Laptop or desktop computer	<ul style="list-style-type: none">• Google Chrome version 42.0 or higher (recommended)• Microsoft Edge version 44.18 or higher	<p>Make sure the resolution display of your computer is configured using the following values</p> <ul style="list-style-type: none">• 1920x1080 (recommended) for a full High Definition (HD) monitor• 1366x768 px or higher (standard resolution) for most non-HD computers

Using Windows 7 and Internet Explorer 11?

Starting with Oracle Clinical One Platform release 22.1, Internet Explorer 11 is no longer supported. The following instructions are still relevant for users continuing to utilize the browser.

Your security settings might prevent you from signing in. If you see a blank white page in Internet Explorer after clicking Sign In, perform the following steps in Internet Explorer to disable compatibility view.

1. In the upper-right corner, click the Tools button, and select **Compatibility View settings**.
2. Below the list of websites, make sure **Display intranet sites in Compatibility View** is **not selected**.
3. Click **Close**.
4. Close all instances of Internet Explorer.
5. Open a new instance of Internet Explorer and try signing in again.

9

Revision history

Date	Part number	Description
June 2022	F56714-01	Original version of the document.
June 2022	F56714-02	Updated the month of the publication.
June 2022	F56714-03	<ul style="list-style-type: none">• Documented a new fixed issue. For more information, see Issue 34161625 in Reports, archives, extracts, and notifications.• Updated information on system maintenance notifications. For more details, see System maintenance page and status notifications.• Renamed the following topics:<ul style="list-style-type: none">– Information about past releases– Health Sciences Support release announcements– Subscribe to product updates
July 2022	F56714-04	<ul style="list-style-type: none">• Added maintenance and status page details to the Other Enhancements topic, with a link to the new topic.• Updated two links to be more granular.
August 2022	F56714-05	F56714-05: fixed broken link between Release Notes and My Oracle Support (MOS).
August 2022	F56714-06	F56714-06: Created for the 22.2.1 release.

10

Oracle Clinical One Platform Product Verification Pack (PVP)

- [About the Product Verification Pack \(PVP\)](#)
- [Download the Product Verification Pack \(PVP\)](#)

About the Product Verification Pack (PVP)

The Product Verification Pack (PVP) is a collection of product release artifacts that are aimed at helping with your validation efforts.

The documents in the PVP are used by Oracle for product certification purposes and Oracle makes the documents available to you 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:

- Summary report
- Test requirements
- Test cases
- Traceability matrix
- Test results
- Objective evidence

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

Download the Product Verification Pack (PVP)

- [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)

Do I have to do this? Yes, unless you already have a My Oracle Support (MOS) account. Getting an account takes just a couple of minutes.

How many times do I have to do this task? Just one time.

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)

Do I have to do this? Yes. Even if you have a MOS account, you won't be able to download the Product Verification Pack (PVP) or see useful information until you associate your account with your organization's customer support identifier (CSI).

How many times do I have to do this task? Just one time.

1. Obtain your organization's CSI using one of the following methods:
 - Find the CSI in the Welcome letter, if you received it.
If you were identified as the primary contact from your organization for the deployment of Oracle Clinical One Platform when the environment was first provisioned, you received the Welcome letter from Oracle.
 - Consult the documents you received during the onboarding process.
 - Reach out to your Sales contact.
2. Sign in to [My Oracle Support](#).
3. In the upper right, click the drop-down arrow to the right of your name, and select **My Account**.
4. Below Support Identifiers, click **Request Access**.
5. Fill in the fields:
 - **Note to Approver:** Include an optional note about why you need to be associated with the organization's CSI.
 - **Support Identifier:** Enter the numerical CSI for your organization.
6. Click **Request Access**.
7. Review these important guidelines so you understand how your request is approved, next steps, and future responsibilities:

- If you are the first person from your organization to request to be associated with the CSI:
 - You can expect to hear back from Oracle within a couple business days, letting you know that the association has been set up.
 - As the first user at your organization to be associated with the CSI, you automatically become the Customer User Administrator (CUA) for your organization.
 - * **As the CUA, you'll be responsible for approving all future requests for associations to your organization's CSI.**
 - * You'll typically receive requests only when another person at your organization needs to download the PVP. After someone requests access, you'll receive an email, and all you have to do is return to MOS to approve their access.
 - * You also have the ability to identify other users as CUAs. **We highly recommend setting up more than one CUA for your organization.** That way, if the current CUA is on vacation or leaves the company, your organization will still be able to approve requests. If your last CUA leaves your organization, reach out to Oracle Support for help in manually updating the CUA.
- If you aren't the first person from your organization to request to be associated with the CSI, the request for approval is emailed to the Customer User Administrators (CUAs) at your organization. One of them needs to sign in to My Oracle Support and approve your request and then you'll be able to see the PVP. They can also make you a CUA so that you'll have approval rights for future requests.

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

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

Do I have to do this? Yes. 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.

How many times do I have to do this task? The password changes every 90 days, so you'll have to request a new password about four times per year.

1. Open [Support Cloud](#).

 **Tip:**

Your Support Cloud account is the same as your My Oracle Support (MOS) account.

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

Submit a Request to our Product Support Team

Select Customer
ABC Pharma

Select Product *
Clinical One

Select Business Service
Clinical One - ABC Pharma

Oracle Internal *
 Yes No

Environment *
Other

Application URL/Website Address

Severity *
4 - Low

Issue Category *
General Inquiry

Alternative ref number (if applicable)

Summary *
Please provide Password for the latest Clinical One Product Verification Pack (PVP)

Description *
Please provide Password for the latest Clinical One Product Verification Pack (PVP).
Thank you.

Next step: [Step 4. Download the Product Verification Pack \(PVP\)](#).

Step 4. Download the Product Verification Pack (PVP)

The URL for the PVP doesn't change.

1. Navigate to the following URL:

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

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**.

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 pop-up, perform the following tasks:
 - 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.

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.