

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



Release 24.1

F96542-01

May 2024

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ORACLE®

Oracle Life Sciences Clinical One Platform and Oracle Life Sciences Clinical One Digital Gateway Change Log, Release 24.1

F96542-01

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23 Revision history

Preface

This preface contains the following sections:

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

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](#).

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

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

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What should I use this guide for?

- [About this guide](#)

About this guide

This guide contains Release Notes content from previous releases. This includes but may not be limited to the following:

- **Patch Log:** Contains details about patches applied to a minor release.
- **What's new:** Contains details about enhancements and new features.
- **What's fixed:** Contains details about issues that were fixed.
- **Rest API Updates:** Contains details about services that have been updated.

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

2

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 23.3

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)
- [Rest API updates](#)
See the newly added, deprecated, and deleted endpoints of the Oracle Clinical One Platform APIs, available upon the Production release.
- [Release impact for other applications](#)
This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.3 release. None of these fixes affect the user work flow or the application's functionality.

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

Table 2-1 Patch log

Release Number	Release Date	Notes
Release 23.3.1.6	18-April-2024	For this release, we fixed issue 36459618 related to integrations. See Integrations .
Release 23.3.1.5	04-April-2024	For this release, we fixed issues related to forms and visits. For more information, see issues 36373738 and 36430361 in Forms, visits, and rules .
Release 23.3.1.4	30-March-2024	For this release, we fixed issue 36352863 related to the order of questions in a form. See Forms, visits, and rules .
Release 23.3.1.3	22-March-2024	For this release, we fixed several issues related to how subject data is verified in a study: <ul style="list-style-type: none">• For issues 36325535 and 36340891, and 36284515, see Site users and subject data.

Table 2-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.3.1.2	08-March-2024	<p>For this release, we fixed several issues related to subject data, lab normal ranges, and Oracle Clinical One Analytics.</p> <ul style="list-style-type: none"> For issues 36257210 and 36308286, see Site users and subject data. For issue 36260224, see Sites, labs, depots, settings, and user management. For issue 36293970, see Oracle Clinical One Analytics.
Release 23.3.1.1	22-February-2024	<p>For this release, we fixed several issues connected to forms and visits. For more information, see:</p> <ul style="list-style-type: none"> Issues 36246646, 36267457 and 36005744 in Forms, visits, and rules.
Release 23.3.1	10-February-2024	<p>For this release, we fixed several issues connected to forms and visits, subject data collection, as well as reports. For more information, see:</p> <ul style="list-style-type: none"> Issues 35726231, 36070846, and 36109118 in Forms, visits, and rules; Issue 35997964 in Sites, labs, depots, settings, and user management; Issues 35832979 and 36125416 in Reports, archives, extracts, and notifications.
Release 23.3.0.3	05-February-2024	<p>For this release, we fixed two issues related to how subject data is displayed and site events. For more information, see the following:</p> <ul style="list-style-type: none"> Issue 36208670 in Site users and subject data; Issue 36250794 in Sites, labs, depots, settings, and user management.
Release 23.3.0.2	29-January-2024	<p>For this release, we fixed an issue related to lab forms. For more information, see issue 36221890 in Site users and subject data.</p>

Table 2-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.3.0.1	16-January-2024	<div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 10px;">  Note: This fixed issue does not impact any customers working with either Oracle Clinical One Digital Gateway or Oracle Clinical One Platform. </div>

For this release, we fixed an issue related to signing data. For more information, see issue

Table 2-1 (Cont.) Patch log

Release Number	Release Date	Notes
		36177246 in Site users and subject data .

What's new

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

Data collection

- [Replace the subject number with the randomization number after randomization](#)
A new study setting allows the subject number to be replaced by the randomization number after randomization.
- [Undo subjects added in error](#)
If a subject has been added to a study in error, it is now possible to undo this action.

Replace the subject number with the randomization number after randomization

A new study setting allows the subject number to be replaced by the randomization number after randomization.

Before you work with this feature

- To view and configure this new setting for replacing the subject number, a sponsor user must be assigned the new permission called *Manage Subject Number Configuration*.

Tip:

To access the Study Settings tab, a user must be assigned the existing *View Study Settings* and *Edit Study Settings* permissions.

Details for sponsor users

- With the appropriate permission, you can find the new setting on the **Study Settings** tab. The setting is called **Replace Subject Number with Randomization Number**.
- This new feature is available in all modes: Testing, Training, and Production and it is mode-specific. This means you can enable the setting in Production mode, where no subjects have been screened or enrolled, even if subjects were already screened or enrolled in Testing or Training mode.
- Subjects are still initially assigned a subject number after being screened or enrolled. After randomization, the subject number is replaced by the randomization number, and the original subject number is referred to as the screening number in the User Interface (UI) and reports.
- The new subject number is propagated throughout the system in the following application areas:
 - The User Interface (UI)
 - All dialog windows
 - Post-randomization notifications
 - All reports that include the subject number
 - The Subject Data Extract
 - Oracle CRF Submit archives and reports
 - Select Oracle Clinical One Digital Gateway configured integrations

Impact on reports and notifications

- The **Subject Data report** includes a new column called **Screening Number**.
- The Subject Number column in the **Subject Events report** has been renamed to **Screening Number**.
- The **Subject Data Extract** includes a new column, called **SCRNID**, to collect the Screening Number.

WARNING:

As stated above, a new column, SCRNID, has been added to the Subject Data Extract, resulting in a new header. If you have programming based on the column positions in the extract, modifications to your programming may be required.

Already working in a live study?

- This feature is available for existing studies started before 23.3, when no subjects have been screened or enrolled.
- The setting is grayed out if subjects were screened or enrolled in a specific mode.

More information about this feature can be found in the *Sponsor and CRO User Guide*, under Study Settings, after the Release Assessment Environment (RAE) upgrade.

Undo subjects added in error

If a subject has been added to a study in error, it is now possible to undo this action.

Details for site users

Users assigned the *Edit Form Data for Subjects* permission can now remove a subject that has been added in error, so long as no data has been recorded for that subject.

Once the action of adding a subject is undone, their subject number is returned to the pool for reuse. The subject's GUID, however, is not reused.

Impact on reports

The Subject Events report now features an **Add Subject Cancelled** entry if the subject is undone. Moreover, when the subject number of an undone subject is reused, two entries are included for that subject in the following reports:

- ODM-XML Extract
- Subject Data report
- Subject Events report
- Subject Queries report

Data review

- [Create queries on the visit date](#)
It is now possible to set up an automated validation of a visit's date against the visit window! Additionally, a visit's date can be selected to raise manual queries, as well as automated queries, and notifications through custom JavaScript rules.

Create queries on the visit date

It is now possible to set up an automated validation of a visit's date against the visit window! Additionally, a visit's date can be selected to raise manual queries, as well as automated queries, and notifications through custom JavaScript rules.

Configure alerts for visit dates out of window

Study designers can now configure rules to alert a site user if a visit's date is outside of the visit window, either through a warning or by raising a query. When defining the visit schedule, there is a new field called **Alert if Outside the Visit Window**. This field displays the following options:

- **Off**
- **Warning**
- **Query**

By default, the field is set to **Off**. This means it will not display any kind of alert, and all visits in current live studies will be set to **Off**, as well. Choosing to alert, either through a warning or a query, can help correct data entry errors and collect protocol deviation details to determine if the subject should remain in the study or if it should be included in the investigational product analysis at all.

As soon as this release is complete, you can start configuring these alerts. However, Advanced Study Versioning (ASV) is not supported, which means you need to make the change in a draft study version and move the updated study version to either Testing or Approved, and then apply that study version to the respective sites. Queries and warnings only display for visits added or updated after the Study Version change is applied.

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

Raise manual queries on a visit's date

Previously, Clinical Research Associates (CRAs) and data managers would need to raise queries on the visit date targeting another question within one of the forms associated to the visit, which made it difficult to track and report. With this enhancement, CRAs and Data Managers can now raise queries directly on the visit date field. This helps streamline the data review processes, letting them associate queries to the correct question, document them properly, and generate clean reports with accurate information regarding these visit dates and their queries.

Raise queries on the visit date through custom rules

Besides the visit window validation, there may be other requirements related to visit dates that require custom rules, whether they're scheduled or unscheduled visits. The same way you can now raise manual queries on visit dates, rule developers can now select the visit date as the target for custom rules that raise automated queries and send notifications. The **Add Rule** function is now available when selecting the visit date field. Rules added to the visit date question have the following actions available:

- **Create Query**
- **Create Assigned Query**
- **Send Notification**

 **Note:**

The action option called **Calculate Value** is not available for visit date target rules.

You can find additional details on how to create different types of rules and the available rule helper functions in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

Integrations

- [Enhancements to integrations](#)
This section includes enhancements to integrations configured in the Oracle Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

Enhancements to integrations

This section includes enhancements to integrations configured in the Oracle Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

Depot-to-depot shipments support for Almac Global Depot Network

Users can now optionally configure depot-to-depot shipments in the Almac integration. The integration will also update these shipments' statuses accordingly.

For more information about depot-to-depot shipments, see [About depot-to-depot shipments](#).

Replacing the subject number with the randomization number is supported in downstream systems

A new study setting allows the subject number to be replaced by the randomization number after randomization.

When the setting is enabled, a new event introduced in Oracle Clinical One Platform notifies external systems of a subject number change in a study.



Note:

In addition to the new setting being enabled, a configuration update is required to take advantage of this feature. Work with your Oracle Services Consultant to apply the necessary updates.

Supported integrations

- Oracle Clinical One Platform to Oracle InForm

More information about this feature can be found in the *Sponsor and CRO User Guide* after the Release Assessment (RAE) upgrade.

Site management

- [Manage sites, depots, and labs in one place](#)
Sponsor and CRO users can now manage organizations (sites, depots, labs) and their contacts at a global level.

Manage sites, depots, and labs in one place

Sponsor and CRO users can now manage organizations (sites, depots, labs) and their contacts at a global level.



Tip:

Did you know that you can now create and manage locally sourced kits at a site? This new feature can be particularly useful now that you can manage organizations and contacts at a global level. For more information, see [Manage locally sourced kits](#).

To further improve your study management capabilities, you can now create and manage sites, labs, or depots, and their contacts for all studies at your organization, all in one place.

**Note:**

Additional information and step-by-step instructions on managing organizations and vendors for multiple studies can be found in the *Sponsor and CRO User Guide* and the *Add Users Guide* after the RAE upgrade.

Before you work with this feature

This new feature can impact all users who work with sites, depots, labs, or administrate a study in general. The following users should be assigned the *Manage Contacts and Organizations* and *View Contacts and Organizations* global roles to be able to manage organizations and their contacts at a global level:

- Global user managers
- Site administrators
- Study managers
- Clinical supply managers

Codelist guidelines when working with this feature

During your environment's upgrade, while the contacts and organizations for your site addresses are populated, the **State/Province/County** and **Prefix** fields are verified using the Oracle Clinical One Platform system code lists. If the data in these fields does not match, any contact or organization, State/Province/County and Prefix data is cleared during the upgrade.

**Note:**

These fields are case sensitive; periods (.), and special accents (´) are ignored.

After the migration, if your study has an integration that uploads the **State/Province/County** and **Prefix** fields into Oracle Clinical One Platform, the data is verified against the Oracle Clinical One Platform code lists prior to them being imported into the Oracle Clinical One Platform. If the data in these fields does not match, the data points are cleared in Oracle Clinical One Platform only. This does not cause the full integration to fail.

Sponsor users can be notified when the State/Province/County data is cleared via notification. To receive the notification, the user must be assigned the *State Set to Null Notification* permission. This informs the user that the **State/Province/County** field has been cleared during integration. The notification includes the following information to help determine the mismatch, so that it can be resolved in the source system:

- Study Name
- Site Name
- Site ID
- Site Mode

For more information, contact your Oracle Project Manager.

Updates to the existing site and depot workflows

If you're a site manager creating sites or labs, or a clinical supply manager setting up depots, here's what you should know about the workflow you used to follow to set up these organizations:

- All sites, depots, and labs are created at the global level only. Their addresses and their associations with specific contacts are maintained only at the global level. You can still add a site, depot, or lab to a specific study and this action can be performed at the study level only after that site, depot, or lab was configured at the global level.
- On the Sites & Labs tab, you can now click **Create Site** to add an existing site created at the global level to a study. On the Add Site dialog, you can then enter or modify information, such as the Site ID, Status, Mode, and permissions you'd like to give the site users. You can also associate existing addresses created at the global level with your site and select different shipment addresses by kit type. The same applies for depots.
- On the Sites & Labs tab, when you click **View Labs**, you can now click **Add Lab**. On the Add Lab dialog you can then search for a lab created at the global level to add it to your study. You can also further assign a lab to a site at the study level.

Details about contacts

When it comes to managing contacts, here's what's new for you:

- On the Global Settings page, a new tab called **Contacts** is introduced.
- On the Contacts tab, you can create new contacts, edit or retire them, and filter through them, as well as transfer study sites.
- You can filter contacts by study mode, their status, country, state, specialty, or search for a specific contact's name.
- For every contact that you create, you must specify any required information and their addresses. A contact can have multiple types of addresses, such as a primary address, a billing address, a shipping address, or an alternate address.
- Once you create a contact on the Organizations tab, you can associate that contact with an institution. For example, you may associate the contact of a Principal Investigator with the selected institution.
- You can associate the same contact with multiple institutions at your organization.

Details about organizations

When it comes to managing organizations and contacts, here's what's new for you:

- On the Global Settings page, a new tab called **Organizations** is introduced.
- On the Organizations tab, you can create, edit, delete, or retire any organization, as well as filter through the organizations that are associated with the organization you work at.
- Your options for creating an organization include creating an institution (such as a hospital) or a vendor (such as a lab or a depot facility).
- For every organization that you create, you must specify any required information, as well as their addresses. An organization can have multiple types of addresses, such as a primary address, a billing address, a shipping address, or an alternate address.

- For an institution, you can also create departments to better organize the hierarchy and workflows at that specific organization.
- Upon creating an institution, you can associate a contact with that institution, and then you assign that institution to a study and a specific study mode at your organization. This effectively creates a site that becomes available in the studies that you associated that site with. For example, if you create Hospital A and associate it with Contact B, and assign it to Study-123 in Production mode, Hospital A will show up on the Sites & Labs tab, in Study-123.

Details about setting up a master address

You can now reduce the amount of places you update a primary address by creating that address once and using it throughout your studies, letting you manage a recurring address in one place, as opposed to updating it in numerous contacts or organizations. Here's what's new when it comes to setting up a primary address:

- Smart search identifies new addresses, enabling you to quickly add or update addresses.
- Creating or modifying a master address updates the address across all associated contacts and organizations.
- The first address entered in the system becomes the default primary address.
- The checkbox option allows you to copy the primary address into other address fields, such as Billing or Shipping.
- At least one address is required and must be selected as the main primary address.

Already working in a live study?

If you're currently working in a live study that has sites, depots, or labs setup, you must know that Oracle will handle the migration of all of your organizations and vendors at the global level. The transition will be seamless, ensuring that your studies are not compromised throughout their study conduct period.

This new feature is not available in the Release Assessment Environment (RAE), but you can reach out to your Oracle Project Manager for more specific information, as well as to request a separate testing environment.

Randomization and trial supply management

- [Control depot users' access](#)
Sponsor users can now restrict access for depot users and control what they can view in the application on a study-to-study basis.
- [Manage locally sourced kits](#)
When defining inventory settings, sponsor users can now include locally sourced kits and allow site users to manage their dispensation.
- [Pool kits easily across studies](#)
Global users who are assigned the appropriate roles and permissions can now define and manage pooled kits across studies at their organization.

Control depot users' access

Sponsor users can now restrict access for depot users and control what they can view in the application on a study-to-study basis.

Before you work with this feature

As a user administrator or any other sponsor user, you must be aware of the following changes introduced for permissions and study roles:

- *Blinded Depot User* is a new permission that lets the user access the new **Depot Inventory** tab and provides access to view the kit numbers, but doesn't see the descriptions for all blinded and Unblinded Pharmacist kits.

Caution:

Use with caution. The *Blinded Depot User* permission grants access to view the Sequence Number, which could potentially unblind the study for blinded site users and blinded sponsor users.

- *Blinded Depot User* is also introduced as a new template study role. The study role contains several existing permissions compiled to give the adequate access to a depot user who must be blinded in a study.
- To unblind the *Blinded Depot User* study role, add the permission *Create Shipments to Depots* that exposes all kit descriptions to the blinded depot user.
- The existing *Clinical Supply Manager* study role template is modified to include the new *Blinded Depot User* permission.
- The following permissions are no longer unblinding:
 - *Receive Notification of Depot Shipment*
 - *Release Shipments from Quarantine*
 - *Receive New Shipments at the Depot*
 - *Receive and Reconcile Shipments at the Depot*

You can find additional information on the *Add Users Guide* after the Release Assessment environment (RAE) upgrade.

Details for blinded depot users

If you're a depot user who is assigned the *Blinded Depot User* permission or study role, here's what's new for you:

- To view supplies at a specific site or all sites, request permission from your user administrator.
- On the Study Supplies page, you can view a new tab called **Depot Inventory**.
- The **Depot Inventory** tab displays data on a study's blinded inventory and contains columns, such as: Kit Number, Sequence Number, Block Number, Kit Description, Status, Expiration Date, and Units per Kit.
- On the new tab, you can filter blinded kits by depot, status, blinded lot, shipment ID, and quarantine ID. Also, you can search for kits by kit or sequence number.

- You can update the status of kits in your depot's inventory to **Available**, **Dispensed**, or **Quarantined**.
- The word *blinded* now appears in the search bar or for filters to indicate that some treatment descriptions may be unavailable to the blinded depot user.
- As a blinded depot user, you cannot modify the inventory received at a site, as per contract, except for releasing kits from quarantine, if you have the appropriate permissions. You also cannot view the full description of kits, as well as upload or generate kit lists.

You can find additional information on the *Depot User Guide*, after the Release Assessment environment (RAE) upgrade.

Details for user administrators and sponsor users

As a sponsor user, here are some new things you can do to control a depot user's access:

- You can let each depot user only view shipments for their assigned depots.
- As a clinical supply manager, you can remove the location from the kits when they are assigned to the depot in error. For example, if you didn't receive the kit to the site, you can change it back to the depot.
- If you want to give a blinded depot user viewing access to the Site Inventory tab, you must assign one or more sites in the study to the depot user. By default, a blinded depot user doesn't have access to the Site Inventory or the Study Inventory tab.
- If you want to give a blinded depot user access to view Unblinded Pharmacist kits, assign them with the *View Unblinded Pharmacist Kits* permission.

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

Impact on reports

The following reports will reflect depot user activity:

- Kit Chain of Custody (Blinded) report
- Shipment Order Summary report
- Kit Inventory (Blinded) report
- Kit Reconciliation report

You can find additional information about these reports on the *Reporting Guide* after the RAE upgrade.

Manage locally sourced kits

When defining inventory settings, sponsor users can now include locally sourced kits and allow site users to manage their dispensation.

You can now configure locally sourced kits for your studies to accommodate their many needs, such as:

- Sites may need different kit types to be sent to different locations due to storage purposes.
- The protocol utilizes multiple kit types distributed by different depots.
- A drug is approved in a specific geographical area, but not in another.

Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- On the Supply Settings tab, a new section called **Locally Sourced Kit Settings** is now displayed. In here, you can add a kit and define its details so it can be locally sourced.

 **Note:**

The kit type must be set to Unblinded at the time it is created in order for it to be available to be locally sourced.

- Any kit type within a specific titration event can be selected to be added as locally sourced. Once a kit has been added and saved as locally sourced, the kit type cannot be edited.
- Multiple countries can be selected and added to either **Locally Sourced Countries** or **Sourced by Site Countries**.

 **Note:**

A country can only be added to either **Locally Sourced Countries** or **Sourced by Site Countries**, but not added to both.

- All locally sourced countries must be removed in order to disable or delete a locally sourced kit.

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

Details for site users

When it comes to your workflow, here's what you should know:

- Information on locally sourced kits is provided in the dispensation details and Subject History.
- The **Subject Dispensation notification** includes details on locally sourced kits for users assigned one or all of the following permissions:
 - *Receive the Dispensation Notification*
 - *Receive the Dispensation with Dosing Instructions Notification*
 - *Receive the Unblinded Dispensation Notification*

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

Impact on reports

Updates to the following reports can be found in the *Reporting Guide* after the RAE upgrade:

- Kit Dispensation report
- Shipment Order Summary report
- Shipment order form
- Study Design report
- Subject Dispensation report
- Subject Visits (Blinded) report
- Subject Visits (Unblinded) report
- Titration Summary (Blinded) report
- Titration Summary (Unblinded) report

Already working in a live study?

As soon as the upgrade for this release is complete, you can begin locally sourcing kits in existing studies.

Pool kits easily across studies

Global users who are assigned the appropriate roles and permissions can now define and manage pooled kits across studies at their organization.

As opposed to defining kit types for a single study only, pooling kits lets you strategically distribute the investigational product across different studies. In turn, you can now create powerful supply strategies that can significantly reduce drug overages and preserve supplies for all study patients.



Note:

You can find more information in the following user guides, after the Release Assessment (RAE) upgrade:

- *Add Users Guide*
- *Sponsor and CRO User Guide*
- *Study Designer User Guide*

Before you work with this new feature

As a global user manager or a user administrator, you should know that your workflow hasn't changed. However, there are some new roles and permissions that you need to be aware of. The following new global roles and permissions are new or modified:

New role or permission	Description
<i>Create and Edit Library Kits for Pooled Supplies</i>	This is a global role. You can assign this role to a library user or a study designer so that they can create and edit a kit while it has a status of Draft in a library study.

New role or permission	Description
<i>Approve Library Kits for Pooled Supplies</i>	This is a global role. You can assign this role to a library user or a study designer so that they can approve a kit in a library study.
<i>Delete Library Kits</i>	This is a global role. You can assign this role to a library user or a study designer so that they can delete kits in a library study.
<i>Create Manual Shipments (Unblinded)</i>	This is an existing permission that is updated to become unblinded. This means that whoever is assigned this permission can now view pooled kits to include them in a shipment request.

 **WARNING:**

This update partially unblinds a depot user if they are granted this permission. You are not restricted or prevented from assigning a user with this permission as this change doesn't present the risk of compromising your study's integrity.

Details for library managers and study designers

If you're a library manager, here's what's new for you:

- On the Library page, you can now see a new tab called **Kit Types**.
- With the right role, you can now create or edit kit types in a library study, and import them into a Production study.
- When defining a kit type as a library object, you can specify several details for it, such as the pooling ID, a description, as well as information about its storage requirements and the units per kit.
- In your study's library, on the Kit Types tab, you can also change the status of a kit to any of the available statuses: **Draft**, **Approved**, **Published**, and **Archived**.
- On the Kit Types tab, you can monitor the entire history of a kit type in a library study.

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

- In a study's design, on the Kits tab, you now have a new button called **Import Kit Type** that takes you to the study's library where you can choose which kits to import.

- Upon selecting a kit to import, you can define its usual details that you specify when you create a kit type in your Production study.

Details for clinical supply managers and depot users

Whether you're a clinical supply manager or a depot user, here's what's new for you:

- When creating shipments, you now have to specify the manufacturing lot ID for a pooled kit type. For example, if you want to create a shipment that contains multiple types of kits, and one of those kits is pooled, you need to select a manufacturing lot ID for that specific pooled kit type. When a shipment that has both pooled and non-pooled kits is created, the system generates separate shipment order - one for pooled kits and one for non-pooled kits.
- On the Shipments tab, you can see the specific category of a shipment in the new Category column. This column indicates whether the shipment is pooled or not.
- The system doesn't generate a kit order form for a shipment that contains pooled kits until the shipment is returned (and it has an **In Transit** status).
- When it comes to kit lists for pooled kits, you cannot deactivate or upload a kit list when that kit list contains pooled kits. Pooled kits are dynamically uploaded to the database as they are submitted in the integration file from the depot.

Details for site users

As a site user, there are no workflow changes for you. However, you should know that anytime you register a pooled shipment at your site, the receipt will contain the kit numbers, as usual. The lot numbers and the kits' sequence numbers are displayed only if you have unblinded access to the study.

Details for integration managers

If you're an integration manager and the study you're working with is integrated with another supply system, here's what you need to know:

- A pooled manual shipment can be raised through this integration by specifying the kit type and the kit count in the integration template. Pooled shipments can also be generated automatically as part of a study's resupply strategy.
- You or another user cannot add or remove kits from a pooled shipment.
- A pooled shipment's date is sent to the supply system as part of the integration. Another user cannot modify that pooled shipment's date in the User Interface (UI).
- A pooled shipment that is sent from one depot to another is handled outside of the system. For an Oracle Clinical One Platform user, this means that they cannot modify the shipment in Oracle Clinical One Platform.

Reporting, archives and analytics

- [Analyze your patients' data with the Subject Data Analysis dashboard](#)
Sponsor users can now gather more insights into a patient's journey through different stages in a clinical study.
- [New Blinded Kits dataset in Oracle Clinical One Analytics](#)
Blinded users can now work with the new Blinded Kits dataset in Oracle Clinical One Analytics.

- [Create pixel-perfect reports using BI Publisher](#)
Oracle Clinical One Analytics users can now create pixel-perfect reports in BI Publisher and schedule them to be run and emailed.
- [Enhancements to Oracle CRF Submit archives and reports](#)

Analyze your patients' data with the Subject Data Analysis dashboard

Sponsor users can now gather more insights into a patient's journey through different stages in a clinical study.

Tip:

Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study or just starting to work with analytics, reach out to your Oracle Project Manager to learn more about the Subject Data Analysis dashboard.

Analyzing your patients' data throughout a study has never been easier. With the Subject Data Analysis dashboard template, available in Oracle Clinical One Analytics, you can now oversee relevant parameters for patients during different stages in a clinical study. This dashboard assists you in making sound medical decisions, improving your subjects' safety, and improving the quality of your study's data.

Remember this template is available to you so that you don't have to create a dashboard from scratch and rather customize it to meet your needs. All you have to do is download the template, re-import it, adjust filters and tweak the data. For more information, see [Customize templates](#).

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can view data in a corresponding dashboard. To work with the Subject Data Analysis dashboard, you must have access to the following datasets :

- The Subject Form Items dataset
- The Subject dataset

Details for sponsor users

In Oracle Clinical One Analytics, the Subject Data Analysis dashboard leverages the existing functionality by combining data elements from multiple existing datasets. The main features of this dashboard consist of displaying the demographics of a subject, the events schedule, the severity of each adverse event and the concomitant medication, as well as lab data and other vitals of a subject. With this combination of key features, you can use the Subject Data Analysis dashboard in a variety of use cases:

- To identify a subject's crucial data such as ethnicity, age, gender, and much more.
- To monitor the progress of a patient on their study journey.
- To detect the occurrence of adverse events, their duration, and the concomitant medication that was administered during the course of the treatment.
- To get an overview of the lab test results during a subject's medication period.

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

New Blinded Kits dataset in Oracle Clinical One Analytics

Blinded users can now work with the new Blinded Kits dataset in Oracle Clinical One Analytics.

Particularly useful to clinical supply managers, the Blinded Kits dataset allows users to create blinded custom reports based on kit-related data collected within Oracle Clinical One Platform. This way, sponsor users with appropriate permissions can track shipments, lots, and kit statuses within their studies without unblinding risk.

Details for user administrators and global user managers

A new permission, *Run the Blinded Kits Dataset*, has been added to grant access to the Blinded Kits dataset. As a user administrator or global user manager, you can assign this permission to any sponsor user who must have the ability to work with this dataset in Oracle Clinical One Analytics. This new permission is included, by default, in the following predefined template study roles:

- Clinical Supply Manager
- View Only for Blinded Support Users
- Study Manager

Details for clinical supply managers and other sponsor users

The Blinded Kits dataset contains additional study metadata about, sites, depots, and kits. Not only does this allow you to control your supply system better, but it also provides the opportunity to answer numerous questions related to supply elements within your studies while remaining blinded. For example, you can build blinded custom reports and visualizations to get insights on kit inventory statuses, shipments, kit dispensation, lots, and so much more.

Remember that to properly visualize data when working with any dataset, you must include at least one element from the folder listed as required. When working with the Blinded Kits dataset, include data elements from the Kits (required) folder on your custom reports and start analyzing your study's supply system data.

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

Create pixel-perfect reports using BI Publisher

Oracle Clinical One Analytics users can now create pixel-perfect reports in BI Publisher and schedule them to be run and emailed.

Oracle BI Publisher is a reporting product from Oracle that lets you create and manage highly formatted reports, also known as pixel-perfect reports. Starting with this release, you can access BI Publisher from the Oracle Clinical One Analytics application.

The pixel-perfect reports you create through BI Publisher can use any of the existing datasets as data source. The same permissions that let you access specific datasets in Oracle Clinical One Analytics, which are assigned in Oracle Clinical One Platform, control your access to each dataset in BI Publisher. Additionally, for each report you can specify parameters to filter

data, select different layouts, select an output type from a wide list of available options, and many actions to manage the view and share of your reports. Some of these actions include:

- Export
- Share via link
- Send via email
- Schedule a job to run and distribute the report
- Manage report jobs

You can find additional information about pixel-perfect reports and BI Publisher in the *Analytics User Guide* after the Release Assessment (RAE) upgrade.

Enhancements to Oracle CRF Submit archives and reports

Subject PDFs now include Visit Date query details

Now, custom and manual queries can be created to check that the date entered for the **Visit Date** fits within the specified visit window defined for a study.

Visit Date query details are included in the subject PDF **eCRF Audit Trail History** section of Submission, Archival, and Custom archive requests.

Replacing the subject number with the randomization number is supported in subject PDFs and reports

Now, users can configure studies to replace the subject number with the randomization number after randomization. When configured, the randomization number is visible anywhere the subject number was displayed in the study.

The **Subject No:** field in the subject PDF header and the **Subject ID** column in the **Download Log** report display the original subject number assigned after screening or the updated subject number assigned after randomization, depending on when the PDF or the report is generated.

 **Note:**

The **Download Log** contains a history of all downloads and may include both values if subject PDFs were generated before and after randomization.

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

Form associations for two-section forms are now supported in subject PDFs

In a previous release, we introduced the ability to link between the sections of a two-section form (flat and repeating) and other form types.

Such associations, the removal of these associations, and all audit history details are now included in the subject PDFs.

More information about Linking forms can be found in the *Site User Guide*.

Email and in-application notifications are now available

Email and in-application notifications can be configured to notify sponsor and site users about the status of PDF and report requests and to inform sponsor users about site-level PDF request, download, and confirmation activities.

This feature, available in Testing and Production modes only, is turned off by default. To enable the feature and manage notifications, the *Manage Archives Settings* permission must be assigned to access the new **Archives Settings** tab available under Study Settings.

Table 2-2 Notification name, details, and required permissions

Notification name	Notification details	Required permissions to receive the notification
Request available for download	Site and sponsor users receive this notification when a request has been completed successfully and is available for download.	<ul style="list-style-type: none"> • <i>Run Archival PDFs for your site(s) (Site)</i> • <i>Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation</i>
Request failure	Site and sponsor users receive this notification when a request has failed to complete successfully.	<ul style="list-style-type: none"> • <i>Run Archival PDFs for your site(s) (Site)</i> • <i>Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation</i>
Request submitted by site user	Sponsor users receive this notification when a site user has generated a new request.	<ul style="list-style-type: none"> • <i>Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation</i>
Request shared with site downloaded	Sponsor users receive this notification when a request shared with a site has been downloaded by that site.	<ul style="list-style-type: none"> • <i>Run and download Site Confirmation and Download Log audit reports</i>
Request confirmed by site	Sponsor users receive this notification when a request shared with a site has been confirmed by the site after they have downloaded and reviewed its contents.	<ul style="list-style-type: none"> • <i>Run and download Site Confirmation and Download Log audit reports</i>
Storage limit has exceeded	Sponsor users receive this notification when the storage limit has reached 75% capacity.	<ul style="list-style-type: none"> • N/A: Sponsor users with access to Oracle CRF Submit receive this notification.

More information about this enhancement can be found in the *Reporting Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- [The clearChoice\(\) helper function now clears data](#)
- [Manage all custom rules in one place](#)
A new Rule Management page is available for rule designers to see and manage all custom rules in a study.

The clearChoice() helper function now clears data

The clearChoice helper function has been enhanced to clear the answers from multiple-choice questions like check boxes and drop-downs. Previously, the function removed the answers, converting them to null values, which is not a true clear.

Note:

When data is cleared, the answer is removed, and the questions status is reverted to that of an unanswered question.

For more information, see `clearChoice (Multiple-choice questions)` in the *Rules Developer Guide* and *Understanding data clearing* in the *Site User Guide*.

Manage all custom rules in one place

A new Rule Management page is available for rule designers to see and manage all custom rules in a study.

Rule designers with rule management related permissions can now access the new **Rule Management** page. You can still see existing rules by navigating directly to the visit and form where the rule exists in either Production, Testing or Training modes. However, this new page allows you to see and easily manage all custom rules within a study, for all modes, in one single place.

The rules in the Rule Management page are classified into two different tabs: **Design & Testing** and **Production & Training**. On the Design & Testing tab you can see all rules in any status (*Draft, UAT, Approved, Published* and *Invalid*), while only the published rules are listed under Production & Training. Each rule is listed along with the following details:

- Rule name and description
- Target form
- Target question
- Rule state (Only for Design & Testing)
- Whether the rule is enabled or disabled for a given mode
- Whether, when published, the rule runs on all data or future data only (Only for the Design & Testing)
- Last modified or last published date and user

Aside from viewing your rules, this page also provides you with the options to:

- Enable or disable a rule for a specific mode, either individually or in bulk.
- While in testing, change a rule to run either on all data or future data only when it gets published.

 **Note:**

This change will be applied as part of a study version tile move from Testing to Approved containers. This does not impact rules that are published with the slider (as a change of rule state).

- Find a given rule on the other tab to manage it for a different mode.
- Open a rule in the Rule editor to view it in read only mode.

 **Note:**

As of now, to edit a rule or create a new one you still need to access the rule editor from the study in Testing mode. These abilities are going to be added to the Rule Management page as part of a future release.

The new Rule Management page provides a complete overview of all custom rules within your study letting you streamline processes related to rule management. You can find additional information in the *Rules Developer Guide* after the Release Assessment Environment (RAE) upgrade.

User experience

- [Provide feedback on Oracle Clinical One Platform](#)
Provide feedback regarding Oracle Clinical One Platform within the application.

Provide feedback on Oracle Clinical One Platform

Provide feedback regarding Oracle Clinical One Platform within the application.

Users can now provide their feedback on Oracle Clinical One Platform within the application through a user satisfaction survey. Completing the user satisfaction survey allows you to promote new system functionality and reflect on the ability to follow guided learning. By collecting this feedback, Oracle is able to identify areas of improvement and enhance user satisfaction.

Survey configuration and management is available in the Oracle Guided Learning console. For more information, contact your Oracle Guided Learning administrator.

Other enhancements

Transfer active contacts and organizations between studies

Sponsor users can now transfer contacts and organizations (such as institutions, labs, or depots) with an **Active** status between studies without retiring them.

Previously, organizations and contacts had to be retired before users could transfer them to other studies.

Perform a visit edit to reflect its latest status update

 **Note:**

While the behavior described in the section below is not an enhancement, we recommend you follow these guidelines if a visit's status in your study is not updated appropriately after the upgrade to the 23.3 release.

Prior to the 23.3 upgrade, if you created a form that contained hidden and classified questions, and then proceeded to assign that form to a visit in your live study version, you may have noticed that the visit's status remained as **Complete** after the 23.3 upgrade.

As a site user, when you navigate to that visit and the hidden and classified questions remain unanswered in the newly added form, the status of that visit should automatically update to **Incomplete**. However, this doesn't happen until you edit a field in the visit or the form. We recommend you perform an edit that doesn't affect your subject's data to accurately reflect the status of that visit.

Fixed issues

- [All users](#)
- [Code lists](#)
- [Forms, visits, and rules](#)
- [Integrations](#)
- [Oracle Clinical One Analytics](#)
- [Reports, archives, extracts, and notifications](#)
- [Sites, labs, depots, settings, and user management](#)
- [Site users and subject data](#)
- [Fixed issues for integrations](#)
- [Fixed issues for reports and notifications](#)

All users

Subject Number scrolls off the screen when viewing previous visits

Now, the first three columns, the subject avatar, Subject, and Logs, are static and no longer disappear when scrolling through a subject's previous visits.

Retracted workaround: None. (Issue **35001431**)

Code lists

Consecutive validation messages for required Custom Code list fields are not read by the screen reader (former known issue)

Now, if you forget to complete multiple mandatory fields when creating a custom code list (on the Code List tab), your screen reader successfully reads all validation messages, ensuring you can complete the creation of the custom code list.

Retracted workaround: None. (Issue [34647715](#))

Forms, visits, and rules

Visits containing a large volume of data take too much time to load

Now, when you click to view visits that have a large volume of data captured, the page takes an adequate amount of time to load.

Retracted workaround: None. (Issue [36373738](#))

Radio button selections do not appear after saving a form

Now, selections made for radio buttons are shown after saving a form. Previously, at intermittent times, when you selected a radio button option and saved a form that contained a dynamic question, the value of the selection would not appear for that radio button option.

Retracted workaround: None. (Issue [36430361](#))

Questions in a form may appear unordered

Now, when you update one or multiple questions in any form type through Advanced Study Versioning (ASV), the order of the questions is preserved when you start a subject visit with an older version of the form in a live study version. (Issue [36352863](#))

All queries are closed in all instances for both repeating and two-section forms

Now, only impacted queries on cleared dynamic questions are closed for the instances on repeating and two-section forms. Previously, any time a dynamic question was cleared, all queries were closed for that question.

Retracted Workaround: None. (Issue [36005744](#))

The Complete option is not available for subjects when all visits are optional

Now, the **Complete** option, which appears under the Manage Subjects dropdown, on the Subjects page, is available when a study has been designed with all visits as optional and no **Earliest Visit to Complete Study** has been configured. In this case, only the Screening visit would need to be completed to progress the subject to study completion.

This also covers the following use cases:

- When a dynamic optional visit was triggered, even if no data was entered and the visit was not started or incomplete.
- When a dynamic optional visit was triggered in error.

This fix supports scenarios not covered in issue [36007300](#).

Retracted Workaround: None. (Issue [36246646](#))

The Complete option is not available for subjects with incomplete or in progress optional visits

Now, the **Complete** option is available to manage a subject when having an optional visit started, with a status of either Incomplete or In Progress.

This fix supports a scenario not covered in issue [36007300](#).

Retracted Workaround: None. (Issue [36267457](#))

Exit questions do not trigger the expected visits for branches with multiple visits

Now, selecting **Yes** for a branch visit exit question, thus opting to continue on the same branch, triggers the appropriate follow-up visit. Previously, in the context of a branch with multiple visits, three dashes (---) would be displayed in the visit train, preventing the subject from progressing on its current branch.

Retracted workaround: None. (Issue [35726231](#))

Unexpected number of optional visits appears when trigger question is answered

Now, in the context of a dynamic visit design, the correct number of optional visits appears when a trigger question is answered. Previously, all optional visits would appear in the visit train once the trigger question was answered.

Retracted workaround: None. (Issue [36070846](#))

Visits are not displayed in the correct order when multiple tiers are present

Now, visits are ordered logically whenever the study design features three or more tiers, each with multiple branches. Given the same study design, visits would previously be ordered incorrectly.

Retracted workaround: None. (Issue [36109118](#))

The Complete option is not available under Manage Subjects

Now, the **Complete** option, which appears under the Manage Subjects dropdown, on the Subjects page, is available when all visits left for a subject are optional, as long as all required visits are complete including the one set as the **Earliest Visit to Complete Study**, if defined.

In this scenario, only the required visits would need to be completed to progress the subject to study completion.

Retracted workaround: None. (Issue [36007300](#))

A user can't update a dynamic-visit trigger question

Now, a user can successfully update the answer to a question that triggers a dynamic visit after clearing all the data entered in the dynamic visit. Previously, a trigger question could not be updated, even after clearing the data.

Retracted workaround: None. (Issue [35717145](#))

Creating a new draft study version fails after importing from a library study

Now, creating a new draft study version that includes importing from a library study no longer fails if the library study is deleted after import.

Retracted workaround: None. (Issue **35940490**)

Kits added to an unscheduled visit for a copied library study are not visible in the study (former known issue)

Now, kits added to unscheduled visits in a copied library study that includes randomization design are visible in the study after saving its details.

Retracted workaround: None. (Issue **35712173**)

Queries can be created on a deleted repeating form instance (former known issue)

Queries for the following use cases can no longer be created on a deleted repeating form instance:

- When using a direct API call. The back-end API call now checks for the deleted form state before creating a query.
- When two users have the same repeating form instance open in their browsers. If User 1 deletes the form instance while it's still available in the browser of User 2, User 2 can no longer create a query via the User Interface (UI).

Retracted workaround: On the Queries sidebar, you no longer have to close queries if opened on a deleted row. (Issue **35604053**)

Dynamic visits are not displayed correctly when a decision visit is unskipped

Now, when you skip a decision visit and proceed past the dynamic visits it controls, then unskip the visit and answer the decision form, you can complete the dynamic visit without the requirement to complete the preceding dynamic visits.

For example, after un-skipping the decision visit and answering the item on the decision form to trigger dynamic Visit 4, you no longer need to complete the preceding visits: Visit 1, Visit 2, and Visit 3 first.

Retracted workaround: None. (Issue **35921814**)

A rule associated with the Visit Date does not run when the system automatically populates the Visit Date

Now, rules run successfully when the Visit Date is populated automatically by the system.

Retracted workaround: None. (Issue **35909061**)

Hidden and required questions are not considered when calculating a visit's status (former known issue)

Now, hidden and required questions are considered when determining whether a visit is complete. Previously, they were not.

Impact on already completed visits: After the upgrade to 23.3, if existing completed visits are opened or edited and contain at least one hidden, required question that is not complete, the visit status remains **Incomplete** until those questions are completed.

Retracted workaround: None. (Issue **35857474**)

Duplicate rows are displayed when viewing associated forms

Now, the system only lets one user at a time create or update a row association for a repeating form, avoiding the possibility of duplicate associations. Previously, duplicate associations could be made if two users created associations for a subject during the same log in session.

Retracted workaround: None. (Issue **35756400**)

The partialDateDiff Rules helper function incorrectly considers UNK as 00

Now, when UNK is entered for hours or minutes as part of a date-time item, the Rules helper function no longer considers that as 00 when comparing date values.

Previously, using the example below, the helper function (at the database level) considered UNK:UNK as 00:00 in the comparison logic, which resulted in an incorrect comparison.

- Date1: 2-Jun-2023 UNK:UNK
- Date2: 2-Jan-2023 00:01

Retracted workaround: None. (Issue **35904823**)

A lab form shows Completed even though all tests have not been entered

Now, view-only users no longer see a green icon indicating a Completed form when data entry on the lab form is incomplete. This issue did not impact users with data entry permission

Retracted workaround: None. (Issue **35835251**)

Integrations

Updates made through integration with Data Capture service are showing successful response but value is not updated

Now, when an update to a data element is sent through an integration with the Data Capture service, using REST APIs, changes are properly validated and identified. This results in an actual value update.

Retracted workaround: None. (Issue **36459618**)

Oracle Clinical One Analytics

Rows deleted from a two-section form are marked as not deleted in (DMW) Clinical data extract tables if you update the flat section of the form

Now, rows deleted in the repeating section of a two-section form retain the status DELETED = Y (Yes) in Oracle Clinical One Analytics data extract tables after editing a question in the flat section of the form.

Previously, the status of the deleted repeating rows was updated to DELETED = N (No), adopting the status of the item edited in the flat section of the form. (Issue **36293970**)

 **Note:**

The scope of impact and fix for this bug (36293970) is limited to Clinical data extracts, which are used exclusively in the DMW integration and are not available/accessible in Oracle Clinical One Analytics.

Study data elements are not loading after using drag-and-drop

Now, the page loads successfully after using drag-and-drop to move study data elements such as STUDY_ID_NAME and STUDY_TITLE in the **Kits and Randomization Design Dataset**.

Retracted workaround: None. (Issue **35854892**)

Admin API calls are not producing a result

Now, Admin API calls no longer fail to produce a result. This issue was caused by an Oracle internal change to the View Only for Unblinded Support Users (template) study role that has been corrected.

Retracted workaround: None. (Issue **35937653**)

The Unblinded visits REST API v6.0 requires excessive time to execute

Now, due to improved pagination, v6.0 of the Unblinded visits REST API generates in an acceptable amount of time.

Retracted workaround: None. (Issue **35775900**)

SCHEDULED_FROM_EVENT_NAME incorrectly displays the visit title refname

Now, the SCHEDULED_FROM_EVENT_NAME correctly displays the visit title, and a new data element displays the visit title refname. Previously, the visit title refname was displayed under SCHEDULED_FROM_EVENT_NAME.

Existing records in all applicable datasets where the SCHEDULED_FROM_EVENT_NAME column is present have been corrected; this includes the related DMW-loaded extracts DHVW_RAND_KITS_DESIGN_DATASET_V, DHVW_SUBJECT_VISITS_V, and DHVW_UNBLD_KITS_DATASET_V.

A new data element, SCHEDULED_FROM_EVENT_REFNAME, was added to the Event folder for the following Analytics datasets to address this issue going forward.

 **Note:**

For more information about the new data element, see Dataset descriptions.

- Blinded Kits dataset
- Blinded Subject Event dataset
- Kits and Randomization Design dataset
- Queries dataset
- Study Codelist dataset

- Study Design dataset
- Subject Form Items dataset
- Unblinded Kits dataset
- Unblinded Subject Event dataset

Retracted workaround: None. (Issue **35017937**)

Unable to view hidden items when data classification is applied

Now, hidden items with data classification applied can be viewed under ITEM_NAME in Oracle Clinical One Analytics datasets. Previously, a system-imposed character limit impacted what was displayed.

Retracted workaround: None. (Issue **36017180**)

Reports, archives, extracts, and notifications

User Assignment report takes a long time to generate

Now, the User Assignment Report generates within a reasonable time frame, as a result of performance improvements.

Retracted workaround: None. (Issue **35832979**)

Subject Data Extract fails to generate

Now, the Subject Data Extract generates as expected, following performance improvements.

Retracted workaround: None. (Issue **36125416**)

An Oracle CRF Submit Custom request, Advanced Setting is not configurable

Now, the Oracle CRF Submit Advanced Setting, **Include Study Name in the Subject File Name**, for Custom PDF requests, which defaults to Yes, can be changed to No.

Retracted workaround: None. (Issue **35758876**)

The Subject Data extract contains the incorrect site for an item edited after subject transfer (former known issue)

Now, if an item on the flat section of a two-section form is updated after a subject is transferred, the Subject Data extract includes the new site name for the updated item and not the previous site name.

Retracted workaround: None. (Issue **35904395**)

The Subject Data Extract (SAS) report fails if data values contain leading zeros

Now, the Subject Data Extract (SAS) report is generated successfully even when data values contain leading zeros. For example, if the Heart Rate captured on the Vital Signs form is 078.

Retracted workaround: None. (Issue **35606065**)

Form item options starting with < (less than) are not in a Blank Form PDF request

Now, form item options that start with < are present in the output files of an Oracle CRF Submit Blank Form PDF request.

Retracted workaround: None. (Issue **35905179**)

Oracle CRF Submit Custom PDF header limits display to 11 items

Now, Oracle CRF Submit Custom PDF requests can accommodate all 12 possible header items.

Retracted workaround: None. (Issue **35869771**)

The query count in the Subject Queries report does not match the user interface

Now, the query count in the Subject Queries report matches the query count in the Oracle Clinical One Platform user interface. Previously, the report included duplicate entries for some queries; other queries were missing, which caused the discrepancy.

Retracted workaround: None. (Issue **35976595**)

The Study Design report contains an incorrect Last Modified date

Now, updating kits in treatment arms does not result in an incorrect **Last Modified** date being displayed for kits in other treatment arms in the kit dispensation portion of the Study Design report.

Retracted workaround: None. (Issue **35760784**)

Sites, labs, depots, settings, and user management

The Effective Date for a lab normal range reduces by one day when a range update is saved

Now, the Effective Date, defined when you configure a lab normal range, is no longer reduced by one day after saving updates to the lab normal range. Previously, the system applied a conversion to the date based on the user's time zone, and in some cases, resulted in a reduction of one day. (Issue **36260224**)

Error encountered when trying to access the Source Data Verification tab

Now, users assigned to the *Rule Designer (template)* study role no longer encounter an error accessing the Source Data Verification tab on the Settings page.

Retracted workaround: None. (Issue **35997964**)

Processing data related to sites may take longer than expected

Processing and sending data related to site events for Oracle Clinical One Analytics no longer takes more time than expected. This issue was caused by the absence of a specific parameter that would return all data for all sites in a study, instead of data for a specific site in the study.

Retracted workaround: None. (Issue **36250794**)

Text entry when creating sites and depots for Chinese language studies caused randomization to fail (former known issue)

Now, when you create a site or depot for a Chinese language study, you are presented with a predefined list for the State/Province/County field, and text entry is no longer permitted. Previously, text entry allowed special characters to be entered; for example, 北京 could be entered for Beijing, resulting in failed randomization.

Retracted workaround: None (Issue **34765926**)

The tabs on the Global Settings page do not load or refresh as expected (former known issue)

Now, when you are on the Global Settings page, the settings displayed align with the tab selected.

Retracted workaround: Select the Users tab, then select the other tab that you want to access. (Issue **34638369**)

The Add Subject button is still visible despite system configuration

When a site has been selected from the Site filter, and the user clicks **Add Subject**, the system presents a message to the user informing them that they can no longer add subjects.

Now, when the filters on the subject listings page are set to All, users are also presented with the same message: You can no longer manually add subjects to this site. Previously, no message was displayed when the filters on the subject listings page were set to All and **Add Subject** was clicked.

Retracted workaround: None. (Issue **34742872**)

Site users and subject data

A repeating row or instance unexpectedly becomes unsigned or unverified

Now, when you clear a result only that instance of the form is unverified or unsigned. The SDV and **Signed** status of other repeating instances is not impacted. (Issue **36325535**)

A visit's status is incorrectly displayed as Unverified

Now, when you verify a visit that was previously unverified, and you refresh, close, and re-open that visit, its status is still displayed as **Verified**, as expected.

After the upgrade of release 23.3.1.3 is complete, we recommend you open any visits impacted by this issue. You will notice that their status is correctly updated as **Verified**. We do not recommend refreshing the **Subjects** page to ensure that your verified visits display the expected status.

 **Note:**

The existing Audit History for any impacted visits will display a new record indicating that the visit was verified appropriately. No other new changes will be displayed in a visit's audit history.

(Issue **36340891**)

A deleted row reappears when a user conducts Source Data Verification (SDV), Signs, Locks or Freezes at the visit level

Now, a row deleted from a repeating form, or the repeating section of a two-section form does not reappear when a user conducts visit-level Source Data Verification (SDV), Signing, Locking or Freezing. The deleted row previously appeared when the following actions occurred:

1. A user entered data in at least two questions in an instance, leaving at least one other question unanswered.
2. A user then cleared at least one question (using the clear functionality).
3. A user then deleted the row.
4. Visit level SDV, **Sign**, **Freeze** or **Lock** is performed.

After these steps, the deleted row is present in the UI. (Issue **36284515**)

Data for choice questions is not displayed for a visit

Now, the data for choice questions (drop-down, check box, and radio button) displays in a visit when you change the filter selection (within the visit) from **All reviews** to **Ready to Verify**. (Issue **36257210**)

Users in different time zones see different time data for the same date/time question

Now, the value entered for the time component of a date/time question is displayed to all users as entered, regardless of the viewing user's computer time zone setting.

Previously, the system converted the time value based on the time zone setting of the user viewing the data. (Issue **36308286**)

Visit schedule and data may not correspond to a selected subject

When you access a subject's visit, then access a second subject's visit, and return to the **Subjects** page, the expected visit schedule, as well as their associated and collected data is displayed in the application. Previously, you may have encountered an issue where you would see the projected visit schedule and form data associated with a different subject than the one you previously selected.

If you experienced this, know that this was an issue only affecting the User Interface (UI) and it didn't affect your study's data. (Issue **36208670**)

Partial dates prevent data from being collected in a lab form

If a subject's date of birth is configured as a Date/ Time question allowing partial dates, this no longer prevents a site user from properly collecting data in a lab form for lab units and ranges. Previously, when a subject's date of birth allowed the collection of partial dates (such as YYYY), the lab form wasn't loading and the application displayed a message stating that demographic data was required before filling in a subject's lab normals. (Issue **36221890**)

Username and password fields are not displayed in the Sign Data window

In the Production environment, when you attempt to sign data in your study, the Sign Data window displays the **Username** and **Password** fields, as expected. Previously, the window displayed an error message that didn't provide any helpful information and prevented you from successfully signing data. (Issue **36177246**)

Users cannot view or add form-level comments in a repeating form (former known issue)

Now, users can view and add form-level comments in a repeating form after clicking the hamburger icon at the form level, followed by clicking **View Comments** or **Add a comment**.

Retracted workaround: Open one of the records in the repeating form table, then click the hamburger icon at the form or item level to view or add comments. Issue (35682899)

Users with the Japanese language selected are unable to enter dates

Now, Japanese language users can enter dates, for example, Informed consent date and Date of Birth, using the calendar to select a date for an item. Previously, users were presented with the error, The month you selected is out of scope, please select a value from 1 to 12.

Retracted workaround: None. (Issue 35475774)

Rest API updates

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

Permissions

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

Services updates

The following service is added:

- [Designer EDC](#)

The following services are updated:

- [Codelist](#)
- [Data Action](#)
- [Data Hub](#)
- [Data Integration](#)
- [Data Capture](#)
- [Designer](#)
- [File Upload](#)
- [Notifications](#)
- [Library](#)
- [Randomization and Supplies](#)
- [Query](#)
- [Rule Designer](#)
- [Sites and Depots](#)

Designer EDC

**Note:**

Designer EDC endpoints are listed under the Designer category.

Change	Endpoint
New	<ul style="list-style-type: none"> POST /v1.0/studies/{studyId}/formSummaryInfo

Codelist

Change	Endpoint
Deleted	<ul style="list-style-type: none"> DELETE /v2.0/codelist/code/{codeId}

Data Action

Change	Endpoint
New	<ul style="list-style-type: none"> GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/validate/dataelements
Deprecated	<ul style="list-style-type: none"> GET /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements

Data Hub

Change	Endpoint
New	<ul style="list-style-type: none"> POST /v1.0/tenant/{tenantId}/studies/{studyId}/{mode}/blindedKits POST /v2.0/tenant/{tenantId}/studies/{studyId}/codelists POST /v3.0/tenant/{tenantId}/studies/{studyId}/dataCollection POST /v3.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems POST /v8.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

Change	Endpoint
New	<ul style="list-style-type: none"> • PUT /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/formStatus • GET /v2.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v2.0/studies/{studyId}/{mode}/subjects/history/all • GET /v2.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Data Capture

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/studies/{studyId}/{mode}/subjects/screeningnumber • PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/randomizationnumber/{randNumber} • GET /v1.0/studies/{studyId}/{mode}/svf • PUT /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/undoSubject • POST /v11.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v3.0/studies/{studyId}/{mode}/subjects/migratesubject • POST /v4.0/studies/{studyId}/{mode}/dataelements/multiple • GET /v4.0/studies/{studyId}/{mode}/subjects • GET /v8.0/studies/{studyId}/{mode}/visitstatus • GET /v9.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • PUT /v9.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}

Change	Endpoint
Deprecated	<ul style="list-style-type: none"> • PUT /v1.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/visit/verify/history • GET /v1/studies/{studyId}/{mode}/subjects/history/all • GET /v1/studies/{studyId}/{mode}/subjects/history/{subjectId} • POST /v1/studies/{studyId}/{mode}/subjects/migratesubject • POST /v1/studies/{studyId}/{mode}/subjects/visitschedule • GET /v1/studies/{studyId}/{mode}/visitstatus/dateRange/{subjectId} • POST /v10.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v2.0/studies/{studyId}/{mode}/dataelements/verify • GET /v2.0/studies/{studyId}/{mode}/subjects/history/all • POST /v2.0/studies/{studyId}/{mode}/subjects/visitschedule • POST /v3.0/studies/{studyId}/{mode}/dataelements/freeze • GET /v3.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId} • GET /v3.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId} • GET /v4.0/studies/{studyId}/{mode}/subjects/history/all • GET /v4.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v5.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • GET /v6.0/studies/{studyId}/{mode}/subjects/history/{subjectId} • POST /v7.0/studies/{studyId}/{mode}/dataelements • GET /v7.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v7.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • PUT /v7.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId} • PUT /v8.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v8.0/studies/{studyId}/{mode}/visitstatus/subjects • PUT /v8.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId} • GET /v9.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId} • PUT /v9.0/studies/{studyId}/{mode}/dataelements/{dataElementId}

Designer

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/studies/{studyId}/versions/{version}/forms/{formId}/formLogo • GET /v5.0/studies/{studyId}/kits • POST /v7.0/studies/{studyId}/versions/{version}/kits • GET /v7.0/studies/{studyId}/versions/{version}/kits • GET /v7.0/studies/{studyId}/versions/{version}/kits/{kitId} • POST /v9.0/studies/{studyId}/versions/{version}/kits • GET /v9.0/studies/{studyId}/versions/{version}/kits • GET /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • PUT /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • DELETE /v9.0/studies/{studyId}/versions/{version}/kits/{kitId} • GET /v9.0/studies/{studyId}/versions/{version}/visits
Re-instated	<ul style="list-style-type: none"> • POST /v1.0/report/{reportName} • POST /v2.0/report/{reportName}

File Upload

Change	Endpoint
Deleted	<ul style="list-style-type: none">• POST /v3.0/storage/{bucketName}/{objectName}

Notifications

Change	Endpoint
Deprecated	<ul style="list-style-type: none">• POST /v1.0/studies/{studyId}/{mode}/notificationlog• GET /v1.0/studies/{studyId}/{mode}/notificationlog• POST /v2.0/studies/{studyId}/{mode}/notificationlog• POST /v3.0/studies/{studyId}/{mode}/notificationlog

Library

Change	Endpoint
New	<ul style="list-style-type: none">• POST /v1.0/libraryObjects/kits• GET /v1.0/libraryObjects/kits• POST /v1.0/libraryObjects/kits/bulk/{status}• GET /v1.0/libraryObjects/kits/pagination• GET /v1.0/libraryObjects/kits/{libraryKitId}• PUT /v1.0/libraryObjects/kits/{libraryKitId}• DELETE /v1.0/libraryObjects/kits/{libraryKitId}• GET /v1.0/libraryObjects/kits/{libraryKitId}/history

Randomization and Supplies

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • PUT /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits • GET /v1.0/studies/{studyId}/{mode}/depots/{depotId}/inventory/kits/{inventoryId}/historyById • POST /v1.0/studies/{studyId}/{mode}/locally-sourced-kits • GET /v1.0/studies/{studyId}/{mode}/locally-sourced-kits • GET /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • PUT /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • DELETE /v1.0/studies/{studyId}/{mode}/locally-sourced-kits/{id} • POST /v1.0/studies/{studyId}/{mode}/orders/{shipmentNumber}/assignkits • GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/details • GET /v1.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/locally-sourced-kits • POST /v1.0/studies/{studyId}/{mode}/visits/subjectvisits2s • POST /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots • PUT /v2.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • GET /v3.0/studies/{studyId}/{mode}/kitlists • GET /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots • GET /v3.0/studies/{studyId}/{mode}/lots/manufacturing-lots/{id} • POST /v3.0/studies/{studyId}/{mode}/resupply/manual • GET /v3.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits • GET /v5.0/studies/{studyId}/{mode}/shipments • GET /v7.0/studies/{studyId}/{mode}/orders • GET /v7.0/studies/{studyId}/{mode}/orders/{shipmentId}

Query

Change	Endpoint
New	<ul style="list-style-type: none"> • PUT /v9.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate
Deprecated	<ul style="list-style-type: none"> • PUT /v2.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate

Rule Designer



Note:

Rule Designer endpoints are listed under the Rules category.

Change	Endpoint
New	<ul style="list-style-type: none">• POST /v1.0/rulemgt/studies/{studyId}/{mode}/filteredlist• PUT /v1.0/rulemgt/studies/{studyId}/{mode}/{publishRun}• GET /v1.0/rulemgt/studies/{studyId}/{ruleId}/rulehistory• GET /v2.0/rule/studies/{studyId}/{mode}/simple• POST /v6.0/studies/{studyId}/{mode}/report/{reportName}

Sites and Depots

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/addresses • POST /v1.0/contacts • GET /v1.0/contacts • DELETE /v1.0/contacts/contact/{contactId} • PUT /v1.0/contacts/deleteContact/{id} • POST /v1.0/contacts/validateFields • GET /v1.0/contacts/{contactId} • PUT /v1.0/contacts/{contactId} • PUT /v1.0/entitymanagement/entities/{entityType}/{srcEntityId}/manage • PUT /v1.0/entitymanagement/entities/{entityType}/{srcEntityId}/manage/all • GET /v1.0/entitymanagement/studyentities/{entityType}/{tenantEntityId}/details • GET /v1.0/entitymanagement/tenantentities/{entityType}/{tenantEntityId}/details • POST /v1.0/facilities/{InstitutionId} • GET /v1.0/facilities/{InstitutionId} • PUT /v1.0/facilities/{InstitutionId} • POST /v1.0/organizations • GET /v1.0/organizations • PUT /v1.0/organizations/deleteOrganization/{id} • POST /v1.0/organizations/validateFields • GET /v1.0/organizations/{id} • PUT /v1.0/organizations/{id} • DELETE /v1.0/organizations/{id} • POST /v1.0/sdfs/migration • GET /v1.0/sdfs/migration/{tenantId}/status • POST /v1.0/studies/{studyId}/{mode}/report/{reportName} • GET /v1.0/studies/{studyId}/{mode}/sdfs/depot/{pathAttr} • POST /v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties • PUT /v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties • POST /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties • PUT /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propName} • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType} • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/country/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{kitTypeId}/shipToAddress • POST /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/kitSettings/{sdfId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId}

Change	Endpoint
	<ul style="list-style-type: none"> • PUT /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId} • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/sdf/{sdfType}/{sdfId} • DELETE /v1.0/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId} • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/kitSettings/{kitTypeid} • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/locallySourced • GET /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/sdfRegion/{sdfId} • PUT /v1.0/studies/{studyId}/{mode}/sdfs/{sdfType}/status • DELETE /v1.0/tenantsite/associations/{associationId} • GET /v1.0/tenantsite/associations/{associationId}/addresses • POST /v1.0/tenantsite/associations/{associationId}/studySites • GET /v1.0/tenantsite/associations/{associationId}/studySites • GET /v1.0/tenantsite/{associationType}/associations • POST /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • GET /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • PUT /v1.0/tenantsite/{entityType}/{entityId}/{associationType}/associations • POST /v2.0/studies/{studyId}/{mode}/labs • GET /v2.0/studies/{studyId}/{mode}/labs • POST /v2.0/studies/{studyId}/{mode}/labs/siteslabs • PUT /v2.0/studies/{studyId}/{mode}/labs/{studyLabId} • DELETE /v2.0/studies/{studyId}/{mode}/siteslabs • POST /v3.0/studies/{studyId}/{mode}/report/{reportName}
Deprecated	<ul style="list-style-type: none"> • POST /v1.0/studies/{studyId}/{mode}/labs • PUT /v1.0/studies/{studyId}/{mode}/labs/{id} • DELETE /v1.0/studies/{studyId}/{mode}/labs/{id} • POST /v1.0/studies/{studyId}/{mode}/siteslabs • DELETE /v1.0/studies/{studyId}/{mode}/siteslabs • POST /v1/studies/{studyId}/{mode}/sdfs • DELETE /v1/studies/{studyId}/{mode}/sdfs/deleteDepotEmail • POST /v1/studies/{studyId}/{mode}/sdfs/sdf • PUT /v1/studies/{studyId}/{mode}/sdfs/sdf/{sdfId} • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId} • POST /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address/{addressId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/address/{addressId} • POST /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property • PUT /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId} • DELETE /v1/studies/{studyId}/{mode}/sdfs/{sdfId}/property/{propId}

Release impact for other applications

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

Oracle Life Sciences Data Management Workbench (DMW)

- Queries created to validate the Visit Date are not available in Oracle DMW. For more information about these queries, see [Create queries on visit date](#).
- Subject numbers replaced by the randomization number are not available in Oracle DMW. For more information, see [Setting impact: Replace Subject Number with Randomization Number](#).

Oracle Clinical One Analytics also known as Data Hub

- Queries created to validate the Visit Date are not available in Oracle Clinical One Analytics. For more information about these queries, see [Create queries on visit date](#).
- The following site set-up enhancements are not supported in Oracle Clinical One Analytics.
 - Creating and managing study organizations, such as sites, labs, or depots, along with their contacts at the global level. For more information about this feature, see [Manage study organizations in one system](#).
 - The option to transfer active contacts and organizations between studies. For more information about this feature, see [Transfer active contacts and organizations between studies](#).
 - Subject numbers replaced by the randomization number are not available in Oracle Clinical One Analytics or in the ODM XML extract. For more information, see [Setting impact: Replace Subject Number with Randomization Number](#).

Oracle Clinical One Digital Gateway configured integrations

- Replacing the subject number with the randomization number is not supported for all integrations. For a list of supported integrations, see [Setting impact: Replace Subject Number with Randomization Number](#).

Oracle Central Coding

- Replacing the subject number with the randomization number is not supported in Oracle Central Coding. If this setting is enabled, the new subject number does not appear in Oracle Central Coding. For more information about this setting, see [Setting impact: Replace Subject Number with Randomization Number](#).

3

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 23.2

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)
- [Rest API updates](#)
See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs, available upon the Production release.
- [Release impact for other applications](#)
This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.2 release.

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

Table 3-1 Patch log

Release Number	Release Date	Notes
Release 23.2.1	30-October-2023	<p>For this release, we fixed six issues related to forms, visits, rules, reports, and notifications. For more information, see:</p> <ul style="list-style-type: none">• Issues 35560725, 35692719, 35726231, 35401876 in Forms, visits, and rules.• Issues 35781902 and 35826804 in Reports, archives, extracts, and notifications. <p>Enhancements related to Oracle Central Coding and Oracle Clinical One Analytics have also be introduced in this release. For more information, see:</p> <ul style="list-style-type: none">• Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects• Enhancements to Oracle Clinical One Analytics

Table 3-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.2.1.1	22-November-2023	<p>For this release, we fixed some issues related to data collection and reporting. For more information, see:</p> <ul style="list-style-type: none">• Issues 35852581, 35963321, 35917673, and 35917721 in Site users and subject data.• Issue 35972590 in Reports, archives, extracts, and notifications.• Issue 35994707 in Oracle Clinical One Analytics.• Issue 35940121 in Facilities, settings, and user management.

What's new

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

Data collection

- [Enhanced way of clearing dynamic questions and forms](#)
Site users can now easily clear dynamically-displayed questions, forms, repeating sections in a two-section form, and form associations included in the same visit with fewer manual steps.
- [Lock a subject](#)
Sponsor users can lock a subject to prevent any user from making further changes to that subject.

Enhanced way of clearing dynamic questions and forms

Site users can now easily clear dynamically-displayed questions, forms, repeating sections in a two-section form, and form associations included in the same visit with fewer manual steps.

If you complete a dynamically-displayed question (child question) in error and then need to update the determining question (parent question), you can do this in a much

easier way. Previously, you had to first manually remove the data from all of the dynamically-displayed questions to update the answer of the determining question. Now, the user experience is easier and faster - once you attempt to clear a determining question, the system indicates which of its dynamically-displayed elements are automatically cleared and which ones you'll have to manually clear.

 **Note:**

This enhancement applies to any type of dynamic question, dynamic form, dynamic section in a two-section form, and form associations included in the same visit as their determining question, except for dynamically-displayed questions that are frozen, locked, read-only, or hidden, as they need to be manually cleared. Clearing form associations only removes the link between the forms, the data already collected in the linked forms will not be impacted.

 **Caution:**

While this enhancement applies to forms, dynamic sections in a two-section form, and form associations, too, for the sake of clarity and brevity the enhancements below are described referring to dynamic questions. Every behavior described below applies to all of the above-mentioned elements, as well.

Whether you want to update or clear a determining question, here's what you need to know:

- Whenever you attempt to update a determining question's answer, a new dialog is displayed informing you that you're attempting to update data that would result in the clearing or hiding of certain questions in your form in the same visit. The dialog lists the impacted questions or forms. This dialog is displayed only if the dynamically-displayed questions were previously answered. If there is no answer associated with them, you are prompted directly to enter a reason for this change.
- If there are any dynamically-displayed questions that are locked, frozen, hidden, or read-only associated with the determining question that you're trying to update, all of these questions that are not hidden to you are also displayed in the dialog.
- If you want to clear answers for dynamically-displayed questions, besides being prompted to enter a reason for this change, the same dialog appears indicating that data will be cleared for these questions.
- If the questions you are attempting to clear or update are also associated with future visits, the dialog indicates that you have to manually clear dynamically-displayed questions before updating the determining question.
- If there are multiple layers of dynamically-displayed questions (for example, a child question can act as the determining parent question for other dynamic questions), then you must manually clear any "grandchildren" questions. For example, if you attempt to clear the answer for parent question A, the system could clear the answer to child question B. But if child question B has other dynamic questions determined by its answer (questions C and D), then you must first clear the answers for the grandchildren questions (questions C and D). Only after that, will the dialog display the dynamically-displayed questions that are directly impacted by the given determining question (parent).
- If you attempt to clear any dynamically-displayed questions that were previously signed or verified, those questions become unsigned and unverified.

- All dynamically-displayed questions that are cleared are displayed, in the Answer & Visit History, with a status of **Cleared-Dynamic hidden**.

More information on this enhancement can be found in the *Site User Guide* after the Release Assessment Environment (RAE) upgrade.

Lock a subject

Sponsor users can lock a subject to prevent any user from making further changes to that subject.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can lock an entire subject to prevent users from adding new or updating existing data for that subject, including:

- New visits and events (Scheduled or unscheduled)
- Signing
- Verifying
- Freezing
- Unfreezing
- Screening
- Randomization
- Transfer
- Withdrawal
- Completion
- Dispensation
- Changing a subject's number
- Data entering or API loading data
- Running programmable rules

Users assigned the *Lock Subject Data Entered at a Site* permission can also unlock a subject.

Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- Subject locking is available in Testing, Training, and Production mode.
- On the Subjects page, under the View filter, you can now select **Locked** or **Unlocked** to view any locked or unlocked visits for subjects.
- On the Subjects page, a lock icon () appears next to the subject, indicating that it is locked, along with a *Subject Locked* status in the Subject History side panel.

 **Note:**

While subject locking is in progress, the *Subject Locked* status will not be reflected in the subject's history until the lock action has completed.

- When unlocked, an icon () appears next to the subject, along with a status of *Subject Unlocked* in the subject's history.
- Locking all subjects at a site does *not* prevent additional subjects from being added. On the Sites page, the **Add Subjects** option must be set to Off to disallow users from adding additional subjects.
- A subject can be locked even if there are incomplete visits or open queries for that subject.
- When a subject is locked and any data is unlocked at the visit level, the subject's status will update to *Subject Unlocked*.
- If all data is locked at the visit level, the subject is locked at the casebook level.
- When a subject is locked, the subject's existing data becomes read-only.
- Existing data remains signed, verified, and frozen as it was prior to the subject lock.

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

Details for site users

Site users can view the statuses for locked and unlocked subjects, so long as they have the corresponding permissions to see that element.

- A lock icon () appears next to a subject, along with a status of *Subject Locked* in the Subject History, indicating the subject has been locked by a sponsor user.
- An unlocked icon () appears next to a subject, along with a status of *Subject Unlocked* in the Subject History, indicating the subject has been unlocked by a sponsor user.

Impact on reports

Updates to the Subject Events Report can be found in the *Reporting Guide* after the RAE upgrade.

Already working in a live study?

At the time of the RAE upgrade, if all visits are locked, you will still need to explicitly lock the subject in order for the subject to be considered locked. It will also be possible to lock or unlock a subject that was entered in a study prior to this upgrade.

Additional information on subject locking can be found in the *Sponsor and CRO User Guide* after the RAE upgrade.

Related Topics

- Lock a form or visit

- Unlock a form or visit
- Lock a query
- Unlock a query

Data review

- [Auto-update of support template roles for existing studies](#)
Starting with this release, the View Only for Unblinded Support Users (template) role is updated automatically with new permissions.

Auto-update of support template roles for existing studies

Starting with this release, the View Only for Unblinded Support Users (template) role is updated automatically with new permissions.

With the introduction of this enhancement, support users who are assigned the View Only for Unblinded Support Users (template) role are automatically updated with any new permission introduced for a given release. Previously, new permissions for new features had to be manually assigned to the support users and only then could they have access to the new functionality to assist customers in existing studies that take advantage of any new feature.

Details for support users

The View Only for Unblinded Support Users (template) role will update only during Oracle Life Sciences Clinical One Platform upgrades. With this release, the View Only for Unblinded Support Users (template) role receives the following permissions:

- Permissions related to Analytics View classified data
 - View Classified Subject Data Only
- Permissions related to re-running rules
 - *Re-run rules*
- All the permissions of the ODM
 - Execute ODM Clinical Data API with Hidden Data
 - Execute ODM Clinical Data API without Hidden Data
 - Execute ODM Metadata API
 - Execute ODM Administrative Data API
- Extract role Permission to run Archives by site
 - Run the Archival PDF for your site

Also, we removed the permission to *Edit classified subject data*.

Already working on a live study?

Users with the *View Only for Unblinded Support users (template)* role will have their permissions updated on live studies, as soon as the Release Assessment Environment (RAE) upgrade completes, and subsequently with every new permission on future releases.

For more details, see *View only for Unblinded Support Users*.

Integrations

This section includes enhancements to integrations configured in the Oracle Clinical One Digital Gateway and other integrations such as Oracle Central Coding.

- [Oracle Siebel CTMS \(report\) now supports the ability to map multiple form items](#)
- [Screen fail enhancements](#)
- [Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects](#)

Under the Study Settings tab, you can prevent Oracle Clinical One Platform from sending verbatim terms entered by users to Oracle Central Coding for New or Screen Failed subjects.

Oracle Siebel CTMS (report) now supports the ability to map multiple form items

You can now map multiple form items, for example, Date of Birth (partial) and Date of Birth (full) to a common element in the configuration file.

 **Note:**

This enhancement only applies to the Oracle Siebel CTMS (report) and not the standard report available in the user interface, Subject Data for CTMS report.

Screen fail enhancements

Study completion and withdrawal events for screen failed subjects can now integrate with downstream systems

Integrating the study completion and withdrawal events for screen failed subjects with downstream systems is now possible. Previously, this was only possible for screened subjects.

 **Note:**

This enhancement is applicable for those studies where subject completion and withdrawal are supported for screen failed subjects. This is controlled by the study setting **Screen Failed Subjects**. For more information, see Specify study, enrollment, and visit settings

User-entered screen fail visit dates now integrate with downstream systems

Screen fail visit dates entered manually in Oracle Life Sciences Clinical One Platform studies now integrate with downstream systems. Previously, only the system-generated screen fail date was integrated.

What do you need to do to take advantage of these enhancements

An integration template update is required to take advantage of these enhancements. Work with your Oracle Project Manager to make the necessary updates.

Disable sending verbatim terms to Oracle Central Coding for New or Screen Failed subjects

Under the Study Settings tab, you can prevent Oracle Clinical One Platform from sending verbatim terms entered by users to Oracle Central Coding for New or Screen Failed subjects.

A new study setting, **Code data for new and screen failed subjects**, has been added to the Study Settings tab to control the flow of verbatim terms to Oracle Central Coding for subjects with a status of *New* or *Screen Failed*.

Details for sponsor users

When it comes to your workflow, here's what you should know:

- No new permissions are required to access the setting.
- The **Code data for new and screen failed subjects** is set to **Yes** by default to maintain the current system functionality of sending verbatim terms for all subjects.
- This setting can be changed at any time.
 - Changing the setting to **No** has no impact on verbatim terms already sent to Oracle Central Coding, and new verbatim terms are sent once the subject status is changed to *Enrolled* or *Active*.
 - Changing the setting back to **Yes** results in verbatim terms, entered before and after changing the setting to be sent to Oracle Central Coding.
- There is no impact to reports.

For more information, see Specify study, visit, limit, and cohort settings in the *Sponsor and CRO User Guide*.

Reporting, archives, and analytics

- [Enhancements to Oracle Clinical One Analytics](#)
- [Enhancements to Oracle CRF Submit archives and reports](#)
- [Enhancements to Randomization and Trial Supply Management reports](#)
Improvements have been made to some of the reports related to Randomization and Trial Supply Management (RTSM).
- [Diversity & Inclusion dashboard in Oracle Clinical One Analytics](#)
The Diversity & Inclusion dashboard is now available in Oracle Clinical One Analytics allowing you to visualize the diversity on the subject population of a clinical study. This dashboard can provide an insight of the trial objectivity to test the safety and efficacy of a drug formulation.
- [New Study Codelist datasets](#)
You can now work with the Study Codelists dataset in Oracle Clinical One Analytics to create reports to identify the current global and study-level code lists, as well as the historical changes to the code lists configuration.

Enhancements to Oracle Clinical One Analytics

Support for data classification security

With the support for the data classification security, all questions in a form that you can view in Oracle Clinical One Platform are now visible to you in Oracle Clinical One Analytics, as well. Your view is determined by any data classifications that are applied to those questions and your permissions to view them. Before this enhancement, all questions that had any data classifications applied to them were hidden to all users in Oracle Clinical One Analytics, regardless of their permissions.

The data classification security is only applicable for the Subject Form Items dataset and the Queries dataset.

Oracle Analytics Server (OAS) upgrade

Oracle Clinical One Analytics Data Visualizer is getting an OAS upgrade from 5.9 to 6.4. Although the current functionality remains basically the same, there are some minor changes in appearance of the Data Visualizer user interface (UI). These changes shouldn't affect the way you currently work with Oracle Clinical One Analytics. However, you can refer to the *Analytics User Guide* for step by step help on different tasks or reach out to your Oracle Project Manager for more information on Oracle Clinical One Analytics training and mentoring.

This upgrade is not impacting any of your saved reports, projects and data.

New data elements for query and verification reporting

With the new data elements added to multiple datasets in Oracle Clinical One Analytics, data managers can now create enhanced reports about query and verification. These changes include:

- A boolean flag for items containing queries, irrespective of the status, in the Subject Form Items dataset.
- A boolean flag for events requiring verification in the Blinded and Unblinded Subject Event dataset.
- Current user role data in the audit and reference folders.

Tip:

Never heard of a boolean flag? A boolean flag is a True or False value to identify an object as having a particular characteristic or not.

Additional kit identifiers

The Unblinded Kits dataset now has two additional kit identifiers, to allow data managers to monitor kits in a closer manner. The two new data elements are available in the Kit folder and, because this data is unavailable from the Oracle Clinical One Platform user interface, these are populated through integration.

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

Enhancements to Oracle CRF Submit archives and reports

Study withdrawal and completion data for screen fail subjects is now included in subject PDFs

If the study setting, **Screen Failed Subjects**, is set to either **Allow Withdrawal** or **Allow Completion**, a site user can complete a withdrawal or completion visit for a screen-failed subject. The data captured in the visit is now included in the subject PDFs.

 **Note:**

For more information about this setting, see Specify study, enrollment, and visit settings.

Sponsor users can now share the Kit Chain of Custody (Blinded) report with sites

Both sponsor and site users are required to archive the **Kit Chain of Custody (Blinded)** report, but site users are only sometimes granted access to this report. For more information about this report, see the Kit Chain of Custody (Blinded) report.

Sponsor users can now generate and share the **Kit Chain of Custody (Blinded)** report. The (new) site shareable report is under the Archives tab. The (existing) non-shareable report is under the Reports tab.

 **Note:**

The permission, *Run the Blinded Chain of Custody Report* is required to generate the shareable report.

Although the settings for each report are different, the output is the same, as the output is generated from the same database tables and includes the following for each kit.

- Creation of the kit
- Assignment to a lot
- Assignment to a depot
- Shipped to a site
- Dispensation to a subject
- Destruction of a kit

Site users can only download this report. The report appears under the **Download Archives** side panel after being successfully generated by the sponsor and it only contains information for the site that you're assigned to.

**Note:**

Site user download and confirmation actions are tracked in the Download Log report and the Site Confirmation report.

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

PDF headers now include the Locked form status for non-repeating and repeating forms for locked subjects

As a part of the 22.3 release, we announced that the **Locked** status is included in the PDF header when forms are locked at the visit and form level.

For this release, the subject PDF header, specifically the Form Status row, now displays the **Locked** status for all forms in all visits when a subject is locked. The status appears in the output files generated for Submission, Archival, and Custom PDF requests.

Subject PDF behavior when a dynamic question is edited after data entry has already occurred

Suppose a site user incorrectly answers a determining (parent) question, such as a question that determines the treatment arm for a subject, and enters data in any dynamically generated element, such as a form question. The determining (parent) question can be edited by the user to remedy the situation. For more information about this feature, see *Clearing dynamic questions and forms*.

If the determining (parent) question is edited, the system asks the user to confirm if the data entered incorrectly on the dynamically generated elements should be cleared. If yes, the data except for data on frozen, locked, read-only, and hidden forms and questions is cleared.

If this occurs, subject PDFs capture information in the following ways.

- The cleared questions display as empty cells in the subject PDF, and the Reason for Change, selected when the dynamic question was updated, is displayed in the question audit trail.
- Form statuses, for example, **Complete**, **Signed**, and **Verified**, update accordingly when the dynamic question is edited. The statuses are accurately reflected in the subject PDF.
- A signature is invalidated if clear data is applied to already signed data. If this happens, the subject PDF includes the signature invalidation audit for the form.
- If the value cleared is a variable in a calculation, the calculation runs again upon saving. The calculated value is updated based on the logic of the calculation rule. The subject PDF reflects the correct data displayed in the question and the calculated value.
- Open queries (auto and manual) are closed with the Reason for Change, *Item Cleared*, captured for each query.
- Form disassociation details are captured in the subject PDF audit history if form associations are removed.
- If a dynamic visit containing multiple forms is triggered, and the visit is canceled with no data entered into the dynamic visit, the Date of Visit form status is updated to **Not Started**, and the remaining added forms do not appear in the subject PDF.

- If a dynamic visit containing multiple forms is triggered with data entered for the dynamic visit, and the entered date is cleared, the visit is canceled, and all forms have a status of **Incomplete**, with the exception of the Date of Visit form.

Enhancements to Randomization and Trial Supply Management reports

Improvements have been made to some of the reports related to Randomization and Trial Supply Management (RTSM).

Certain edge cases are also addressed through this update, primarily in the context of replacement kits.

Details for clinical supply managers

The following improvements have been brought to reports:

Report	Enhancements
Shipment Order Summary report	<ul style="list-style-type: none"> • A new Received By column has been added. • Users can now schedule the report.
Kit Dispensation report	In addition to .html and .pdf, this report is now available in CSV format.
<ul style="list-style-type: none"> • Subject Events Report • Kit Chain of Custody (Blinded) report • Kit Chain of Custody (Unblinded) report 	<ul style="list-style-type: none"> • These reports have been updated to include kit replacement data, in order for sponsor users to be able to determine which kits have been replaced in a study. • This includes new columns for dispensation dates, replacement kit numbers, as well as reasons for replacement.
<ul style="list-style-type: none"> • Subject Visits (Blinded) report • Subject Visits (Unblinded) report 	<ul style="list-style-type: none"> • These reports now include kit replacement data, in order for sponsor users to be able to determine which kits have been replaced in a study. • This includes new columns for dispensation dates, replacement kit numbers, and reasons for replacement. • Users can now filter on projected window dates.
	<div style="border: 1px solid green; padding: 10px; background-color: #e0f2f1;"> <p> Tip:</p> <p>as a sponsor user, use this new feature to preview potential upcoming kit dispensations within a particular window of time.</p> </div>
Kit Inventory (Blinded) report	New Blinded Lot ID and Blinded Lot Expiry Date columns have been added for better supply management.
Kit Inventory (Unblinded) report	New Manufacturing Lot Expiry Date , Blinded Lot ID , and Blinded Lot Expiry Date columns have been added for better supply management.

Report	Enhancements
Study Design report	<ul style="list-style-type: none"> The following column names from the Signature Configuration section have been updated: <ul style="list-style-type: none"> – Required Forms to Required Form(s) – Required Visits to Required Visit(s) – Effective Scope to Required on Selected Visits – Target Date to Target The visit summary of the report has been updated to display the visit branch, in order for users to differentiate between visits when these are named identically.
Study Enrollment report	<ul style="list-style-type: none"> This report has been updated to feature the following site enrollment audit data categories: <ul style="list-style-type: none"> – Screening Limit – Randomization Limit – Last Modified – Last Modified By A new Site ID column has been added. The name of the Site column has been updated to Site Name. This report can now be exported in CSV format, part of which each report section will have its own sheet.

Diversity & Inclusion dashboard in Oracle Clinical One Analytics

The Diversity & Inclusion dashboard is now available in Oracle Clinical One Analytics allowing you to visualize the diversity on the subject population of a clinical study. This dashboard can provide an insight of the trial objectivity to test the safety and efficacy of a drug formulation.

Tip:

Whether you are working in a live study (and already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle Project Manager for more information on Oracle Clinical One Analytics training and mentoring.

With the introduction of the new Diversity & Inclusion dashboard template in Oracle Clinical One Analytics, you can get a holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to a customizable and interactive dashboard. This contains reports and visualizations that can help improve your decision-making on subject screening and randomization, to increase diversity within the group of study participants. With a more diverse group of participants, you are more likely to objectively test the safety and accuracy of the drug formulation for everyone.

Since they are templates, you do not have to create dashboards from scratch, but you can customize them to meet your needs. All you have to do is download the template and re-

import it to tweak the data in and adjust filters, making sure that you are viewing data relevant to your work. For more information see [Customize templates](#).

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. To work with the Diversity & Inclusion dashboard, you must have access to the Subject Items Dataset.

Access to a dataset is given based on the permission that you must be assigned in Oracle Clinical One Platform. To access the Subject Form Items dataset, and so this new dashboard, make sure you are assigned with the *Run the Subject Form Items Dataset* permission. For more information on these permissions, see [About your access to Clinical One Analytics](#).

Details for data managers

With the new Diversity & Inclusion dashboard, data managers can monitor subjects' diversity by age, gender and demographics across studies and sites. Even though this dashboard is intended to assist data managers with their duties, the Diversity & Inclusion dashboard is available to any user with the appropriate permissions. This customizable dashboard offers you complex data on the clinical study population diversity, organized within the following interactive reports:

- Diversity & Inclusion Overview
- Diversity By Sites
- Diversity by Age Group
- Patient Demographics

The reports and visualizations grouped in this dashboard can help data managers to analyze the study population and subject distribution across sites and studies. With this, the study team can identify a possible need of randomization design and limits update, as well as screening requirement adjustments.

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

New Study Codelist datasets

You can now work with the Study Codelists dataset in Oracle Clinical One Analytics to create reports to identify the current global and study-level code lists, as well as the historical changes to the code lists configuration.

Codelist managers and other sponsor users can now use the Study Codelists dataset to analyze and visualize customized codelist at either global or study level, as well as current code configurations and changes made over time. With this dataset you can:

- Reference all code lists available for an organization and their details, such as: title, description, type (system or custom), localization, as well as codes, values and labels.
- View all available code list items in multi-select questions, instead of just selected choices.
- Reference the study codelist dictionary when reviewing clinical data extracts.
- Review updates made to a code list at the study level.

- Review updates made to code configuration at the global level.

The Study Codelists dataset is available to any user assigned the new *Run the Analytics Study Codelist Dataset* permission. Global level codelists data is available to global users assigned with the *Code List Manager* or the *Oracle Admin* roles. If you are a sponsor user who needs to work with this dataset, make sure you reach out to your user administrator or Oracle project manager to get the appropriate permission.

You can find additional information regarding these datasets and their permissions in the *Analytics User Guide* after the Release Assessment Environment (RAE) upgrade.

Rules management

- [Predictive text in the Rule editor](#)
Rule developers can now reduce coding efforts using predictive text in the rule editor.

Predictive text in the Rule editor

Rule developers can now reduce coding efforts using predictive text in the rule editor.

Oracle provides rule helper functions to facilitate the creation of custom rules. A new predictive text feature is available to help rule developers work with the existing helper functions, as well as suggest variable names and some standard JavaScript syntax. As you type in your expression, this feature provides a list of suggestions, including helper functions along with a brief description, which gets narrowed as you type to include only relevant functions matching the entered text. You can then go through the list and select a helper function to add to your expression. The added functions include the correct syntax with placeholders for you to complete the required parameters.

Using the predictive text to review and enter helper functions, variables and standard syntax can help you reduce your coding efforts. By letting you have all the rule helper functions at hand, along with their purpose and correct syntax, you can get an overview of how you can simplify your rule logic with the available helper functions and make sure you use them correctly.

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

Study design

- [Enhancements to library studies](#)
Library users can now make their work more collaborative and much faster with a new set of enhancements implemented for library studies.
- [Template role names include new unblinding label](#)
Role names have been updated to reflect the alert of unblinding potential for particular template user roles.

Enhancements to library studies

Library users can now make their work more collaborative and much faster with a new set of enhancements implemented for library studies.

As a user administrator or global user manager, you must be aware that a user must be assigned the existing permission *View Study Design* to use this new feature.

Whether you're a study designer or a library user, here's what's new for you:

- On the Home page, you have a new option to copy a study into your library. This will help you kickstart your library study design much faster. Conversely, you can copy an entire library study into Production, as well. Upon selecting to copy a study, the Copy Study dialog appears. In there, you will see the options to select whether you're copying the study for Production or for a library.
- If copying a study fails, you will see a warning on the Home page, next to the study that couldn't be copied.. Additionally, all copied studies (whether live or library studies) will indicate the user name of the user who performed the action.
- In your library, in the **Used in Studies** section, you can view how your library objects are used in Production or other library studies.
- You can now better collaborate with fellow library users or designers when working a library study. With the new comments feature, you can leave each other comments, organize everything by threads, as well as sort through comments, search through them, or resolve them.
- You can leave or reply to comments in both Study Design and Testing mode, and you also get an email notification whenever you are tagged in a specific comment.

More information on these new library enhancements can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Template role names include new unblinding label

Role names have been updated to reflect the alert of unblinding potential for particular template user roles.

To alert user managers to the potential of particular study roles for unblinding data, the following template study role names have been updated:

- Clinical Supply Manager - Unblinded (Template)
- Pharmacy User - Unblinded (Template)
- Statistician - Unblinded (Template)

Note:

This name change doesn't impact the permissions included in these study role templates. Moreover, users who are assigned custom study roles are not impacted by this change at all.

Impact on reports

The new template role names will be reflected in all user management reports:

- Global study roles report
- Study roles report by study
- User assigned across studies
- User assignment
- User assignment by site
- User upload error

- User upload template

Already working in a live study?

If you have been assigned any of the roles mentioned above and are currently working in a live study, the name of your role will also be updated.

User experience

- [Enhanced Chat & Help experience](#)
The Chat & Help screen has been enhanced to provide a better and simplified user experience.

Enhanced Chat & Help experience

The Chat & Help screen has been enhanced to provide a better and simplified user experience.

On the Oracle Clinical One Platform home page, when you click **Chat & Help** you now get a simplified dialog with the following options to help you get the assistance that you need:

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

When you click **Chat with Customer Support** and fill in the details, a chat window opens. The screen indicates your number in the queue and an estimated time of response. In the chat window, when connection is established, you can start your conversation with a support agent and get realtime assistance.

For more information on how to use this feature, see [Chat in real time with Oracle Support](#).

Other enhancements

Form associations are now reflected in ODM-XML extracts

Association between forms is now reflected in ODM-XML extracts. Within the extract, form associations are presented as sets of transactions, conforming to the CDISC standard.

To reflect form associations, the new **KeySet** and **annotation** elements are added to the clinical data and metadata responses.

For a detailed breakdown of all the newly-added attributes, see the [ODM-XML reference](#) documented as part of the *API Guide*

A study's dashboard now displays all subjects

On the Home page, the total number of a study's subjects is now displayed on a study's dashboard, regardless of site status.

Previously, the dashboard would only count subjects at active sites.

Fixed issues

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

All users

HAR files are no longer needed for issue resolution

Oracle Support no longer requires customers to provide HAR files for Service Request (SR) analysis. They now have tools to gather the information previously provided in a HAR file.

Retracted workaround: The steps defined in [KnowledgeBase Article 3011](#) are no longer needed.

Issue: 35856377

System slowness/freezing after clicking the Subject History or Queries right side panels

Now, you no longer encounter system slowness or freezing after clicking the **Subject History** or **Queries** right side panel for subjects with more than thirty (30) visits that contain multiple queries.

Retracted workaround: None. (Issue **35684076**)

The Select Language drop-down on the What's New window does not work

Now, the Select Language drop-down on the What's New window allows users to select a language (English, Chinese, or Japanese) upon initial log in.

Retracted workaround: None. (Issue **35385066**)

An error occurs after filtering sites and viewing queries under the Queries side panel

Now, you no longer encounter an error after filtering subjects by site on the Subjects page, followed by clicking View on the Queries side panel.

Retracted workaround: None. (Issue **35387816**)

A site's status changes without user action (former known issue)

Now, if you retire an active site, then navigate through the tabs (the Sites tab, the Depots tab, the General tab), the site's status no longer fluctuates between Active and Retired.

Retracted workaround: None. (Issue **33874708**)

Facilities, settings, and user management

Users with the View Only for Unblinded Support Users cannot view the Users tab

Now, any user who is assigned the *View Only for Unblinded Support Users* study role can properly view data on the Users tab without requiring other specific permissions, other study roles, or global roles to be assigned to them. (Issue **35940121**)

The edit depot countries window does not display the full list of associated countries

Now, when editing a depot, the Countries window displays the complete list of associated countries under the <depot name> Depot Countries table (on the right side).

Retracted workaround: Click the Primary Countries tab to confirm which countries are checked off. Or hover over Supply Countries on the Depot tab to view the complete list. (Issue **35504845**)

Users assigned the *Edit Form Data for Subjects* permission can also skip and unskip visits (former known issue)

Now, users assigned to a role that includes the permission *Edit Form Data for Subjects* cannot skip/unskip visits.

Retracted workaround: None. (Issue **35204854**)

Clinical Supply Manager with proper permissions receives an error when creating a depot

Now, you only need the permissions, *Create and Manage Depots*, and *View Depots* to successfully create depots. The permission, *Create and Manage Sites* is no longer required to achieve this.

Retracted workaround: None. (Issue **34206639**)

Forms, visits, and rules

A Subject's visit data of event type Visit_Inserted is not reaching Data hub

Now, Visit_Inserted records for new visits applied to a study via advanced study versioning (ASV) are inserted into the DC_VISITS_INFO table in Data Hub, making the data available in Oracle Clinical One Analytics.

Retracted workaround: None. (Issue **35560725**)

Subject PDFs generated under the Archives tab include incorrect usernames

Now, when multiple users sign forms in a single visit, subject PDFs generated under the Archives tab show the username associated with the signing action. Previously, the username of one signatory showed for all form signatures.

Retracted workaround: None. (Issue **35692719**)

The next logical visit does not appear after answering a branch visit exit question

Now, when the rule execution occurs only for the current visit and does not impact the previously calculated or answered target questions in the previous visits, no issues are observed, and the next logical visit appears as expected. Previously, when branch exit questions were answered in a certain way, the next logical visit did not appear in the visit train. Instead, the Next Visits column was populated with three (3) dashes (---).

Retracted workaround: None. (Issue **35726231**)

Error encountered when multiple rules try to update the same form or visit

Now, errors no longer occur when multiple rules attempt to update the same form or visit simultaneously.

Retracted workaround: None. (Issue **35401876**)

A visit remains IN PROGRESS after clearing all form data, limiting the ability to skip the visit

Now, a visit no longer remains in the status of IN PROGRESS after clearing all data in the visit, allowing the visit to be skipped. Previously, the visit would be stuck at IN PROGRESS after clearing all form data, limiting the ability to skip the visit.

Retracted workaround: PL SQL script execution to version end the active data element record with a null value and version end the currently active IN PROGRESS visit status. This results in a new record introduced in the visit status table with a status of NEW. (Issue **35541809**)

The Visit Date field for a new visit displays the date of the previously completed visit

Now, the **Visit Date** field for a new visit is blank after clicking a previously completed visit, followed by returning to the new visit. Previously, the date from the previously completed visit was displayed in the Visit Date field for the new visit.

Retracted workaround: None. (Issue **35741399**)

Clicking Start Visit multiple times for a skipped visit can result in system slowness (former known issue)

Now, after clicking **Start Visit** (for a skipped visit), the system blocks the ability to click Start Visit again. Previously, the system allowed Start Visit to be clicked multiple times, impacting study performance.

Retracted workaround: None. (Issue **35654270**)

An auto-assigned query is not appearing in a Screen Fail visit after being generated

Now, auto-assigned queries are visible in a Screen Fail visit. Previously, the auto-assigned query would generate successfully, but it was not visible in the visit, as queries could not be assigned to a Screen Fail visit.

Retracted workaround: None. (Issue **35333522**)

A source data verified (SDV) visit gets unverified after a read-only item is populated by a rule in another visit

Now, a source data verified visit (ex. Visit_1) is no longer unverified when a new read-only item (not eligible for verification) is populated by a rule generated in another visit (ex. Visit_2).

Retracted workaround: None. (Issue **35266051**)

Rules fail to populate multiple items when the visit date is a variable in the rule

Now, when Visit Date is referenced as a variable in a rule, rule target items are populated correctly when the Visit Date is entered or updated.

Retracted workaround: To avoid screen-blocking issues related to this bug, mark your rules as 'unblocking' in the rule-design dialog. This allows a user to proceed to enter data without getting blocked. The rule executes in the background, and the user must reopen/refresh the visit to see the rule execution results. (Issue **34526808**)

No action takes place when clicking Save or Save and Close after completing a form association (former known issue)

Now, you are automatically taken back to the **All Subjects** page when clicking **Save** or **Save and Close** after completing a form association.

Retracted workaround: After saving, click into the white space of the visit to return to the All Subjects page. (Issue **35139761**)

Users can delete a Library study even when it includes forms and associated visits (former known issue)

A Library study can be deleted if its design objects have not yet been imported into another study. If library objects have been imported into another study, end-users are now presented with a message stating why the study cannot be deleted.

Retracted workaround: None. (Issue **35283510**)

An automated query is not being displayed for an age field (former known issue)

Now, when the target field of an automated query is an age (read-only) field, the query is displayed automatically without the need to refresh the browser.

Retracted workaround: Use the time and date (date of birth) question as the target field of the automated query rule. (Issue **31895089**)

A predefined label included in a rule does not work (former known issue)

Now, for a tabular form, rules work as expected when you define a rule that includes the tabular form's predefined labels as variables.

Retracted workaround: Use an OR clause in the rule expression that includes the item value string and index. For example, if the first record in the predefined block is "Glucose", the rule expression would be: if (var1 == "Glucose" || var1 == 0) (Issue **31979445**)

Dynamically displayed forms do not behave as expected in an Adverse Event (former known issue)

Now, a dynamic child form in the Adverse Event visit is not hidden based on the answer to the determining question in another scheduled visit.

Retracted workaround: None. (Issue **34287388**)

The delete form confirmation window remains after clicking Delete for a two-section form (former known issue)

Now, when deleting a two-section form, the delete form confirmation window no longer remains open after clicking Delete.

Retracted workaround: Manually close the window, then refresh your browser. (Issue **35293584**)

The validation rule error message does not change when a rule is copied

Now, the error message associated with a copied validation rule changes correctly based on the type of validation rule selected and no longer displays the error message associated with the original validation rule.

For example, if you create a validation rule, Select at Least, then copy that rule and change the type to Select at Most, the correct error message is displayed for the second rule instead of the error message associated with the initial validation rule.

Retracted workaround: None. (Issue **35552799**)

The Share Form drop-down does not include all expected users

Now, when you double-click a form (in the test container) and select Preview, then Share, all relevant users are available in the Share Form drop-down. Previously, a fifteen (15) user maximum was enforced.

Retracted workaround: None. (Issue **35528467**)

Error encountered after entering data in a two-section form and clicking Save (former known issue)

The error no longer occurs if you have different values stored for the Label and Value in a codelist.

Retracted workaround: Create a new form and assign the corrected codelist to the label question. (Issue **35508707**)

A deleted row on a repeating form is visible after verification

Now, if you clear an item on a repeating form and then delete that row, the row does not appear after verifying the visit.

Retracted Workaround: None. (Issue **35487676**)

Rule execution fails when trying to write to a question on a form in a skipped visit (former known issue)

Rule execution no longer occurs when the rule target items are in a skipped visit. The rule runs as expected on all other visits.

Retracted workaround: None. (Issue **35386395**)

Queries closed automatically after clearing a visit date are not reflected on the screen (former known issue)

Now, when you clear a visit date, queries automatically closed on a form in that visit show as closed on the screen without requiring a screen refresh

Retracted workaround: Refresh your browser's page to see the updates on your screen. (Issue **35143313**)

Auto-queries are applied when the rule logic controlling the query is not met

Now, auto-queries are no longer applied incorrectly on associated form items when the query rule logic controlling the query is not met. Previously, the system misinterpreted the `dateTimeValueUTC` as null for date/time items resulting in the query being applied.

Retracted workaround: None. (Issue **35338504**)

Repeating Label form status shows Incomplete, but the visit status shows Completed

Now, the system considers label form items, Label (Repeating table only), as data when calculating the visit status for lab forms.

Retracted workaround: None. (Issue **35281506**)

Clinical ODM API call returns different record counts when no toTimestamp parameter is passed

Now, when no `toTimestamp` is specified in the output ODM, the `toTimestamp` is set to the maximum value (the most current `DHTimeStamp` transaction) of all available levels (visit, subject, form, item, and query).

Retracted workaround: None. (Issue **35260813**)

Queries display as Opened on the Query side panel but are not present on the form

Now, queries created in an unscheduled visit are visible on the associated form and the Query side panel.

Retracted workaround: Action the queries from the Queries tab. (Issue **35111514**)

Visit status is stuck at In Progress when it should be Complete

Now, if you have a visit containing, for example, a lab form and a standard form and save the data entered on each simultaneously, the visit status is changed to Complete.

Retracted workaround: None. (Issue **35554827**)

Kit dispensed for an In Progress visit

Now, kits are no longer dispensed for an In Progress visit. Previously, this occurred when form data for multiple forms was saved simultaneously (see bug 35554827), resulting in a completed visit being stuck at an in-progress status.

Retracted workaround: None. (Issue **32975691**)

A screening visit may remain incomplete (former known issue)

Now, a screening visit no longer remains incomplete after dispensing kits or randomizing a subject.

Retracted workaround: None. (Issue **34314545**)

Using an API to hide a dynamic dispensation visit marks the visit status as New instead of Incomplete

Now, when using an API to clear all data in a dynamic dispensation visit, including changing the determining question and hiding the visit, the user is presented with the following dialog related to the determining question; *You cannot change this answer at this time. Some visits are available based on the data in this answer. To update the answer, you must clear any data that is included in those related visits.* This results in the status of the visit being set to Incomplete.

Retracted workaround: None. (Issue **35201062**)

Question hint text for an item in the flat portion of a two-section form persists after navigating away from the item

Now, the question hint text associated with an item in the flat portion of a two-section form, displayed under the Question Hint text in the right-side panel, is no longer displayed after moving to the repeating section of the same form.

Retracted workaround: None. (Issue **34275441**)

The unlock icon is not orange for a required in-progress visit

Now, the unlock icon displays in orange for a required in-progress visit making it easy for users to distinguish between the locked and unlocked icons.

Retracted workaround: None. (Issue **34722585**)

Dynamic form in a future visit – Visit reordering occurring

Now, multiple updates to a determining question which results in a change to the visit status, for example, Complete to Incomplete for future completed visits, no longer results in visits appearing out of order or repeatedly changing positions in the visit train.

Previously, for example, entering No for the Childbearing Potential determining question, then changing to Yes, then back to No would result in inconsistent visit order in the visit train.

Retracted workaround: None. (Issue **35388908**)

Integrations

The InForm to Argus Safety integration fails when special characters are present

Now, the integration supports special characters in the narrative for the InForm to Argus integration.

Retracted workaround: None. (Issue **35518789**)

Oracle Clinical One Analytics

Data is not loading properly in the CRA and Data Manager dashboards

Now, when you access the CRA dashboard or the Data Manager dashboard, data is properly displayed in the Missing Forms Report and in the Missing Visits Report, without the information taking a long time to display. (Issue **35994707**)

The VALUE field in the Analytics Queries dataset is populated with the latest value

The VALUE field, which stores the raw value for a form question where a query is opened, answered, closed, or deleted, is now populated correctly based on the audit history in the Queries dataset.

Retracted workaround: None. (Issue: **35363371**)

The tile names in the CRA Dashboard in Clinical One Analytics are not visible when display settings are set to Recommended (former known issue)

Now, when you view the CRA Dashboard with the recommended display settings configured, you can see the tile names in the dashboard.

Recommended settings:

- **Scale:** 150% (Recommended)
- **Display resolution:** 1920 x 1080 (Recommended)

Retracted workaround: Switch the display settings to the following to view all tile names in the dashboard.

- **Scale:** 100%
- **Display resolution:** 1920 x 1080 (Recommended)

(Issue **34830326**)

Randomization and kits

A misallocated kit is not reflected in the Subject History, Visit History, or Kit History

Now, if the removal of the old visit association and assignment of the new visit association for a misallocated kit occur simultaneously, the misallocated kit is reflected correctly in the system under the Subject History, Visit History (on the Subjects page), and Kit History (on the Supplies page).

Retracted workaround: None. Issue (**35755272**)

Reports, archives, extracts, and notifications

The Subject Queries report doesn't properly display audit-related data

Now, when you generate the Subject Queries report with the **Include Audit Trail** set to **Yes**, you'll notice that the expected and relevant data is displayed in the following columns:

- Query State
- Query Comment
- Value
- Unit of Measure
- Last Updated On Site
- Last Modified By
- Last Modified Date

Previously, these columns were populated with a value of N/A. Moreover, the columns would only display data when the **Include Audit Trail** setting was set to **No** and this issue could only be reproduced for some subjects. (Issue **35972590**)

The Site Status Change Alert email notification fails with a system error

Now, the Site Status Change Alert email notification is sent successfully. Previously, the email notification failed to send with the error, `userList Size exceeds maxLength: 4000`.

Retracted workaround: None. (Issue **35781902**)

The SDV Configuration column in the Study Design Dataset does not populate correctly

Now, the SDV Configuration column in the Study Design Dataset in Oracle Clinical One Analytics accurately reflects what is recorded in the system when generated.

Retracted workaround: None. (Issue **35826804**)

Cannot generate the Subject Queries report for large studies

Now, you can generate the Subject Queries report successfully when the setting **Include Audit Data** is set to Yes.

Retracted workaround: None. (Issue **35571602**)

Kit Dispensation report does not display visit branches for the Visit Title filter (former known issue)

Now, visit branches, defined in a study, are displayed in the **Visit Title** drop-down on the Settings side panel when running the Kit Dispensation report. The permission, *Run the Kit Dispensation Report* is required to generate this report.

Retracted workaround: Use All (default option) for the Visit Title filter when running the report. (Issue **32411770**)

Form status (signature details) displays incorrectly in CRF Submit Submission PDF archive (former known issue)

Now, if both form and visit level signatures are configured and a user signs at the visit and subject level (not at the form level), then edits an item on a form in the signed visit, the Form Status (signature details) in the Submission PDF header displays *Ready to Sign* instead of *Ready to Sign, Unsigned*.

In this scenario, the Form Status should not include Unsigned as the form was never signed.

Retracted workaround: None. (Issue **35272192**)

The Study Enrollment standard report includes incorrect Screened Subjects count

The Country Enrollment tab in the Study Enrollment standard report now displays the correct number under the Screened Subjects column. This column includes the number of subjects with a state of screened at the time the report was run. Previously, screen-failed subjects that were never screened were counted as screened and counted in the report.

Retracted workaround: None. (Issue **35332850**)

Training Completion date discrepancy between HS Learn and the Clinical One Training report

Now, the training completion date for training assigned in UMT matches when comparing HS Learn and the Clinical One Training report. Previously, the completion date in the Clinical One Training report showed the training completion date one hour earlier than the date in HS Learn.

Retracted workaround: None. (Issue **35369914**)

The Clinical One Training report fails when it includes email addresses containing a single quotation mark

Now, the Clinical One Training report generates successfully when it includes users with a single quotation mark in their email addresses. A check has been implemented to check and escape when a single quotation mark is present in an email address.

Retracted workaround: None. (Issue **35469774**)

Date values in the Subject Data Extract are swapped (former known issue)

Now, the Entered Date and Last Changed Date values are no longer switched in the Subject Data Extract output and appear under the appropriate columns.

Retracted workaround: None. (Issue **35506296**)

The Notifications icon on the home page does not turn blue, indicating unread notifications (former known issue)

Now, the notifications icon on the Home page, Studies list, turns blue when new notifications are available.

Retracted workaround: Hover over the Notification icon; it displays the number of unread notifications. Click the notification icon to view them. (Issue **35355647**)

The Annotated Case Report Forms & Study Design report (in PDF) fails when a SAS Variable includes an invalid XML character

Now, additional validation during study design does not allow invalid XML characters to be entered in a SAS Variable. This removes the possibility of downstream impact when generating these reports in PDF format.

Retracted workaround: Generate the reports in HTML format or remove the invalid XML character (Issue **35120652**)

The Study Design report does not properly display code list data (former known issue)

Now, if a code list's name is identical to the questions reference code, the code list name, code values, descriptions, and codes are displayed consistently in the List of Values column in the Study Design report.

Retracted workaround: To properly display code list details in the Study Design report, change the code list's name or the question's reference code; they should not match. Otherwise, code list data will not be displayed as you would expect. (Issue **34751953**)

The Annotated Case Report Forms and Study Design reports contain no Forms section

Now, the correct visit details are included in the Forms section of the Annotated Case Report Forms and Study Design reports after a new study version has been applied using Advanced Study Versioning (ASV).

Retracted workaround: None. (Issue **35386033**)

The Study Roles report (by study) does not include the study name

Now, when filtering by all studies, the Study Roles report (by Study) includes the study name in the blue banner above the report table and not the studies GUID value.

Retracted workaround: None. (Issue **35455370**)

The Study Design Delta report results in an error when generated for approved study versions

Now, the Study Design Delta report, used by study designers to identify study design configuration differences and verify changes between study versions before moving to Production, no longer results in errors and displays the changes between the chosen study versions.

Retracted workaround: None. (Issue **35484673**)

Cyclic visits have the same Projected Visit Date in the Subject Visits (Unblinded) report affecting the predictive resupply

Now, the Projected Visit Date (for cyclic visits) in the Subject Visits (Unblinded) report includes the correct dates. This ensures there is no impact to the resupply algorithm, which uses the Projected Visit Date in the Subject Visits (Unblinded) report for drug projection for predictive resupply. For more information, see the Subject Visits (Blinded) report.

Retracted workaround: None. (Issue **35598456**)

Site users and subject data

Loading subject data takes more time than expected

Now, when you access subject visits associated with a large site, the forms and their collected data load properly and without exceeding the expected loading time. (Issue **35852581**)

Incorrect message appears on the Forms left side panel

Now, when you access a subject's visit, all forms are displayed without delay on the Forms left side panel, and the message *No items to display* is no longer presented to the user. (Issue **35963321**)

Large-sized repeating forms and two-section forms take longer to load

Now, when you access a subject's visit containing form tables with dozens of rows (in a simple repeating form) or instances (in a two-section form), it no longer takes an extended period of time for the page to load. (Issue **35917673**)

Large-sized repeating forms and two-section forms with queries take longer to load

Now, when you access a subject's visit containing form tables with dozens of instances (in a two-section form), rows (in a simple repeating form), and queries, it no longer takes an extended period of time for the page to load. (Issue **35917721**)

Subjects show as completed in the APIs but not in the user interface (UI)

Now, on the subject list page, the complete and withdraw options appear in the Manage Subjects drop-down after a subject completes the earliest required visit allowing a subject to complete the study.

Retracted workaround: None. (Issue **34787534**)

Incorrect results on the Subjects screen when filtering with a country with multiple sites

Now, when filtering subjects using a country that includes multiple sites, the correct subject list is displayed even when one of the sites is retired and has no subjects.

Retracted workaround: Filter with an individual site, then filter using United States for Country and All sites to show the correct subjects. (Issue **34728469**)

On the Data Capture page visit train, the focus is on another visit instead of the selected visit

Now, the focus is on the selected visit and not other visits in the visit train on the Data Capture page. Users no longer need to scroll to the first visit to confirm that the correct visit is selected.

Retracted workaround: None. (Issue **34605036**)

Subject tags disappear in the user interface after being added

Now, subject tags defined in your study design no longer disappear in the user interface after creation. This bug only impacted the user interface. The Study Design report accurately reflected the subject tags even when they were not visible in the user interface after creation.

Retracted workaround: None. (Issue **35463949**)

Subject status is not updated from Screened to Enrolled

Now, the subject state changes from Screened to Enrolled after completion of the first non-dispensation visit, even if there is a dynamic form included in the design.

Retracted workaround: Use the Save and Close or Return to All Subjects buttons to properly complete the process. (Issue **35561229**)

Rest API updates

See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs, available upon the Production release.

The following service has been added:

- [Comment](#)

The following services have been updated:

- [Codelist](#)
- [Data Action](#)
- [Data Hub](#)
- [Data Capture](#)
- [Designer](#)
- [Library](#)
- [Query](#)
- [Randomization and Supplies](#)
- [Reporting](#)
- [Sites and Depots](#)
- [Users, Permissions, and Roles](#)

Comment

Change	Endpoint
New	<ul style="list-style-type: none">• POST /v1.0/studies/{studyId}/comments• POST /v1.0/studies/{studyId}/comments/markAsRead• POST /v1.0/studies/{studyId}/comments/markAsUnRead• POST /v1.0/studies/{studyId}/comments/objects• POST /v1.0/studies/{studyId}/comments/objects/unreadCount• GET /v1.0/studies/{studyId}/comments/objects/{objectId}• GET /v1.0/studies/{studyId}/comments/objects/{objectId}/unreadCount• PUT /v1.0/studies/{studyId}/comments/{commentId}• DELETE /v1.0/studies/{studyId}/comments/{commentId}

Codelist

Change	Endpoint
New	<ul style="list-style-type: none">• GET /v1.0/history/codes• GET /v1.0/history/codevalues• GET /v1.0/history/groups

Data Action

Change	Endpoint
New	<ul style="list-style-type: none"> • POST /v1.0/studies/{studyId}/{mode}/dataelements/freeze • GET /v1.0/studies/{studyId}/{mode}/dataelements/sdv • POST /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/lock/allvisit • POST /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/validate/multiplevisits • GET /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/lock • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/unlock • POST /v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/unlockvisits • PUT /v1.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/validate/multipleitems • GET /v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks

Data Hub

Change	Endpoint
New	<ul style="list-style-type: none"> • POST /v1.0/tenant/{tenantId}/codelists • POST /v1.0/tenant/{tenantId}/studies/{studyId}/codelists • POST /v2.0/tenant/{tenantId}/studies/{studyId}/dataCollection • POST /v2.0/tenant/{tenantId}/studies/{studyId}/kitsAndRandomizations • GET /v4.0/studies/{studyId}/{mode}/odm/metadata • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects • POST /v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/blinded • GET /v6.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits • POST /v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems • POST /v7.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Capture

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/studies/{studyId}/{mode}/subjects/count • GET /v1.0/studies/{studyId}/{mode}/dataelements/{dataelementId}/{operationType}/childItems • PUT /v1/studies/{studyId}/{mode}/subjects/{subjectId}/undoSubject • PUT /v11.0/studies/{studyId}/{mode}/dataelements/{dataElementId} • POST /v12.0/studies/{studyId}/{mode}/visitstatus/subjects • POST /v2.0/studies/{studyId}/{mode}/visitstatus/multiple • POST /v3.0/studies/{studyId}/{mode}/subjects/visitschedule • POST /v4.0/studies/{studyId}/{mode}/subjects/randomizeordispense • POST /v4.0/studies/{studyId}/{mode}/subjects/visitschedule • PUT /v6.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}/clearruleerror/{message}
Deprecated	<ul style="list-style-type: none"> • GET /v1/studies/{studyId}/{mode}/dataelements/sdv • POST /v2.0/studies/{studyId}/{mode}/dataelements/freeze • PUT /v2.0/studies/{studyId}/{mode}/unfreeze/{dataElementId} • POST /v1.0/studies/{studyId}/{mode}/asynch/report/{reportName} • POST /v1/studies/{studyId}/{mode}/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/report/{reportName} • POST /v1.0/studies/{studyId}/{mode}/reports/{reportName} • POST /v2.0/studies/{studyId}/{mode}/report/{reportName} • POST /v3.0/studies/{studyId}/{mode}/report/{reportName} • POST /v4.0/studies/{studyId}/{mode}/report/{reportName}

Designer

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/studies/{studyId}/versions/{versionId}/cohorts • GET /v2.0/studies/library/{libraryId}/studyType/{studyType}/studyUses • GET /v2.0/studies/{studyId}/approved/choiceoptions • GET /v2.0/studies/{studyId}/approved/objectids • POST /v2.0/studies/{studyId}/forms/formitems • GET /v2.0/studies/{studyId}/forms/{formId}/formitems • GET /v2.0/studies/{studyId}/forms/{formId}/itemhistory • GET /v2.0/studies/{studyId}/objectids • GET /v2.0/studies/{studyId}/randomizationfactors • GET /v2.0/studies/{studyId}/versions/{version}/forms/numericItems • GET /v2.0/studies/{studyId}/visitsforms • GET /v2.0/studies/{studyId}/{mode}/forms • POST /v3.0/studies/{studyId}/lockObjectDetails • GET /v3.0/studies/{studyId}/{mode}/forms • POST /v4.0/studies/{studyId}/allForms/coding • GET /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule • POST /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • PUT /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • DELETE /v4.0/studies/{studyId}/versions/{version}/visits/{visitid}/schedule/{fromEventRefId} • POST /v5.0/studies/{studyId}/allForms • GET /v6.0/studies/{studyId}/studyversionobjects • GET /v7.0/studies/{studyId}/versions/{version}/arms/{armId}/dispensings • GET /v7.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo • GET /v8.0/studies/{studyId}/studyDesign • POST /v8.0/studies/{studyId}/studyDesign/paginated • POST /v8.0/studies/{studyId}/versions/{version}/kits • GET /v8.0/studies/{studyId}/versions/{version}/kits • GET /v8.0/studies/{studyId}/versions/{version}/kits/{kitId} • DELETE /v8.0/studies/{studyId}/versions/{version}/kits/{kitId} • GET /v8.0/studies/{studyId}/versions/{version}/visits/{visitid}/dispensings • GET /v8.0/studies/{studyId}/versions/{version}/visitschedules • POST /v9.0/studies/{studyId}/design • POST /v9.0/studies/{studyId}/studyDesign • GET /v9.0/studies/{studyId}/versions/{version}/design • POST /v9.0/studies/{studyId}/versions/{version}/visits • GET /v9.0/studies/{studyId}/versions/{version}/visits/{visitid} • PUT /v9.0/studies/{studyId}/versions/{version}/visits/{visitid} • DELETE /v9.0/studies/{studyId}/versions/{version}/visits/{visitid}

Change	Endpoint
Deprecated	<ul style="list-style-type: none"> • POST /v1.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule • PUT /v1.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule • DELETE /v1.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule • POST /v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule • PUT /v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule • DELETE /v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/schedule

Library

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/libraryHistory/{libraryId} • POST /v1.0/libraryObjects/studies/{studyId}/versions/{studyVersion}/revertCopyObjects • POST /v2.0/libraryObjects • GET /v2.0/libraryObjects • DELETE /v2.0/libraryObjects • POST /v2.0/libraryObjects/bulk • GET /v2.0/libraryObjects/pagination • POST /v2.0/libraryObjects/studies/{studyId}/versions/{studyVersion}/{copyObjectMethod}/copyObjects • POST /v2.0/libraryObjects/updateStudyVersion • PUT /v2.0/libraryUses • GET /v2.0/libraryUses/library/{libraryId}/studyType/{studyType} • GET /v2.0/libraryUses/studies/{studyId}/versions/{studyVersion} • GET /v2.0/libraryUses/study/{studyId}/studyType/{studyType}
Deprecated	<ul style="list-style-type: none"> • GET /v1.0/libraryObjects/{libraryId}

Query

Change	Endpoint
New	<ul style="list-style-type: none"> • PUT /v1.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/bulkCloseDelete

Randomization and Supplies

Change	Endpoint
New	<ul style="list-style-type: none"> • POST /v1.0/studies/{studyId}/{mode}/reports/locallysourcedkits • GET /v15.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v16.0/studies/{studyId}/{mode}/visits/subjectvisit • POST /v2.0/studies/{studyId}/{mode}/reports/unblinded-visit-schedule • POST /v3.0/studies/{studyId}/{mode}/reports/kits/blindedInventory • POST /v3.0/studies/{studyId}/{mode}/reports/kits/blindedchainofcustody • POST /v3.0/studies/{studyId}/{mode}/reports/kits/unblindedInventory • POST /v4.0/studies/{studyId}/{mode}/reports/order-summary • POST /v4.0/studies/{studyId}/{mode}/reports/subjects • GET /v4.0/studies/{studyId}/{mode}/shipments • POST /v5.0/studies/{studyId}/{mode}/reports/order-summary • GET /v6.0/studies/{studyId}/{mode}/orders • GET /v6.0/studies/{studyId}/{mode}/orders/{shipmentId} • POST /v7.0/studies/{studyId}/{mode}/reports/kits/chainofcustody

Reporting

Change	Endpoint
New	<ul style="list-style-type: none"> • POST /v2.0/scheduled/reports
Deprecated	<ul style="list-style-type: none"> • GET /v1.0/reportmetadata/downloadList • GET /v1.0/reportmetadata/reportId/{id} • GET /v1.0/reports/download • POST /v1.0/reports/page • GET /v1.0/studies/{studyId}/{mode}/reportmetadata/reportId/{id} • POST /v1.0/studies/{studyId}/{mode}/reports • DELETE /v1.0/studies/{studyId}/{mode}/reports • GET /v1.0/studies/{studyId}/{mode}/reports/download • POST /v2.0/reports/page • GET /v2.0/studies/{studyId}/{mode}/reports/download

Sites and Depots

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals • PUT /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals • GET /v2.0/studies/{studyId}/{mode}/labs/{studyLabId}/labnormals/lookup • GET /v5.0/studies/{studyId}/{mode}/sdfcountry

Users, Permissions and Roles

Change	Endpoint
New	<ul style="list-style-type: none"> • GET /v1.0/userinfo/bulk • GET /v2.0/userinfo/bulk

Release impact for other applications

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

Oracle Life Sciences Data Management Workbench (DMW)

- The new fields related to queries and Source Data Verification (SDV) introduced in Oracle Clinical One Analytics will be made available in Oracle DMW in a future release.
For more information on these new fields, see [Enhancements to Oracle Clinical One Analytics](#).

4

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 23.1

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)
- [Rest API updates](#)
See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs for 23.1, available upon the Production release.
- [Release impact for other applications](#)
This document describes the known impact and limitations that new features and enhancements introduced in this release may have on downstream applications.

Patch log

This topic briefly describes the history of small fixes we have applied to the 23.1 release.

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

Table 4-1 Patch log

Release Number	Release Date	Notes
Release 23.1.4	11 August 2023	For this release, we fixed an issue pertaining to visits. For more information, see issue 35620027 in Forms, visits, and rules .
Release 23.1.3	17 July 2023	For this release, we fixed three issues related to forms, visits and Subject Queries report. See issues: <ul style="list-style-type: none">• 35554738, 35454836 in Forms, visits, and rules Also, we documented enhancements to the Data Intake integration. For more information see, Data Intake integration enhancements.

Table 4-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.1.2	21 June 2023	<p>For this release, we fixed 13 issues related to visits, rules, training, performance, Inform subject import to Clinical One, notifications, forms, and reports. For more information see:</p> <ul style="list-style-type: none">• Issues 35429014, 35400909, 35383291, 35382903, 35393191, 34896490 in Forms, visits, and rules.• Issue 35362448 in Sites, labs, depots, settings, and user management.• Issues 34159843, 35369692, 35356232, 35299270, and 35143048 in Reports, archives, extracts, and notifications.• Issue 35430907 in Site users and subject data. <p>Also, an update was made in Oracle Central Coding that benefits Oracle Clinical One Platform studies. For more information, see Oracle Central Coding now supports a subject number change</p>
Release 23.1.1.1	28-May-2023	<p>For this release, we fixed one issue related to the Subject Data Extract. For more information, see Issue 35396396 in Reports, archives, extracts, and notifications.</p>

Table 4-1 (Cont.) Patch log

Release Number	Release Date	Notes
Release 23.1.1	16-May-2023	<p>For this release, we fixed six issues related to study design, sites, reports, Analytics, and visit branches. For more information see:</p> <ul style="list-style-type: none">• Issues 35310223, 35309668, and 35285490 in Sites, labs, depots, settings, and user management.• Issue 35279146 in Reports, archives, extracts, and notifications.• Issue 35281545 in Oracle Clinical One Analytics.• Issue 35274867 in Forms, visits, and rules. <p>We also documented enhancements to Signature Configurations and the Unblinded Subject Events dataset. For more information, see Other enhancements.</p>

What's new

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

Data collection

- [Manage screen failure subjects](#)
Sponsor users can now set configurations that allow subjects who have failed screening to complete or withdraw from the study.

Manage screen failure subjects

Sponsor users can now set configurations that allow subjects who have failed screening to complete or withdraw from the study.

Details for sponsor users

Under the Study Settings tab, the new **Screen Failed Subjects** configuration provides you with multiple options to enhance your screen failed subject management:

- By selecting **Allow Screen Fail before Screening**, subjects can be manually screen failed if they have not yet been screened.
- By selecting **Allow Withdrawal**, on the Subjects page, the **Withdraw** option becomes available for screen failed subjects.
- By selecting **Allow Completion**, on the Subjects page, the **Complete** option becomes available for subjects who have failed screening.

 **Note:**

The **Allow Withdrawal** and **Allow Completion** settings are deselected by default for existing studies.

- By selecting **Yes** for the **Allow Withdrawal for Subjects before Enrollment** configuration, the ability to withdraw subjects before they've been enrolled in a study becomes available.
- Screen failed visits can now be included in a subject's visit schedule.

More details on configuring these settings can be found in Specify study enrollment and visit settings after the Release Assessment Environment upgrade.

Details for site users

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

- If your study's settings have been configured to allow for screen failed subjects to withdraw from the study, the **Withdraw** option is enabled in the **Manage Subjects** drop-down, and withdrawal event forms become available to record additional data.
- If your study's settings have been configured to allow for subjects who have failed screening to complete the study, the **Complete** option is enabled in the **Manage Subjects** drop-down, and completion even form become available to record additional data.
- **Withdraw** and or **Complete** are not available in the **Manage Subjects** drop-down if they are not selected in the study settings.

Step-by-step instructions on managing screen failed subjects can be found in the *Site User Guide* after the Release Assessment Environment upgrade.

Impacts on reports

The Study Design report and Subject Events report have been enhanced to include details on screen failed subjects.

Data review

- [Sign off at the form and visit level with custom affidavits](#)
As a sponsor or CRO, you can now define Signature Configurations at the form and visit level, and program the system to remind users about signing data at all levels.

Sign off at the form and visit level with custom affidavits

As a sponsor or CRO, you can now define Signature Configurations at the form and visit level, and program the system to remind users about signing data at all levels.

For the 23.1.1 patch release, we've introduced a minor enhancement for this new feature. For more information, see the [Other enhancements](#).

Before you work with this feature

The following users can sign off at the form and visit level and manage custom affidavits:

- Users assigned the *Approve and Sign Subject Data* permission can sign at the casebook level and their signature is applied to all questions available to them based on their permissions. This permission also allows users to sign data that has been assigned to them in a signature configuration.
- Users assigned the *Approve and Sign Assigned Data Only* permission are only able to sign data that has been assigned for their role at the form or visit level in a signature configuration.
- Users assigned the *Receive the Pending Signatures Notification* permission will receive email notifications informing them when a signature, for a site they are assigned to, has reached the defined target date or become overdue.

 **Note:**

The **Signature Requests** notification is only sent once the **Send Reminder Through Email** setting is configured to **Yes**.

- Sponsor users assigned the *Manage Signature Settings* permission have the ability to create and edit signature configurations.

More details on notifications and permissions for this feature can be found in the *Notifications and Permissions Guide* and the *Add Users Guide* after the Release Assessment Environment upgrade.

Details for sponsor users

As a sponsor user, here's what you should be aware of when it comes to your workflow:

- Signature configurations at the form and visit level are disabled until the **Display signature elements for site staff and sponsors** setting is configured to **Yes** in the Study Settings.

 **Note:**

Signature configurations for casebook level signatures are still available when this setting is configured to **No**.

- The signature option is available in all study modes.
- If you are required to sign off at more than one level, signatures applied at a lower level fulfill those at a higher level only for that specific form or visit. For example, a signature at a form level fulfills visit or subject level requirements.

 **Note:**

Signatures at a higher level do not fulfill those at a lower level, therefore, a signature at the subject level will not fulfill a form level requirement, requiring separate signatures.

This only applies if the user signing is responsible for signing at the higher level, as well.

- The first value in the Affidavit's codelist will be used for subject level signatures if more than one affidavit is included in the codelist.
- Be aware that if a new visit is named the same as a deleted visit, both appear as options in the Signature Configuration.
- Signature icons and requirements for impacted visits are updated for a subject once data is entered into a question or form, when the given question or form is added or modified through Advanced Study Versioning (ASV).

Details for site users

When it comes to your workflow, here's what you should know:

- The **Ready to Sign** filter now includes incomplete forms and visits with signature requirements.
- In order to confirm data accuracy, the forms under the following signature configuration types require a re-signature after previously signed if they are deleted, hidden, or no longer require signing:
 - Subject level
 - Two-section form
 - Visit level

You can find additional information in the *Site User Guide* after the Release Assessment Environment upgrade.

Impact on reports

The following reports have been updated for this feature:

- Study Design report
- Subject Data report
- Subject Events report

More information on these report impacts can be found in the *Reporting Guide* after the Release Assessment Environment upgrade.

Integrations

- [Better shipment management for the Almac integration](#)
This feature allows a user to pick which depots to integrate to Almac in their study.
- [Oracle Central Coding now supports a subject number change in an Oracle Clinical One Platform study](#)
- [Data Intake integration enhancements](#)

Better shipment management for the Almac integration

This feature allows a user to pick which depots to integrate to Almac in their study.

Integration managers can now configure an integration with Almac Global Depot Network to exclude orders from depots that are not managed by Almac Global Depot Network.

Previously, it was expected for Oracle Clinical One Digital Gateway to handle shipment orders for all depots in a study, including the ones that were not specified for an Almac integration.

Oracle Central Coding now supports a subject number change in an Oracle Clinical One Platform study

Starting with Oracle Central Coding 7.0.1.0, a subject number change made in Oracle Clinical One Platform displays correctly in the Oracle Central Coding user interface, reports, and extracts.



Note:

Oracle Central Coding 7.0.1.0 is scheduled for release by the end of June 2023. You will need to upgrade to take advantage of this functionality.

Previously, the updated subject number was not reflected in the Oracle Central Coding user interface. The integration still functions because a unique ID (one that does not change when the subject number is changed) is included in the exchange of information between the systems. This fix ensures that the correct subject number is displayed in the Oracle Central Coding user interface, reports, and extracts.

Data Intake integration enhancements

The Data Intake integration no longer requires the site ID to be included in the data file

The Oracle Clinical One Digital Gateway Data Intake integration, used to load generic data such as subject and questionnaire data into an Oracle Clinical One Platform study, no longer requires site ID to be included in the data file.

Site id can now be derived from the site portion of the subject number, for example, 01-001, where the site id is 01. Previously, site ID was a required value in the data file.

For more information about the Data Intake integration, see Labs & general subject data intake.

The Data Intake integration now supports the date format dd-MM-yyyy (22-02-2023)

The Oracle Clinical One Digital Gateway Data Intake integration now supports importing dates in the dd-MM-yyyy format into Oracle Life Sciences Clinical One Platform studies. This includes visit date and regular date fields, such as a sample collection date.

Randomization and trial supply management

- [Tracking numbers for temperature excursions](#)
You can now provide tracking numbers for kits that have experienced a temperature excursion to improve your tracking and visibility for supply chain issues in a study.

Tracking numbers for temperature excursions

You can now provide tracking numbers for kits that have experienced a temperature excursion to improve your tracking and visibility for supply chain issues in a study.

Details for sponsor users

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

- You can now define the Temperature Excursion Starting Number on the Supply Settings tab when **Yes** is selected for the Allow Temperature Excursions setting.
- Temperature excursion starting numbers can be configured with a starting value of one (1) digit up to eight (8) digits that sequentially increment by 1. For example, 001, 002, 003, 004, and so on.

 **Note:**

The starting number cannot begin with 0.

- All kits that are quarantined together receive the same tracking number.
- Users assigned the *Receive the Quarantined Depot Shipment Notification* permission receive the new *Study Inventory Quarantined* notification. This notification alerts users when available kits at a site or depot are marked as Quarantined.
- Users assigned the *Receive Notification of Shipments* permission receive the new *Pending Shipment* notification when a shipment has not been received at a site within the number of days defined in the supply settings.

Updates to the following reports have been made to reflect the new tracking number feature:

- Kit Chain of Custody (Blinded) report
- Kit Inventory (Unblinded) report
- Study Design report

Details for site users

Be aware that temperature excursion tracking numbers are displayed under the Kit History side-panel on the Site Inventory page only for kits marked as Quarantined.



Note:

If a temperature excursion tracking number is assigned to a kit, it always remains with that kit and can be filtered by Temperature Excursion Number regardless of the kit status.

Reporting, archives, and analytics

- [Enhancements to the Subject Data Extract](#)
The Subject Data Extract no longer includes deleted, cleared, and undone visit data, while the format of date fields has been unified.
- [Enhancements to ODM-XML clinical data extracts](#)
To ensure appropriate data granularity, enhancements have been added to the ODM-XML clinical data extract.
- [Enhancements to Oracle CRF Submit archives and reports](#)
- [RTSM Dashboard in Oracle Clinical One Analytics](#)
The Randomization and Trial Supply Management (RTSM) dashboard is now available in Oracle Clinical One Analytics allowing you to visualize key information related to randomization and supply management.

Enhancements to the Subject Data Extract

The Subject Data Extract no longer includes deleted, cleared, and undone visit data, while the format of date fields has been unified.

Deleted or blank forms will no longer be included in the report

The Subject Data Extract now includes only the current version of data collected at sites. As such, the **DELETED** column has been removed, while any other deleted, cleared, or undone visit data will no longer be included in the report.

Unified date formats

All dates are now exported in the YYYYMMDD format in the report, in accordance with ISO 8601.

Enhanced Subject Data Extract notification emails

The Subject Data Extract notification email will now indicate the site where the data originated, as well as the file type the report was generated in (CSV, CPORT, XPORT, or SAS7BDAT).

Enhancements to ODM-XML clinical data extracts

To ensure appropriate data granularity, enhancements have been added to the ODM-XML clinical data extract.

 **Note:**

for these enhancements to take effect, please ensure you are using the latest version of the clinical and metadata APIs. For more information, see the [REST API for Clinical One Platform](#) guide.

New data fields

To make it easier to track the source of data contained in a lab form, **Lab Id** and **Lab name** have been added to the ODM-XML clinical data extract. These fields only populate whenever the data for the repeating part of a lab form has been entered or updated.

For queries submitted as part of a study, the new **assignedRole** field indicates the role of the user which needs to close that particular query. Moreover, the new **QueryType** field identifies the source of a query, while the new **QueryRaised** co extension indicates how the query was generated.

Improvements made to existing fields

ODM metadata now correctly identifies repeating forms and sections.

A new co extension, **QuestionGroup**, has also been added, which helps identify whether a question group is present.

Data availability and formatting

Users can now extract metadata from Testing study versions which have afterward been moved to Approved or have been Archived; previously, Testing metadata would not have been available in this scenario. The data contained in a study prior to production is marked accordingly within the report.

Measurement units now display properly for both calculated and normal values.

Enhancements to Oracle CRF Submit archives and reports

Form & Visit level Signatures and Affidavits (from code lists) are now supported

Starting with 23.1, signatures can now be configured at the form and visit level. Subject PDFs include the signatures and indicate the type of signature applied, Form, Visit, or Subject. The affidavit text is displayed according to the signature configuration, using the code list value as of the signature date.

Previously, subject PDFs included the signature history at the form level when all items on a form or the subject casebook were signed. The associated affidavit text was displayed using the code list value as of the signature date.

You can find more information about signing at the visit and form level in the *Site User Guide*, and details about signature configuration can be found in the *Sponsor and CRO User Guide* after the Release Assessment Environment upgrade.

The As of Date in the Request Settings PDF now displays in a users time zone

In the request settings PDF, the **As of Date** now displays the date/time based on the time zone settings of the user who generates the request. Previously, the Request Settings PDF displayed GMT by default.

Electronic Trial Master File (eTMF) transfers are now supported

Oracle CRF Submit output files for Archival PDF (sponsor and site), and Custom PDF archive requests can now be delivered to the Oracle sFTP server. These files can be programmatically transferred to your eTMF storage system or downloaded manually in the Oracle Clinical One Platform user interface.

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

RTSM Dashboard in Oracle Clinical One Analytics

The Randomization and Trial Supply Management (RTSM) dashboard is now available in Oracle Clinical One Analytics allowing you to visualize key information related to randomization and supply management.

 **Tip:**

Whether you are working in a live study (and already using Oracle Clinical One Analytics), working in a brand new study, or just starting to work with analytics, reach out to your Oracle Project Manager for more information on Oracle Clinical One Analytics training and mentoring.

With the introduction of the new RTSM dashboard template in Oracle Clinical One Analytics, you can get a holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to a customizable, interactive dashboard containing reports and visualizations that can help improve your decision-making on randomization and supply management processes.

Since they are templates, you do not have to create dashboards from scratch, but you can customize it to meet your needs. All you have to do is download the template and re-import it to tweak the data in and adjust filters, and this way make sure you are viewing data relevant to your work. For more information see [Customize templates](#).

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. To work with the RTSM dashboard, you must have access to the following datasets:

- Unblinded Kits dataset
- Subject dataset

Access to a dataset is given based on a permission that you must be assigned in Oracle Clinical One Platform. For more information on these permissions, see [Descriptions of permissions in Clinical One](#).

Details for clinical supply managers

With the new RTSM dashboard, Clinical Supply Managers (CSM) can monitor randomization and supply details across studies and sites. Even though this dashboard is intended to assist CSMs with their duties, the RTSM dashboard is available to any user with the appropriate permissions. This customizable dashboard offers you complex data on randomization and supply management, organized within the following interactive reports:

- Overall Summaries
- Subject Details
- Subjects Enrolment Summary
- Site Status
- Unblinded Randomization
- Site Overall and Monthly
- Site Overall (Shipment)
- Unblinded Shipment History
- Site Inventory
- Unblinded Visit Summary
- Unblinded Clinical Supplies Return
- Unblinded Site and Depot Kit Status
- Unblinded Depot Inventory

The reports and visualizations grouped in this dashboard can help CSMs to analyze the study inventory and treatment arm distribution across the study. With this, the study team can identify a possible need of randomization design and limits update, as well as supply management adjustments.

You can find additional information regarding dashboards in the *Analytics User Guide* after the Release Assessment Environment upgrade.

Rules management

- [Enhancements to rule helper functions](#)

Enhancements to rule helper functions

Access data from forms in other visits using `getValues()`

You are now able to create variables referencing items that do not exist within the same visit as the rule target. Previously, you could reference all of the visits where the rule target form exist. Now, when defining rule variables, you have a new option in the visit selection drop-down that allows you to declare variables for *Any Visit*. This allows referencing data collected in any other form at different visits, regardless if the target rule form is present or not.

By using `getValues()` you can fetch these values and use them in comparisons and other logical operations with data in the current form. For example, you can get the sample collection date from a previous visit and compare it with the infusion date in the

current form, to make sure the sample collection date is prior to the infusion date. This example considers that sample collection date question exists within a form present in a first visit but not present in a second visit in which infusion is performed.

Refer to values in different table rows

A new helper function now allows you to fetch the immediate previous not-null value from previous rows in repeating forms and repeating sections on two-section forms. The introduction of `getPrevRepeatValue()` facilitates logical operations between values in different rows, whether it is the same or a different question, while reducing programming efforts. For example, you can get the end date of a dose on the immediate previous row and compare it with the start date of a dose in the current row.

You can find additional details about this new helper function in the *Rules Developer Guide* after the Release Assessment Environment upgrade.

Reuse variables passed into helper functions

Previously, when using repeating forms and two-section forms helper functions, you needed to create a second variable for the same question if it also needed to be referenced elsewhere in the expression. Now, the following helper functions have been enhanced to allow the reuse of variables (all item types are supported):

- Repeating forms helper functions:
 - `FindMinInRepeatingForms()`
 - `FindMaxInRepeatingForms()`
 - `FindMatchingRepeatingForm()`
 - `FindMatchingRepeatingFormWithinRange()`
 - `FindDuplicateRepeatingForm()`
 - `FindDuplicateRepeatingFormWithinRange()`
 - `FindRFInstance()`
 - `ListRFInstances()`
 - `getRFValues()`
 - `FindMinDateInRFs()`
 - `FindMaxDateInRFs()`
 - `GetMatchingRepeatingFormsCount()`
- Two-section forms helper functions:
 - `FindMatching2SForm()`
 - `list2SInstances()`
 - `findDuplicate2SForm()`
 - `getCurrent2STableInstance()`
 - `get2SValues()`
 - `findMinDateIn2SForm()`
 - `findMaxDateIn2SForm()`
 - `find2SFormInstance()`

- `getMatching2SFormsCount()`
- `findMinIn2SForms()`
- `findMaxIn2SForms()`
- `findDuplicate2SFormWithinRange()`
- `findMatching2SFormWithinRange()`

Enhancement to use helper functions with codelists

When working with code lists in choice questions, you can now specify whether to get the code or the label value. To do this, you can use the `getArrayFromChoice()` and `getStringFromChoice()` helper functions, which now have a new optional parameter that allows you to define which value to return.

You can find additional information on these and other Helper function reference in the *Rules Developer Guide* after the Release Assessment Environment upgrade.

Study design

- [Create your very own library study](#)
Users at a sponsor organization or Clinical Research Organization (CRO) can now create their own library study and include objects in these libraries to be used in live studies.
- [Preview forms in Draft mode](#)
Study designers can now preview a form's design while in Draft mode, to address any issues and make necessary adjustments before moving a study version to Testing.

Create your very own library study

Users at a sponsor organization or Clinical Research Organization (CRO) can now create their own library study and include objects in these libraries to be used in live studies.

By creating your own library study, you can not only reduce the time for study building, but you can also better manage standards for study metadata and improve the consistency of design throughout all studies at your organization. With every object created and tested within the context of a library, users can then add these objects to a live study ensuring that their protocol is up to the organization's standards.

Before you work with this feature

This new feature can impact global users, as well as study designers. As a global user manager, you can assign the following new global roles to users so they can view and manage library studies:

- Change Library Objects Status
- Manage Library Objects
- View Library Objects

Details for library users

Here's what's new for you:

 **Note:**

For this release, you can only include forms as objects in your library.

- Now, when you navigate to the Library page, you land on the Library Studies page where you can create and manage all of your library studies.
- On the Library Studies page, you can click **View Library**. This takes you to the organization's library where you can navigate between the **Code List** tab and the **Forms** tab. The new **Forms** tab contains all of the forms from your library studies. The **Code List** tab has no functional changes and it will still display all of your organization's custom and system default code lists.
- On the Library Studies page, you can click **Create Library Study**, fill in the fields of the Create Library Study dialog and create a new library study in your library.
- On the Library Studies page, a library study is displayed similarly to how a study is displayed on a Home page. A library study can be versioned and moved through all four different containers: Draft, Testing, Approved, and Archived.
- By clicking a library study in the Draft container, you can navigate to the Forms tab within a library study. You can then choose between creating a brand new form or importing an existing form from another live study or another library study at your organization.
- An object in a library can have various statuses. By default, when you import or create a new object, its status is set to **Draft**. Other statuses that an object can have are **Testing**, **Rejected**, **Approved**, **Published**, or **Archived**.
- After you create an object in a library study, you can test it, approve it, and then publish that object in your library study. Only after you test, approve, and publish an object within your library study, can you add it to a live study and further test it in that updated study version.
- You can choose to version an object that was already published so that your library contains multiple iterations of the same object. For example, you can choose to create two or three different versions of the same Demographics form. All of the different versions can be used across live studies at your organization.
- Irrespective of its status, you can always edit an object's attributes, such as its description and associated tags.
- Along the top of the Library page, you have several options to make navigation of library objects easier: you can filter objects by status or tag, you can expand or collapse all objects to view or hide their details, or you can search for a specific library object.
- On the right side of the Library page, upon selecting an object, you can view its history on the Object History side panel.

Reporting updates

Objects created in library studies will be displayed in reports and datasets in Oracle Clinical One Analytics for a future release.

Impact on integrations

You cannot set up integrations for library studies.

Impact on custom JavaScript rules

As a rule designer and tester, you must know that you can create custom rules in a library study, as well. The workflow for creating, testing, approving, and ultimately publishing a custom rule in a library study is the same as the workflow that you follow for a live study.

When you add an object with custom rules to a live study, keep in mind that all custom rules are imported in the live study with a status of **Invalid**. You will then have to test, approve, and publish the copied rules to ensure that they run correctly in your updated live study version.

Already working in a live study?

As soon as the release upgrade is complete, you can begin creating library studies and adding objects to them. You can add forms to your new library study from any other study whether it is newly created or already live.

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

Preview forms in Draft mode

Study designers can now preview a form's design while in Draft mode, to address any issues and make necessary adjustments before moving a study version to Testing.

With this new feature, study designers can preview forms during design. Beside your own ability to preview a form, you can share preview links to other users in your study team to get feedback before releasing the study version for Testing. This allows users to quickly address any issues that may arise during data collection and make the necessary adjustments while the study design is still available in Draft mode.

Before you work with this feature

To either preview forms or share preview links, you must have at least one of the following permissions for the given study:

 **Note:**

Users with a preview link can forward the preview form invite; however, only authorized users can access the form preview.

- *Design Forms*
- *Design Randomization*
- *Design SDV Properties on Forms*
- *Design Supplies and Dispensation*
- *Design Visits and Events*
- *Move a Study Design to Testing or Production*
- *Run the Study Design Report*
- *Run the Study Rules Report*

- [Upload and Generate Inventory Lists](#)
- [Upload and Generate Randomization Lists](#)
- [View Study Design](#)

Details for study designers and other sponsor users

This feature is available for one and two-section forms, as well as lab forms. Previewed forms display as they would within a visit in a live study. Additionally, users can enter mock data to also preview dynamic questions and dynamic sections. Repeating rows get displayed on their tabular form and, by clicking on any data entry field, the data entry view can be expanded. In the case of lab forms, the preview gets rendered successfully; however, lab normal ranges are not validated.

When accessing through a preview link, if the form design is no longer in Draft mode but still exists within the given study version (whether in Testing or Production), users get to see the latest version of the form. If the requested form is not available for preview, users get notified if the requested form doesn't exist, if it has been deleted, or if you are not authorized to access it.

You can find additional information on the *Study Designer User Guide* after the Release Assessment Environment upgrade.

Other enhancements

Hide or enable user interface elements for signature configurations

Sponsor users can now allow for signature configuration elements to appear in the user interface.

Signature elements on the Study and Subject homepages are hidden by default for existing studies. In the Study Settings, selecting **Yes** for the **Display signature elements for site**



staff and sponsors option enables the Signature widget (Signature) to display in Production mode, while the Signature Request side panel appears in all modes.

Note:

It is not possible to go back and select **No** for the **Display signature elements for site staff and sponsors** option once **Yes** has been selected and saved for the corresponding mode.

New fields in the Unblinded Subject Events dataset

New fields have been added to the Kit and Subject folders of the Unblinded Subject Events dataset in Oracle Clinical One Analytics. The new fields provide information about titration, treatment arm, and unblinding details, allowing users to report subjects and events alongside these data points.

Additional information can be found in the *Analytics User Guide*.

Fixed issues

- [Forms, visits, and rules](#)

- [Integrations](#)
- [Oracle Clinical One Analytics](#)
- [Reports, archives, extracts, and notifications](#)
- [Sites, labs, depots, settings, and user management](#)
- [Site users and subject data](#)

Forms, visits, and rules

Visit cycle is skipped incorrectly

Now, cycle visits that have been skipped and unskipped, resulting in a status of **New** or **In Progress**, are included in the logic used to calculate subsequent visits.

Retracted workaround: None. Issue (35620027).

Lab forms in cyclic visits populate incorrectly with lab normals

Now, if working in a study that uses cyclic visits, the lab normals appear only when the Sample Collection Date is set after the Effective Date. Previously, the lab forms populated incorrectly with lab normals if the Sample Collection Date (or visit date) was set before the Effective Date (the date from which the lab normal range became effective at the laboratory).

Issue (35554738)

Error when adding a custom rule in a lab form

Rules developers: Now, when creating a custom rule referencing fields in the first section of a lab form, that rule returns the correct values when running. Previously, when you created a custom rule that referenced a question such as the Sample Collection Date or the question on Fasting (both located in the first section of a lab form), the system would return an Internal Server Error.

Issue (35454836).

For more information, see [Create and manage custom rules](#)

Cycle visits show the same date

Site users: The scheduled future cycle visits now show different dates. Previously, the same date showed for all future cycle visits in a week. This prompted unrequested shipments for site dispensation.

Issue (35383291).

Error encountered submitting a lab form when UNK is entered as a time component (Former Known Issue)

Site users: Now, selecting UNK for a time component with a partial date shows as expected. Previously, site users encountered an unexpected error after submitting a lab form that included a date item that allowed for partial date entry, and selected UNK for the time component.

Retracted workaround: You no longer have to collect the data first, and then complete the partial date/time question with UNK afterward.

Issue: (35382903)

Re-running a custom calculation value rule results in an error'

Rule designers: Re-running a calculated value rules in a live study now work seamlessly with data re-populating the targeted fields, as expected. Previously, when you re-ran a rule in a live study, you would receive an email that an error has occurred, and data would not be updated in the rule's targeted fields.

Issue (35393191)

Error when editing visit schedule in Draft mode

Study designers: Now, when you specify a visit's window, you can save your changes as expected. Previously, when editing and saving the changes in any of the Visit Window fields, an "Update Scheduled Failed" error message would appear. The targeted field would remain unchanged.

Issue (34896490)

Radio buttons cannot be updated when links are present

Site users: Now, you can modify the answers to a question with radio buttons even when the form containing that question is linked to other forms in a study. Previously, you were unable to modify to answer of a question that was included in a linked form, even though that question did not determine the linking. For example, when you attempted to modify the answer to a question unrelated to a linked form, an error message appeared that stated: "The answer to this question impacts other related questions on this form. You must clear any answers or links to the related questions, as well as answer or update related queries before you can change this answer".

Workaround: Remove the form link and clear the dynamic questions to allow the system to change the option for the radio control.

Issue (35429014)

The cycle visit branch shows incorrect order

Study designers: Now, the future cycle visits you create are displayed in a subject's schedule with their specified dates. Previously, all future cycle visits were displayed with the same date throughout a week. This prompted unrequested shipments for site dispensation.

Issue (35400909).

Subject switches to the wrong branch when configured on form criteria

Study Designers: Currently, the visit branches that you configure using form criteria work as expected. Previously, at times, visits in a branch were not displayed for you as expected when they were configured on form criteria.

For example, if a subject answers a question such as "Do you want to continue with the same treatment?" with "No," they will be moved to the appropriate visit branch that you configured.

(Issue 35274867)

Integrations

ODM Metadata API v2.0 failing due to classnotfound exception

Now, the call is successful when using the ODM Metadata API version 2. Previously, the call would fail due to the absence of a specific class file.

Retracted workaround: None. (Issue **35217778**)

Oracle Clinical One Analytics

Two active records showing for the same form in the Subject Forms dataset

The Subject Forms dataset now shows a single record for each form where the site has been renamed. Previously, entering the data in one of the forms, renaming the site and subsequently entering data in a second form would lead to the Subject Forms dataset to feature two records for each form, one in a **Completed** status and another in a **Scheduled** status.

(Issue **35281545**)

Reports, archives, extracts, and notifications

Error in generating a Kit Reconciliation report in a CSV format

Users can now generate a Kit Reconciliation report in CSV format. Previously, users with the permission to 'Run the Kit Reconciliation report in a CSV format' were unable to successfully generate a Kit Reconciliation Report in CSV format if they are not assigned to the appropriate depot, as a user.

Issue (**35369692**)

Site users receive pending shipment notifications originating from another site (former Known Issue)

Site users: Shipment notifications from sites now activate only when selected. Previously, we reported that site users receive pending shipment notifications originating from a site other than their own. Users should only receive these notifications for the sites they are assigned to.

Retracted workaround: None

Issue (**35356232**)

The User Assignment and User Assignment by site reports do not generate for specific studies and tenants

Site users: Now, generating User Assignment and User Assignment by Site reports work as expected. Previously, specific studies at your organization experienced errors and delays when attempting to generate either the User Assignment or User Assignment by Site report.

Issue (**35299270**)

The Subject Data Extract has columns in the incorrect order

Data managers and statisticians: Now, the Subject Data Extract displays form-related data in the appropriate order without any duplicate data. Previously, the extract displayed data in an unexpected way, with duplicate data being present. This issue is now fixed after introducing a new parameter in the logic of the extract called *baseStudy Version*. This field ensures that any forms you add in between study versions are properly displayed in the extract.

Issue (35143048)

Subject Queries report cannot generate for complex studies when the Audit Trail is on

Now, generating the Subject Queries report for complex studies works as expected. Previously, when users generated the Subject Queries report for complex studies, the action would fail when the option for the Audit Trail was on. Some users received an error message with "Date couldn't be parsed successfully", some would not receive any notification of the incomplete task.

Issue (34159843)

The Subject Data Extract is missing data from lab forms

Data managers and statisticians: Now, in the Subject Data Extract, you can see all of the data that was collected in a lab form, including the data collected through questions in the flat section (Questions Before the Table). For example, data collected for the Sample Collection Date and the Fasting questions are included in the extract, as expected. Previously, any data that was collected for questions in the flat section of a lab form was not included in the Subject Data Extract.

 **Note:**

The previously unexpected behavior was observed when a site user collected data in the flat section as well as selecting a lab to associate with the lab form.

(Issue 35396396)

Study Design report generates without forms

Sponsor users: Now, all forms associated with the visits of a study version display appropriately in the Study Design report when run in the .pdf format. Previously, the .pdf file generated by running the Study Design report did not include all visits and their respective forms as expected. This issue occurred in all modes of a study: Draft, Testing, Training, and Production.

(Issue 35279146)

Data related to form associations might be missing from the Subject Data Extract

Data managers and statisticians: Now, the data related to form associations in the Subject Data Extract within the Form Associations Dataset is appropriately displayed. Previously, you may have encountered the following issues:

- Values displayed for REPEATNUMBER or RREPEATNUMBER and SREPEATNUMBER were reversed.
- Values for SREPEATID or RSREPEATID might have been missing from the dataset.

Going forward, the following values are displayed:

- The two-section form number is displayed for SREPEATNUMBER or RSREPEATNUMBER.
- The two-section form repeating section row numbers are displayed for REPEATNUMBER or RREPEATNUMBER.
- For a two-section form where a repeating section row is linked, the UUID is displayed for SREPEATID.

Retracted workaround: None. (Issue: **35156289**)

Sites, labs, depots, settings, and user management

General slow performance of the Release Assessment Environment (RAE)

Now, any studies you might have in an Assessment Environment (RAE) will work as expected. Previously, some pages would not load, such as the login page, the General tab, a study's settings, or a subject's visit pages. As a user, you had to clean your cache or refresh the page to see an improvement in the environment's performance.

Issue (**35362448**)

Records for randomization lists are not loading in the Randomizations tab

Study designers: When accessing a study version in Production, users can now view the list of randomizations accordingly on the Randomizations tab. Previously, the list of randomizations would only load the first item, making it impossible to select a different randomization.

(Issue **35310223**)

Normal ranges are not loading for lab forms

Site users: Lab normal ranges now populate as expected when selecting a lab to associate with a lab form. Previously, lab normal ranges would not populate during a visit, even when a lab was associated to a lab form.

(Issue **35309668**)

Study version title cannot be changed using Rename

Study designers: You can now rename study versions in the Edit Study panel. Previously, you could not interact with the name of the study version even when selecting Rename.

(Issue **35285490**)

Site users and subject data

Subject number sequences are inconsistent in a study

Study managers: Now, when you add subjects from InForm in your study and add subjects through Oracle Clinical One Platform, too, the sequence numbers of your subjects are displayed as you configure them. For example, if all subjects added through Oracle InForm follow the numbering pattern starting with 0001, the subjects you then add through Clinical One will follow the new numbering pattern you configured (starting with 9001). Previously, after making this change in the subject

number sequence, you may have noticed that any subsequent subjects you added through Oracle Clinical One Platform used the old subject number format and not the new one you specified, instead.

Issue (**35430907**)

A closed query automatically reopens without a data change

Site users: Now, a query closed manually remains closed even after navigating to the next visit, entering the visit date, then returning to the visit where the query was closed. Previously, when the user navigated back to the previous visit, the query status Re-opened was displayed.

Retracted workaround: Create a report to identify the impacted queries and manually close them before a site user can answer them. Issue (**35062639**)

Site users are unable to save a form associated with a new study version after clearing and reentering data

Site users: Now, you can save a form associated with a new study version after clearing data entered in the previous version, then entering data for the new version. Previously, you would encounter an error when trying to save the form..

Retracted workaround: None. (Issue **35155305**)

Reason for undoing a screen failure is displayed for a randomization visit (former known issue)

Site users: Now, when you undo screen fail for a subject, followed by randomization, the reason captured for the randomization visit displays correctly.

Previously, undo screen failure followed by randomization resulted in the reason for undo screen failure showing for the randomization visit. This also affected how data was displayed in Oracle Clinical One Analytics datasets.

Retracted workaround: None. (Issue **34491558**)

Unable to skip an optional visit after clearing the visit date

Site users: With the appropriate permissions, you can now skip an optional visit after clearing the visit date. Previously, you were presented with the following message after clearing the visit date: You cannot skip the <visit_name> visit.

Retracted workaround: None. (Issue **35170613**)

Rest API updates

See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs for 23.1, available upon the Production release.

The following new service has been added:

- [Library](#)

The following services have been updated:

- [Data Action](#)
- [Data Hub](#)

- [Data Capture](#)
- [Designer](#)
- [Notifications](#)
- [Query](#)
- [Randomization and Supplies](#)
- [Rules](#)
- [Rule Designer](#)
- [Users, Permissions and Roles](#)

Library

Change	Method	Endpoint
New	GET	/v1.0/libraryUses/studies/{studyId}/versions/{studyVersion}

Data Action

Change	Method	Endpoint
New	PUT	/v1.0/studies/{studyId}/{mode}/unsign-unverifyforitem
	POST	/v2.0/studies/{studyId}/{mode}/cleardatacheck/{scope}

Data Hub

Change	Method	Endpoint
New	GET	/v3.0/studies/{studyId}/{mode}/odm/metadata
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries
	GET	/v5.0/studies/{studyId}/{mode}/odm/clinicalData/blinded
	GET	/v5.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded

Change	Method	Endpoint
	POST	/v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems

Data Capture

Change	Method	Endpoint
New	PUT	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/codeview
	GET	/v4.0/studies/{studyId}/{mode}/subjects/history/all
	PUT	/v4.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v4.0/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak
	GET	/v5.0/studies/{studyId}/{mode}/subjects/{subjectId}
	GET	/v8.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
Deprecate d	POST	/v2.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/ subject/{subjectId}/code/{code}/orgId/{orgId}

Designer

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/cloneSystemCodelist
	POST	/v1.0/studies/{studyId}/forms/formItems
	POST	/v1.0/studies/{studyId}/forms/{formId}/choiceoptions

Change	Method	Endpoint
	GET	/v1.0/studies/{studyId}/forms/{formId}/formitems
	POST	/v1.0/studies/{studyId}/hasRandomization
	GET	/v1.0/studies/{studyId}/{mode}/forms
	GET	/v1.0/studies/{studyId}/{mode}/forms/{formId}/visits
	GET	/v5.0/studies/{studyId}/studyversionobjects
	POST	/v7.0/studies/{studyId}/studyDesign/paginated

Notifications

Change	Method	Endpoint
New	POST	/v5.0/studies/{studyId}/{mode}/notificationlog

Query

Change	Method	Endpoint
Deprecated	GET	/v1.0/studies/{studyId}/{mode}/queries/queryTable
	GET	/v1.0/studies/{studyId}/{mode}/queries/state
	PUT	/v1.0/studies/{studyId}/{mode}/queries/{queryId}/assignupdate
	PUT	/v2.0/studies/{studyId}/{mode}/queries/{queryId}/answer

Change	Method	Endpoint
	PUT	/v2.0/studies/{studyId}/{mode}/queries/{queryId}/delete
	GET	/v2.0/studies/{studyId}/{mode}/queryDetails
	GET	/v3.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v3.0/studies/{studyId}/{mode}/queries/candidate
	POST	/v3.0/studies/{studyId}/{mode}/queries/open
	GET	/v3.0/studies/{studyId}/{mode}/queryDetails
	POST	/v3.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v4.0/studies/{studyId}/{mode}/openQueryDetails
	GET	/v4.0/studies/{studyId}/{mode}/queries/{queryId}
	PUT	/v4.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v4.0/studies/{studyId}/{mode}/queries/{queryId}/open
	POST	/v4.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v5.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v5.0/studies/{studyId}/{mode}/queries/candidate

Change	Method	Endpoint
	POST	/v5.0/studies/{studyId}/{mode}/queries/open
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/delete
	PUT	/v5.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v5.0/studies/{studyId}/{mode}/queryDetails
	POST	/v5.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v6.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v6.0/studies/{studyId}/{mode}/queries/candidate
	POST	/v6.0/studies/{studyId}/{mode}/queries/open
	GET	/v6.0/studies/{studyId}/{mode}/queries/{queryId}
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/delete

Change	Method	Endpoint
	PUT	/v6.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v6.0/studies/{studyId}/{mode}/queryDetails
	POST	/v6.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v7.0/studies/{studyId}/{mode}/openQueryDetails
	POST	/v7.0/studies/{studyId}/{mode}/queries/open
	GET	/v7.0/studies/{studyId}/{mode}/queries/{queryId}
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/answer
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/close
	PUT	/v7.0/studies/{studyId}/{mode}/queries/{queryId}/open
	GET	/v7.0/studies/{studyId}/{mode}/queryDetails
	POST	/v7.0/studies/{studyId}/{mode}/report/{reportName}

Randomization and Supplies

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/reports/blindedrandreport

Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/{mode}/kits/{inventoryId}/historyById
	POST	/v2.0/studies/{studyId}/{mode}/reports/kits/blindedchainofcustody
	POST	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/quarantined
	POST	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/received
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/historyById
	PUT	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits
	GET	/v4.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	PUT	/v4.0/studies/{studyId}/{mode}/inventory/kits
	POST	/v4.0/studies/{studyId}/{mode}/inventory/kits/audit
	PUT	/v4.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitId}
	GET	/v5.0/studies/{studyId}/{mode}/orders
	GET	/v5.0/studies/{studyId}/{mode}/orders/{shipmentId}
	GET	/v6.0/studies/{studyId}/{mode}/inventory/kit-types
	POST	/v6.0/studies/{studyId}/{mode}/reports/kits/chainofcustody

Change	Method	Endpoint
	PUT	/v9.0/studies/{studyId}/{mode}/supply/settings

Rules

Change	Method	Endpoint
Deprecated	PUT	/v1.0/studies/{studyId}/{mode}/jobStatus
	PUT	/v2.0/studies/{studyId}/{mode}/deleteform

Rule Designer

Change	Method	Endpoint
Deprecated	PUT	/v1.0/rule/studies/{studyId}/bulkcopy
	POST	/v1.0/rule/studies/{studyId}/copyrules
	PUT	/v1.0/rule/studies/{studyId}/{mode}/bulkupdate
	GET	/v1.0/rule/studies/{studyId}/{mode}/item/{itemId}
	GET	/v1.0/rule/studies/{studyId}/{mode}/propertyType/{propertyType}
	GET	/v1.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId}
	POST	/v1.0/studies/{studyId}/{mode}/report/{reportName}
	PUT	/v2.0/rule/studies/{studyId}/bulkcopy

Change	Method	Endpoint
	PUT	/v2.0/rule/studies/{studyId}/{mode}/bulkupdate
	GET	/v2.0/rule/studies/{studyId}/{mode}/item/{itemId}
	GET	/v2.0/rule/studies/{studyId}/{mode}/propertyType/{propertyType}
	GET	/v2.0/rule/studies/{studyId}/{mode}/ruleId/{ruleId}
	POST	/v2.0/studies/{studyId}/{mode}/report/{reportName}
	PUT	/v3.0/rule/studies/{studyId}/{mode}/bulkupdate
	POST	/v3.0/studies/{studyId}/{mode}/report/{reportName}
	POST	/v4.0/studies/{studyId}/{mode}/report/{reportName}

Users, Permissions and Roles

Change	Method	Endpoint
New	GET	v1.0/userinfo/bulk

- [Rest API patch updates](#)
See the newly added endpoints of the Oracle Clinical One Platform APIs for 23.1.1, available upon the Production release.

Rest API patch updates

See the newly added endpoints of the Oracle Clinical One Platform APIs for 23.1.1, available upon the Production release.

The following services have been updated:

- [Data Hub](#)
- [Library](#)

Data Hub

Change	Method	Endpoint
New	POST	/v6.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Library

Change	Method	Endpoint
New	GET	/v1.0/libraryObjects/{libraryId}
	PUT	/v1.0/libraryObjects/{libraryId}
	DELETE	/v1.0/libraryObjects/{libraryId}
	POST	/v1.0/libraryObjects/bulkUpdate
	DELETE	/v1.0/libraryUses
	GET	/v1.0/libraryUses/{libraryId}

Release impact for other applications

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

Oracle Clinical One Analytics also known as Data Hub

- Updates to a signature's status are included in the application's reports and datasets. Information related to affidavits is not included in the application's reports and datasets. This capability will be introduced in a future release.
- Data associated with the new **Temperature Excursion Number** field is not displayed in any reports or datasets. This capability will be introduced in a future release.
- Data related to screen failure visits is displayed in the application's reports and datasets, as expected. **Failure dates** specified by a user and updates to the **Reason for Change** field (for screen failures) will not be displayed in any reports or datasets. Instead, if **Screen Failure Visit** is enabled, the system date specified when a screen failure occurs will be displayed.

Oracle Life Sciences Data Management Workbench

- Data associated with the new **Temperature Excursion Number** field is not displayed in Oracle DMW. This capability will be introduced in a future release.
- Data associated with the new screen failure visit is displayed in Oracle DMW, as expected. **Failure dates** specified by a user and updates to the **Reason for Change** field (for screen failures) will not be displayed in the application. Instead, the system date specified when a screen failure occurs will be integrated.

Expected metadata changes in Oracle Life Sciences Data Management Workbench

The following updates to metadata in Oracle DMW are introduced in this release:

View/Table	Column	Variation Details
DHWV_SUBJECT_VISITS_V 1	ADDRESS_COUNTRY	Attribute differences: Length (100:4000)

Oracle Clinical One Digital Gateway

- Data associated with the new **Temperature Excursion Number** field is currently not supported in Oracle Clinical One Digital Gateway. This capability will be introduced in a future release.
- Screen failure visit dates entered by users are currently not supported and will not be integrated. Only system generated failure dates are integrated.
- While you can include screen failure visits in the new study design, data related to these visits for integration configurations is not supported at this time. This capability will be introduced in a future release.

5

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 22.4

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)
- [Rest API updates](#)
See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs for 22.4, available upon the Production release.

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.4 release. None of these fixes affect the user work flow or the application's functionality.

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

Table 5-1 Patch log

Release Number	Release Date	Notes
Release 22.4.1.1	17-April-2023	For this release, we fixed an issue related to data collection and visit branching. For more information see: <ul style="list-style-type: none">• Issue 35037630 in Fixed issues for forms, visits, and rules.
Release 22.4.1	28-March-2023	For this release, we fixed two issues related to custom JavaScript rules and subject data. For more information see: <ul style="list-style-type: none">• Issue 34775012 in Forms, visits, and rules.• Issue 35171156 in Fixed issues for site users and subject data.

What's new

- [Study design](#)
- [Data collection](#)
- [Randomization and trial supply management](#)
- [Integrations](#)

- [Reporting, archives, and analytics](#)
- [Notifications](#)
- [Other enhancements](#)

Study design

- [Enhancements to code lists](#)
Thanks to these latest enhancements, study designers and code list managers can now make better use of custom code lists and system default code lists.

Enhancements to code lists

Thanks to these latest enhancements, study designers and code list managers can now make better use of custom code lists and system default code lists.

Details for study designers and code list managers

Whether you're a study designer or code list manager, here's what you can now do with code lists:

- You can import a custom code list into the application in a CSV or XLSX format. The imported code list file must contain a maximum of 1000 rows and a minimum of 1 row.
- To import a code list, you can download the template for code lists from the application.
- You can download any code list in an XLSX format only.
- In the application, the icon indicating that a value in the code list is hidden has changed from an X to a new symbol ().
- Only custom code lists can be imported at a study level and at a global level (for all studies at your organization). If you import a custom code list at a global level that code list is not replicated at the study level. If you want the same changes to appear at the study level, you must manually update the custom code list for a specific study.
- You can also copy a custom code list and rename it at both a global level (for all studies at your organization) and at a study level (for a single study). Code list titles must be unique within the study or the library.

Other enhancements

Code lists that are tagged with the Lab Test tag now dynamically add an optional user-entered column to include the Logical Observation Identifiers Names and Codes (LOINC).

Data collection

- [Link two-section form data](#)
Study designers can now add a Link & Show Form rule to either or both sections of a two-section form and this form type can be both the source and the target of the association.

- **Enhancements to Source Data Verification (SDV)**
Sponsor users can now perform Source Data Verification (SDV) more efficiently on questions, forms, and visits using an enhanced status filter, a new status icon, as well as other changes to the behavior of the SDV functionality.

Link two-section form data

Study designers can now add a Link & Show Form rule to either or both sections of a two-section form and this form type can be both the source and the target of the association.

Site users can now link two-section form data, further enhancing Oracle Clinical One Platform's ability to recognize relationships between collected data. For example, site users can link data from a two-section form with other data from other repeating and two-section forms for the purpose of collecting relationships between medical history and medication data. Associating the information on two-section forms can make it easier to recognize possible relationships between all types of collected data, including study drugs, adverse reactions and concomitant medications, and the evaluation of target lesions.

These associations can be made in the same way as existing repeating form associations, via a question, from or to the two-section forms to provide cross-references between the form instances or individual rows of repeating data. In this way, when users display the details of one associated form, they can easily view the details of any instances of the other associated form.

If your study is set up with this feature, when the site user answers the question that creates the association, a window appears directly below the question. It is in this window where the user is presented options to create the correct links. A form can have zero-to-many associations, for example, an instance of concomitant medication can be linked to an adverse event and also to a medical condition.

Note:

Only two-section and simple repeating forms are allowed to be the source of an association. Flat forms, however, can be the target of an association. In this way, a user could link data from a flat form (for example, vital signs) back to a two-section or repeating form.

Details for study designers

If you need to allow site users to link two-section form data, you must know that you can now create form associations for either sections (Questions Before the Table or Questions in the Table) for a two-section form. You can configure two-section form associations by using the Link & Show Form predefined rule.

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

Details for site users

If you need to link forms, here's what's new for you:

- When you make an answer selection that determines whether the rule will show the associated form, a window appears which contains all possible instances of forms or records that have been associated in study design.

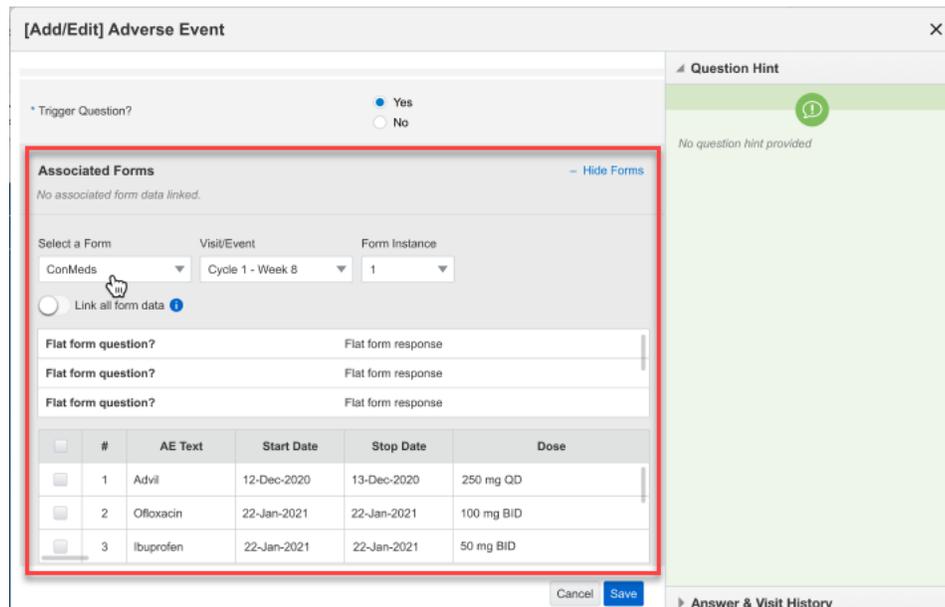
 **Note:**

Data must be entered in the linked form for it to appear in the associated form window. If data has not yet been entered, it can be linked after data entry is complete.

- A new filter appears, prompting you to link the forms depending on the form and visit. An additional **Form Instance** filter is displayed if the target of the form association is a two-section form.
- A **Hide** or **Show** feature appears in the form window to either collapse or expand the associated form. When compressing the form, users can see a short summary of the links created.
- When a two-section form is the target, it displays three drop-down options to: **Select a Form**, **Visit/ Event**, and **Form Instance**. When the repeating and flat forms are the target, it will show two filters: **Design Form** and **Visit**.
- The **Associated Forms** drop-down displays all of the forms that you can link to the form that you're currently in (for example: repeating form, two-section form, and flat forms).
- If more than one form is available to be linked to the parent form, then forms are displayed in alphabetical order in the **Associated Forms** drop-down.
- If a flat form is being linked then the only option for associating data is to turn the **Link all data** toggle on.
- If a two-section form is being linked, then you have the option of linking both the flat and repeating section of form by turning the **Link all data** toggle on, or you can choose to link a specific row or specific rows, only.

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

Figure 5-1 How a site user sees the new updates for linking two-section forms



[Add/Edit] Adverse Event

* Trigger Question? Yes No

Associated Forms - Hide Forms

No associated form data linked.

Select a Form: ConMeds Visit/Event: Cycle 1 - Week 8 Form Instance: 1

Link all form data ?

Flat form question?	Flat form response
Flat form question?	Flat form response
Flat form question?	Flat form response

#	AE Text	Start Date	Stop Date	Dose
1	Advil	12-Dec-2020	13-Dec-2020	250 mg QD
2	Ofloxacin	22-Jan-2021	22-Jan-2021	100 mg BID
3	Ibuprofen	22-Jan-2021	22-Jan-2021	50 mg BID

Cancel Save

Question Hint: No question hint provided

Answer & Visit History

Already working in a live study?

As soon as the release upgrade completes, as a study designer, you can begin creating form associations for two-section forms. After you update the study's design and the sponsor team tests and moves the updated study version to Testing and Approved, a site user can begin linking two-section forms.

Enhancements to Source Data Verification (SDV)

Sponsor users can now perform Source Data Verification (SDV) more efficiently on questions, forms, and visits using an enhanced status filter, a new status icon, as well as other changes to the behavior of the SDV functionality.

Adjustments to the SDV filter

The SDV status filter has been adjusted to make it easier for you to spot visits with outstanding SDV:

- Visits which have a status of **Not Started** are not included in the results when filtering for the status **Ready to Verify**.
- Existing subjects continue to function as they did prior to the upgrade: visits which have not been verified will not have a status icon, regardless of whether the subject has been selected for SDV. The status icons associated with all visits for a subject will be refreshed once one of the following actions is performed:
 - A user accesses a visit.
 - At least one question is unverified due to data change.
 - A subject previously with a status of **No SDV Required** is selected for inclusion in the SDV pool. For more information, see [How do the source data verification settings work together in a strategy?](#).

New icons in the Subjects panel

Two new icons have been added, making it easy for you to identify items that require SDV:

- A new **Verification Required** icon (



) has been added to help identify visits with outstanding SDV.

- A new **Targeted SDV** icon (



) has been added to help identify questions which have been marked as Critical Variables, for subjects which have not been selected for the SDV pool. For more information about how subjects are selected for targeted SDV, see [How are subjects randomly selected for targeted source data verification?](#).

Already working in a live study?

As soon as the upgrade is complete, if your study uses SDV strategies, you can start making use of these new enhancements. You can find additional information in the *Sponsor and CRO User Guide* after the Release Assessment Environment (RAE) upgrade.

Randomization and trial supply management

- [Create titrations with calculated doses](#)
Study designers can now create titrations that include kits with calculated doses.
- [Screening and randomization limits by site](#)
Study managers can now set limits for sites and report on the defined limits.

Create titrations with calculated doses

Study designers can now create titrations that include kits with calculated doses.

With the introduction of this feature, studies with dosing calculations can now allow site users to adjust dosage in dispensation visits. Titration is defined in study design and it can now include both standard kit types and kits with calculated doses.

Details for study designers

When you create titrations, here's what's new for you:

- The **Create Kit Type Titration** button is now called **Create Titration**.
- On the Create Titration dialog, you can add standard kit types or kits with calculated doses. For kit types that contain calculated doses, a sub-menu is displayed so you can select the exact dose within the kit type that should be used to titrate.

 **Note:**

You must specify a dose for every column in a titration: Starting Kits, Down Titrate, Maintain, and Up Titrate.

- On the Settings page in the Create Titration dialog, when you specify the Minimum Time Between Dose Changes to either up or down titration, a checkbox becomes available to enable exceptions. These exceptions allow you to define overrides for the defined time between dose changes.
- If you enable exceptions, a new step in the Create Titration dialog allows to configure exceptions, one step for Up Titration Exceptions and another one for Down Titration Exceptions. On these new sections you will enter a new Minimum Time Between Dose Change for a particular starting and ending dose combination.
- On the Kits tab, when you hover over a titration with calculated doses, you can view the exact doses that are selected for all titration options.
- A calculated dose that is used in a titration can be edited but not removed. If you make an update, the system informs you of the impact of your changes on existing titrations within the study. Also, when a form or visit that is used in the design of a calculated dose is removed from the study, that calculated dose is highlighted as broken () within both the kit type and the titration.

To create titrations with alculated doses in an existing study, you must create the new titration and add it to the dispensation schedule in a draft version and then make the updated study version live. For step-by-step instructions, see [Update the way that subjects titrate during the study conduct period](#).

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

Details for site users

There is no impact on the dispensation process, besides you gaining the ability to titrate kits with calculated doses. The process to complete a dispensation visit with dose changes has not changed either. For more details on how to dispense kits with dosage titration, see [Complete a dispensation visit with dose changes](#).

Screening and randomization limits by site

Study managers can now set limits for sites and report on the defined limits.

With this new feature, study managers can control the number of screened and randomized subjects by site, adding different limits for each site even after the study is live. These limits can be set in all three modes: Production, Testing, and Training. When any of these configured limits are reached during the study, users with the *Receive Study Limits Notifications* permission receive an alert.

Details for study managers

If you want to manage site limits, here's what's new for you:

- On the Sites & Labs tab, a new **Show limits** toggle appears. You can turn it on to display the Screening Limits and Randomization Limits columns. If your study does not include randomization, limits defined for screening will be used for enrollment.
- On the Screening Limits and Randomization limits column, you can enter a number to define the limits for each site included in your study. These limits will override values indicated on the study settings, if any.
- You can leave limits undefined or with a null value in a study and this will not affect the study's development.

Figure 5-2 Changes in the Sites & Labs tab to define screening and randomization limits by site

The screenshot shows the Oracle Clinical One interface for the 'Sites & Labs' tab. The top navigation bar includes 'General', 'Sites & Labs', 'Depots', 'Users', 'Study Roles', 'Study Settings', 'Supply Settings', and 'Device Settings'. Below this, there are tabs for 'Production Sites', 'Testing Sites', and 'Training Sites'. A search bar and filter options are present. The main table lists sites with columns for 'Screening Limits', 'Randomized Limits', 'Study Version', 'Resupply Strategy', and 'SDV Strategy'. A 'Show Limits' button is highlighted in the top right corner.

Sites	Labs	Screening Limits	Randomized Limits	Study Version	Resupply Strategy	SDV Strategy
US001 Massachusetts General Hospital Adam Levine MD, PhD.	View Labs	Limit	Limit	Study Version	Resupply Strategy	SDV Strategy
3Com Site001 Dr. Paul Martins	View Labs	Limit	Limit	Select Study Version	Resupply Strategy	SDV Strategy
3Com Site001 Dr. Paul Martins	View Labs	Limit	500	2.0.0.7 Protocol V2.0	Resupply Strategy	SDV Strategy
3Com Site001 Dr. Paul Martins	View Labs	Limit	Limit	Select Study Version	Resupply Strategy	SDV Strategy

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

Reporting updates

Within the Study Enrollment report, you can find a new section called **Site Enrollment** that contains the details about site limits. New columns for each site will show as Screening limit and Randomization limit.

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

Integrations

- [Oracle Clinical One Digital Gateway productized integrations now support visit date change](#)
- [Supply integration notification enhancement](#)
- [TMMCS standard integrations through Oracle Clinical One Digital Gateway now support password rotation](#)
- [Include commas in code lists for your integration configuration file](#)
For an integration between Oracle InForm and Oracle Argus Safety, commas are now supported for code lists in your integration configuration through Oracle Clinical One Digital Gateway.

Oracle Clinical One Digital Gateway productized integrations now support visit date change

Clear visit date is now supported for Oracle Clinical One Platform to Oracle InForm and other Electronic Data Capture (EDC) productized integrations. For more information, see the Digital Gateway User Guide - EDC Systems.

Supply integration notification enhancement

When block number is used instead of kit number for supply integrations, the **Shipment request** notification now includes the total number of blocks shipped and the unique block numbers; kit details do not appear in the notification. For more information, see Shipment request notification.

TMMCS standard integrations through Oracle Clinical One Digital Gateway now support password rotation

Password rotation is now supported for the Trial Management and Monitoring Cloud Service (TMMCS) standard integration offering.



Note:

This enhancement is not applicable for non-standard TMMCS integrations.

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

Include commas in code lists for your integration configuration file

For an integration between Oracle InForm and Oracle Argus Safety, commas are now supported for code lists in your integration configuration through Oracle Clinical One Digital Gateway.

How does this new enhancement work?

When a code list value contains a comma, the value is properly mapped in Oracle Clinical One Digital Gateway without generating an error. The new mapping in the integration configuration file supports all existing code list requirements.

For example, a value of "KOREA, REPUBLIC OF" will be mapped to a target value of "KR". The string in the integration file will look as displayed in the example below.

```
<Entry Source="KOREA, REPUBLIC OF" Target="KR" Description="Republic of Korea"/>
```

How can I update my current integrations?

If your integration must send code list values that contain commas, you must update the integration file to include the new configuration for code list values with commas. The existing integration should be first disabled and then you can upload the new integration template.

Additionally, with the implementation of this code list, the default code list mapper becomes deprecated. Future integrations you might configure should begin using the new code list mapper that support commas.

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

Reporting, archives, and analytics

- [New Randomization List \(Blinded\) report](#)
With the appropriate permissions, you can now run a blinded version of the Randomization List report.
- [Oracle CRF Submit archives and reports](#)
The following details provide an overview of enhancements for Oracle CRF Submit archives and reports.
- [Enhancements to Oracle Clinical One Analytics](#)

New Randomization List (Blinded) report

With the appropriate permissions, you can now run a blinded version of the Randomization List report.

Before working with this feature

This report is available to users assigned the *Run the Blinded Randomization Report* permission. For more information about this permission, see *Descriptions of permissions* in Oracle Clinical One Platform.

Details for sponsor users and CRAs

The new Randomization List (Blinded) report includes the same columns as the Randomization List (Unblinded) report, with the exception of the *Treatment Arm ID* and *Treatment Arm columns*. This is to avoid unblinding.

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

Oracle CRF Submit archives and reports

The following details provide an overview of enhancements for Oracle CRF Submit archives and reports.

Time only and partial time questions are now supported in PDF output

The ability to capture time only and partial time using a Date/Time question was introduced in Oracle Clinical One Platform 22.3. Starting with this release, the following enhancements are introduced:

- **Blank PDF** output includes time only and partial time questions as active controls when they are included in your study design.
- **Subject PDF** output includes time only and partial time questions and associated data when they are included in your study design.

Include Randomization and Trial Supply Management (RTSM) data in PDF output

A new setting called **Include RTSM Data** has been added to the advanced tab for Submission, Archival (both sponsor and site), and Custom PDF requests. Enable this setting to include randomization and dispensing information for subjects at your site in the PDF output.

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

Subject number changes are now supported in the user interface and output files

Previously, the updated subject number was displayed in the user interface for the **Include In Report**, **Select Subjects**, **Subjects** drop-down and subsequently in the output files even if the **Select Date/Time** entered was prior to the subject number change.

Now, the subject number displayed is based on the **As of Date** setting when creating requests.

- If **Now** is selected, or if a date is entered that is after the update, the **Subjects** drop-down displays the updated subject number which is reflected in the output files.
- If a date is entered for **Select Date/Time** that is prior to the subject number change, the user interface and output files include the original subject number.

Enhancements to Oracle Clinical One Analytics

Tip:

Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study, or just starting to work with analytics, reach out to your Oracle Project Manager to learn more about these new dashboards.

Analyze missing form and visit data in dashboards

Use standard dashboard templates to get a holistic view of study data. The following interactive reports have been added to the CRA and Data Manager dashboard templates:

- Missing Forms Report
- Missing Visits Report

These new reports provide key performance indicators about forms and visits that have not yet been started. They can help CRAs and data managers to plan workload distribution as well as to schedule audit and monitoring visits. In these visits, the study team may provide training for site users to conduct a particular visit or collect data in a particular form, hence reducing the occurrence of missing visits and forms.

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard.

You can find additional information about these new reports in the *Analytics User Guide* after the Release Assessment Environment upgrade.

Updates to support subject number modification

To support the recently introduced feature that allows for subject number change, a new data element has been added to the subject folder for all datasets in Oracle Clinical One Analytics.

The current number assigned to a subject in the system is contained in the existing data element for `SUBJECT_NUMER`. When a subject number change is applied, the number that was assigned to the subject before the change occurred is available in the new data element `PREV_SUBJECT_NUMBER`. This newly added field allows you to keep track of updates to a subject number and to maintain study data integrity.

You can find additional information about dataset descriptions and their data elements in the *Analytics User Guide* after the Release Assessment Environment upgrade.

Notifications

- [New enrollment notifications](#)
New enrollment notifications can be sent to sponsor and site users to enhance the visibility of the first subject activity within the study. Notification permissions need to be updated in order to receive them.
- [Other new notifications](#)
Other notifications in the applications are now enhanced to ensure that users receive the latest updates related to depot inventories.

New enrollment notifications

New enrollment notifications can be sent to sponsor and site users to enhance the visibility of the first subject activity within the study. Notification permissions need to be updated in order to receive them.

The following randomization and screening notifications are being introduced:

- First subject screened for a study notification
- First subject screened for a site notification
- First subject randomized for a study notification
- First subject randomized for a site notification

To receive the new notifications, user administrators must assign the *Receive the Study Limits Notifications* permission to the appropriate users. This permission allows users to receive both notification types, first subject screened and first subject randomized, only for the sites that they're assigned to.

For these notification to be sent out to the appropriate users, study managers must also configure the corresponding settings in the study's settings.

Details for study managers

Here's what you need to do if you want users to receive the new enrollment notifications:

- The enrollment settings section on the Study Settings tab now includes new columns allowing you to activate notifications for **First Subject Screened** and **First Subject Randomized** for either a study or a site.

- By selecting a checkbox, you activate the notification for that specific limit. For example, if you select First Screened Notification for the Study Total, then users with the appropriate permissions will receive a First Subject Screened notification when a site user has screened the first subject in the entire study.
- Notification activation is only required once per site or study.
- If a screened subject is transferred to another site with no screened subjects, a notification will not be sent.

Figure 5-3 New study notification

The screenshot shows the 'Study Settings' page in Clinical One. The 'Enrollment Settings' section is active, showing a table with columns for 'Enrollment Open/Closed', 'First Screened Notification', 'First Randomized Notification', 'Screening Limits', 'Randomized Limits', and 'Notification'. The 'First Screened Notification' and 'First Randomized Notification' columns are highlighted with a red box. Below this, there is a 'Custom Enrollment Settings' section with a table for 'Custom Enrollment Group', 'Subject Limit', and 'Notification'. A message states 'You currently have no custom enrollment groups.' and provides an 'Add Custom Enrollment Group' button.

* Enrollment Open/Closed	First Screened Notification	First Randomized Notification	Screening Limits	Randomized Limits	Notification
<input checked="" type="checkbox"/> Study Total	<input type="checkbox"/>	<input type="checkbox"/>			
<input checked="" type="checkbox"/> Site Total	<input type="checkbox"/>	<input type="checkbox"/>			
<input checked="" type="checkbox"/> Country					

You can find additional information on each study enrollment notification in the *Notifications and Permissions Guide* after the Release Assessment Environment upgrade.

Reporting updates

In the Study Design report, the following new columns are introduced in the Study Settings section:

- Notify when first subject screened
- Notify when first subject randomized
- Last modified
- Last modified user
- Value

In the Study Enrollment report, the following new columns are added to the **General Enrollment** and **Audit** sections:

- First subject screened

- First subject randomized

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

Other new notifications

Other notifications in the applications are now enhanced to ensure that users receive the latest updates related to depot inventories.

When you add a depot, in the **Inventory Kit Level Alert** column, you have the option to enter a number of kits that, when reached, now generates a notification for low supplies at a depot.

The notification connects to the supplies monitoring and is intended to alert clinical supplies managers that the depot runs low on supplies. The alert will activate when the resupply algorithm triggers. Until inventory recharges, the notification will send every time that drug management runs.

To receive these notifications, assign the *Receive Notification of Depot Shipments* permission to anyone who wants to receive this notification. Users receive notifications only for the depots that they are assigned to.

More details on each study enrollment notification will be featured in the *Notifications and Permissions Guide*.

Other enhancements

New Product Verification Pack (PVP) updates!

We've made it easier for you to track any changes that we make to the Product Verification Pack (PVP) for each minor release. If you want to know more each change, see Product Verification Pack (PVP) updates.

User experience enhancements

- When collecting data, form fields no longer auto-populate based on previously entered data. Oracle Clinical One Platform now suppresses any text auto-fill settings your browser may have.

Fixed issues

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

All users

Various security updates

For this release, we made also made various security updates.

Study ID can't be longer than 50 characters (former known issue)

Study designers: Now, the limit of 64 characters for a study's ID works as expected. Even if your study's ID exceeds 50 characters (but doesn't contain more than 64 characters), your study can be successfully activated.

Retracted workaround: You no longer have to make sure that a study's ID is less than 50 characters when the maximum number of characters is 64. (Issue **30147429**)

Training video is unexpectedly displayed for users who can skip visits

From now on, any users who is assigned the Skip Visits permission will no longer see the Dispense and Replace Kits video training within the application. Previously, users who were assigned this specific permission had to complete the Dispense and Replace Kits video training, although their work did not require that. (Issue **34955265**)

Japanese users see complete product training in English (former known issue)

All Japanese users: Now, when you first sign in Oracle Clinical One Platform, as a Japanese user, you can see description of your in-product training displayed in Japanese, as expected. Previously, text surrounding your training was displayed in English.

Retracted workaround: You can continue updating your closed captions to Japanese, so the training videos are translated into Japanese. (Issue **32877184**)

Code lists

Remove Codelist option is displayed for manually entered answer options (former known issue)

Study designers: Now, in a form, when you create a question with radio buttons or checkboxes, or a drop-down question, you will no longer see the option to remove that code list even though the questions you entered were not part of a code list. This issue was only observed when a question's reference code was entered in lower case characters.

Retracted workaround: None. (Issue **34895176**)

Updating the EDCYearRange code list requires multiple renaming steps (former known issue)

Study designers: Now, you can add different code values and modify their labels in the EDCYearRange custom code list without running into any errors related to the values being duplicate in your studies. Previously, when you attempted to add more values to the custom code list, but with different labels, a validation error was displayed for each label stating that it's not unique.

Retracted workaround: You no longer have to perform the workaround of updating your labels with different special characters so the application doesn't flag them as being duplicate. Initially, the following steps were required to work your way around this issue:

1. On the Code List tab, select the **EDCYearRange** code list.
2. Update the labels of the existing code values to **Minimum Year** and **Maximum Year**, respectively.
3. Add two new code values and update their labels to **Min_ Year** and **Max_ Year**, respectively.
4. Click **Save**.
5. Edit the last two added code values and remove the underscore (**_**) from the label.
6. Click **Save**.

(Issue **34783476**)

Newly added custom code list values are not properly displayed in the Subject Data Extract

Data managers and statisticians: Now, for a live study version, when a study designer applies an update containing a new form with new custom code list values, those newly added custom code list values are properly displayed in the Subject Data Extract.

The following columns contain the correct custom code list values:

- Item: displays the Code value.
- Item_R: displays the Label value.
- Item_F: displays the Value.
- Item_D: displays the Code value.

Previously, the items listed above displayed the expected values randomly.

Retracted workaround: None. (Issue **34857896**)

Code list values are not displayed in the Subject Data Extract as expected (former known issue)

Data managers and statisticians: Now, the following Subject Data Extract columns contain the correct code list values for the code list option selected during data collection:

- Item_R (code list label);
- Item_F (code list value);
- And item_D (code list code).

Previously, the Subject Data Extract displayed incorrect or null values for a selected code list option. This issue impacted custom and system code lists differently and did not present itself in the report output in the same way. However, this fix addresses the problem for both system and custom code lists.

Retracted workaround: None (Issue **34769175**)

Facilities, settings, and user management

A subject's status is not updated to reflect source data verification (former known issue)

Clinical Research Associates (CRAs): Now, after you verify the appropriate fields that are marked for SDV, a subject's status is updated to Verified, as expected. Previously, this update did not occur even though you verified all of the fields that would consider the subject verified.

Retracted workaround: None. (Issue **33516395**)

Several issues occurring when attempting to assign new sites to a user

User administrators: Now, on the Users tab, you can assign a new site to a newly created or existing user and the application works as expected when you navigate details of a user's assigned sites. The following specific issues are now resolved on the Users tab and on the Sites & Labs tab:

- For a newly created user, you can see the newly created sites that you can assign to them.
- For an existing user, you can see the newly created sites when you want to modify their current site assignments.
- When you select a user and expand the Assigned Sites side panel, all of their assigned sites in all study modes are displayed, as expected.
- On the Sites & Labs tab, when you scroll through the list of sites, you will notice that newly created sites that do not have an assigned study version are displayed, as expected.

(Issue **35068848**)

A custom study role with the appropriate permissions might not receive screening notifications

User administrators and global user managers: Now, a user who is assigned a custom study role with the *Receive the Subject Screening Notification* permission receives the appropriate notification whenever a subject is screened or fails screening for the sites that the user is assigned. Previously, even though a user's custom study role contained the appropriate permission, they did not receive the screening-related notification. (Issue **35111951**)

A depot's status tooltip is not fully translated to Japanese

Site administrators: Now, on the Depots tab, when you hover over the icon of a depot, you will notice that a depot's status is fully translated to Japanese in the tooltip. Previously, a depot's status tooltip was only partially translated to Japanese while some parts of the text were displayed in English.

This issue was observed when the application's preferred language was set to Japanese. (Issue **32893942**)

Freezing a row in a lab form through APIs does not work (former known issue)

Data managers and API developers: Now, you can successfully freeze a row in a completed lab form using an API endpoint. Previously, attempting to freeze a row in a completed lab form resulted in validation errors. The API endpoint used to test this Known

Issue was the following: <https://docs.oracle.com/en/industries/health-sciences/clinical-one/coapi/op-ec-dc-svc-rest-v3.0-studies-studyid-mode-dataelements-freeze-post.html>

Retracted workaround: We recommend performing this task in the User Interface (UI) only. (Issue **34666440**)

A depot's status tooltip is partially translated to Japanese

Site administrators: Now, on the Depots tab, when you hover over a depot's status, the text displayed in the tooltip is fully translated to Japanese, as expected. Previously, the content in this tooltip was partially translated and there was text displayed in English. (Issue **32893942**)

Note:

This issue occurred when the application's preferred language was set to Japanese.

Forms, visits, and rules

Subjects assigned to wrong branch visit

Study designers and rule developers: Now, the treatment arm assigned to a subject and the answer to a branching question determine a subject's subsequent visits. Previously, only the answer to a branching question determined the next visits, even when the subject was assigned to a treatment arm.

Retracted workaround: None. (Issue **35037630**)

JavaScript custom rules may not work with Adverse Events (former known issue)

Study designers: Now, in a study's draft, you can configure a successful JavaScript rule for all questions in a form assigned to an Adverse Event. Previously, when a form contained many questions, configuring a custom rule for each question caused the API endpoint behind the rule to possibly fail.

Retracted workaround: Study designers are no longer discouraged from configuring custom rules for each question in a form, even if the form contains a high number of questions. (Issue **34775012**)

Study version issues can be encountered after moving a study version to the Approved container if the browser is closed prematurely (former known issue)

Study designers: Now, when you move a study version from the Testing container to the Approved container and you accidentally close your browser before this action is completed in the backend, this won't affect your study design anymore. Previously, if you closed your browser before the action was complete, you may have encountered issues with associating randomization lists to a study version or when randomizing a subject.

Retracted workaround: None. (Issue **34324333**)

Clearing a rule's variable determines the clearing of its target

Rule designers and testers: When a custom rule's variable is cleared, the rule's mechanism is updated to determine whether the target field should be cleared or updated. Previously, after a rule ran, its target field was automatically cleared every time a variable was cleared, as well. For example, if you cleared another question's answer in a form, and that question was used as variable in a Date/ Time helper function, the read-only Date/ Time field was also cleared. Instead, the target field should have been updated with the current date when the latest update in the form was performed. (Issue **34873328**)

Rule targets are not automatically updated for a DateTime rule

Rule designers and testers: Now, when a DateTime rule is configured for a Date/ Time field in a form, the target field of that rule is automatically updated whenever a data change occurs in the form. For example, if all fields in a form are completed, the rule automatically updates the Date/ Time field to the current date. If a field is left empty or cleared, the rule then clears the Date/ Time field, as well. Previously, the rule did not automatically refresh its target field. This issue occurred when the Date/ Time field was read-only. (Issue **34877289**)

An error occurs for a custom rule built with the getCurrentCycle helper function

Rule designers and testers: Now, when you create a custom rule using the getCurrentCycle helper function, and its target is part of a two-section form, the rule is running as expected and no errors occur. Previously, the getCurrentCycle helper function returned the current event instance number of the rule variable, instead of the current event instance number of the rule target. (Issue **34956461**)

Automated query rules cannot run

Rule designers: Now, when you create, test, and then publish rules for automated queries, the rules work as expected. Previously, custom rules for automated queries, when published in a live study version, started failing although they passed the testing phase. (Issue **34869167**)

The getDateDMTFormat () helper function is returning an incorrect time

Rule designers: Now, the getDateDMYFormat () helper function returns the time in the format of "HH::mm:ss", as expected. Previously, the time was displayed incorrectly using this helper function.

For example, if a site user entered the time as "10:10", the helper function would return a "10:10" value. If a site user entered the time as "10:00", the helper function would return a "10" value. Now, when a site user enters the time as "10:00", for example, the helper function returns a "10:00:00" value, counting the hour, the minutes, and the seconds. (Issue **34867905**)

The Rule Editor takes several minutes to load variables in a drop-down (former known issue)

Rule designers: Now, on the Rule Editor dialog, when you attempt to select a visit from the Variable drop-down, values in the drop-down load immediately, as expected. Previously, it took around 2.7 minutes for the variables to load in the drop-down. This used to be a performance issue caused by the high number of visits configured in a larger study.

Retracted workaround: None. (Issue **34789014**)

A validation rule for a partial date does not work (former known issue)

Study designers: Now, when you create a Date/ Time question with a Minimum Allowed Answer of YYYY and an On or After validation rule (specifying that the date must not be earlier than the year 2022), site users can complete that Date/ Time question without running into any issues.

Previously, because the validation rule used the date of its creation as the time reference, whenever a site user did not enter the complete date of when the validation rule was created, an error message was displayed in the form. This issue was fixed by modifying certain parameters in the backend of the application to ensure that site users can successfully complete a Date/Time question in this particular use case.

Retracted workaround: None. (Issue **34734551**)

Oracle Clinical One Analytics

A form's status is incorrectly displayed in the Subject Forms dataset

Now, a form's status is properly displayed in the Subject Forms dataset, on the FORM_STATUS column. Previously, even though a form was complete in the Oracle Clinical One Platform UI, in the Oracle Clinical One Analytics application, the form was still displayed with a status of **IN_PROGRESS**. (Issue **35087486**)

The Unblinded Kits dataset does not properly display data related to an updated kit (former known issue)

Now, when a kit is dispensed to a subject, and you update its status to **Not Dispensed to Subject**, the Oracle Clinical One Analytics application displays a separate record for this kit with the appropriate details, such as the subject and visit details. Previously, after the status of a dispensed kit was updated to **Not Dispensed to Subject**, related data was displayed for both records of the same kit with a status of **Dispensed** and the newly updated status of **Not Dispensed to Subject**. Instead, data related to the subject, events, treatment arms, randomization, or dosage calculation should not be displayed for a kit that is considered removed from a subject's dispensation history.

Retracted workaround: None. (Issue **33533953**)

The Unblinded Kits dataset does not properly display historic data (former known issue)

Now, the Unblinded Kits dataset displays the latest data, as well as historical records for both dispensed and lost kits. This includes data related to the subject, events, randomization, dose calculations, and many more. Previously, the dataset did not properly display historical data for certain kits in different states. For example, the dataset only displayed data for kits with a **Lost by Subject** status. This issue was due to the way the application refreshed any data updates coming from the Oracle Clinical One Platform.

Retracted workaround: None. (Issue **33516214**)

Clearing a visit's date is not properly reflected in the Oracle Clinical One Analytics app (former known issue)

Now, when data is refreshed after a visit date has been cleared in the Oracle Clinical One Platform, the visit's date field displays a value of Null, as expected. Previously, you may have noticed that the cleared visit date was still displayed.

Retracted workaround: None. (Issue **34773970**)

A two-section form's status changes to Incomplete or In Progress

Now, when a site user completely clears a row in the second section of a two-section form, the status of that entire two-section form changes to **Completed** in the Oracle Clinical One Platform and in the Oracle Clinical One Analytics application, as well. Previously, the form's status was updated to **In Progress** or **Incomplete** instead of **Completed** and this status change was reflected in the Oracle Clinical One Analytics application, as well.

Retracted workaround: None. (Issue **34787304**)

Deleted depots in a study are not accurately reflected in the Analytics app (former known issue)

Now, when you delete a depot in the Oracle Clinical One Platform, the removal of that depot is properly displayed properly in the application's database.

Retracted workaround: None. (Issue **34563971**)

The Study Design Delta report does not show added or deleted forms in a visit (former known issue)

Oracle Clinical One Analytics application users: Now, any changes to forms, items, visits, and branches in a live study appear in a separate column (**Is_Deleted**) in the Study Design Delta report. Previously, we reported that the Study Design Delta report did not show changes to forms in a visit. For example, in a live study, if you assigned Form A to Visit 3 when you've already connected Form A to Visit 1, the Study Design Delta report didn't show the new association between the existing form and the new visit. The same behavior happened when removing a form from a visit.

Retracted workaround: None. (Issue **34270507**)

Integrations

Event OID is missing from several clinical transactions

API developers: Now, the Event OID attribute is displayed for all clinical transactions related to a transferred subject. Previously, this issue was observed for subjects that were transferred to another site and that site was associated to a study version in which a visit had been removed. For example, subject A completed a Safety Follow-up visit at Site A1. After completing the visit, the subject was transferred to site B2. Site B2 was associated to a newer study version where the Safety Follow-up visit was removed and that caused the Event OID attribute to not appear for any clinical transactions related to subject A. (Issue **34840242**)

Randomization and kits

Cannot titrate when a previous kit is replaced (former known issue)

Site users: Now, you can titrate when a kit that was previously marked as **Not Dispensed to Subject** is successfully replaced. Previously, when a kit was marked as **Not Dispensed to Subject** and a new kit was dispensed to the subject instead, you were unable to titrate during a study. When you attempted to titrate, you received an error message that stated that you cannot dispense a kit to subject.

Retracted workaround: None. (Issue **31791917**)

An error message is displayed when uploading a kit list (former known issue)

Clinical supply managers: Now, on the Upload Kit List, when you attempt to upload a kit list a second time (after you encountered an error the first time), you can successfully re-upload the kit list. Previously, after uploading a kit list a second time, another error message was displayed stating that the title of the kit list has already been used. This error message was displayed even though the kit list was never actually uploaded in the system.

Retracted workaround: You no longer have to use a different name for the kit list that you upload multiple times (after errors were identified by the system) because you will no longer encounter an error message even though no other kit list with the same title has been uploaded. (Issue **34144529**)

Reports, archives, extracts, and notifications

OIDs are not unique in the ODM-XML metadata API (former known issue)

API developers: Now, the API response for the ODM-XML metadata no longer indicates that there are several validation errors for duplicate metadata values. Because different design elements in a study had the same reference code, their OIDs did not show up as unique in the ODM-XML metadata and clinical data extracts. Now, OID attributes contain unique GUIDs that will ensure the API no longer marks them as duplicates.

This fixed issue also ensures that there is no impact on a code list's OID, since code lists usually have the same reference codes and they showed up as duplicate in a clinical data extract.

Retracted workaround: None. (Issue **34702467**)

Notifications are not properly filtered (former known issue)

Site and sponsor users: You can now successfully filter any notifications related to randomization, dispensation, or shipments by study mode and site. Previously, the site filter was not working.

Retracted workaround: None. (Issue **33729560**)

The Kit Chain of Custody report displays incorrect data (former known issue)

Clinical supply managers and other sponsor users: Now, in the Kit Chain of Custody report, in the column Returned, Missing, Balance Units, data points for a shipment pending destruction and containing available kits are displayed as follows:

- Missing units are displayed as "0".
- Balanced units are displayed as "0".

Previously, instead of displaying "1 -0 -0" for when a shipment contained missing units or balanced units, the column displayed "1 - -".

Retracted workaround: None. This is a display issue only. (Issue **33689816**)

Site users with valid permissions could not view or download an Archival PDF (former known issue)

User administrators: Now, creating a role that includes the permissions, *Download Archival PDFs and Audit Reports*, and *Confirm Download of archival PDFs and content* allows site users to view, download, and confirm PDFs generated and shared by the sponsor without the need to add the permission, *Run Archival PDFs for your sites* to the role, which would allow site users also to generate PDFs.

Previously, if a site user was assigned to a role including both permissions, the user could not view or download the PDFs unless the *Run Archival PDFs for your sites* permission was added to the role.

Retracted workaround: Work with your user administrator to get temporarily assigned to the Run Archival PDFs for your site(s) permission. After downloading the archives, make sure your permission is revoked. (Issue **34655475**)

Archive download failed if the request name included Chinese characters

Sponsor users: Now, the **Download** link does not appear if a request fails to generate successfully. Previously, the link would appear even if a request did not generate successfully. In cases like this, download attempts failed. This was due to Chinese characters being included in the request name.

Retracted workaround: None (Issue **34719206**)

Chinese localization: File Type is not translated in the Download Log report

Sponsor users: Now, the File Type values: Archival PDF, Submission PDF, and Custom PDF, included in the report output, are translated correctly. Previously, the values under the File Type column appeared in English.

Retracted workaround: None (Issue: **34770064**)

Chinese localization: No Records Found is not translated in the Site Confirmation report

Sponsor users: Now, when the Site Confirmation report is run and no records are found, the value No Records Found is translated correctly. Previously, the value appeared in English.

Retracted workaround: None (Issue: **34770019**)

Site users and subject data

Subject IDs are truncated in Oracle Clinical One Platform

Site users: Now, a subject's full ID (up to 20 characters) is visible in Oracle Clinical One Platform on the Subjects page and on a visit's page. Previously, subject IDs were abbreviated if the ID exceeded 13 characters. (Issue **35171156**)

A cleared form cannot be unlinked from another form (former known issue)

Site users: Now, as you clear all data in a form that is linked to another form, the link between these two forms is also removed. Previously, after you cleared all data in a form that was linked to another form, you may have noticed that you couldn't clear the question that determined the linking between the two forms. This issue has been observed with repeating forms.

Retracted workaround: You no longer have to clear questions in a linked form in any particular order. As long as you clear a form its links are also removed. (Issue **34713911**)

Cannot add new subjects in a migrated study

Site users and study managers: Now, when a site user attempts to add a new subject in a migrated study, they can create that subject successfully and select a specific subject number for the subject, as well. Previously, even though a study manager configured the Allow Site to Select Subject Number setting to Yes, a site user could still not add a subject in a migrated study. (Issue **34245534**)

Rule targets are not updated after starting a skipped visit

Site users, rule designers, and API developers: Now, when a site user enters the visit date for a visit that was previously skipped, any existing custom rules are refreshed and their target fields are highlighted accordingly, depending on the data entered in those fields. Previously, when a site user re-started a skipped visit, they may have noticed that the existing custom rules weren't working in the associated forms anymore. The custom rules may have started working only after a site user refreshed their browser's page.

This issue is now fixed, but it was initially caused by an API refresh operation that did not take place when a skipped visit was re-started. (Issue **34882471**)

Rest API updates

See the newly added and newly deprecated endpoints of the Oracle Clinical One Platform APIs for 22.4, available upon the Production release.

The following services have been updated:

- [Code list](#)
- [Data Actions](#)
- [Data Capture](#)
- [Data Hub](#)
- [Data Integration](#)
- [Designer](#)
- [Randomization and Supplies](#)
- [Rules](#)
- [Sites and Depots](#)
- [User, Permissions, and Roles](#)

Code list

Change	Method	Endpoint
New	POST	/v1.0/codelist/code/copy/{codeId}
	GET	/v1.0/codelist/values/export/{codeId}
	GET	/v3.0/codelist/values/{fieldName}
	POST	/v4.0/codelist/code
	PUT	/v4.0/codelist/code/{codeId}

Data Actions

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/signconfiguration
	GET	/v1.0/studies/{studyId}/{mode}/signconfiguration
	DELETE	/v1.0/studies/{studyId}/{mode}/signconfiguration/{id}
	PUT	/v1.0/studies/{studyId}/{mode}/signconfiguration/{signConfigurationId}
	GET	/v1.0/studies/{studyId}/{mode}/signevaluation/configchange/studysummary
	POST	/v1.0/studies/{studyId}/{mode}/signevaluation/processque
	POST	/v1.0/studies/{studyId}/{mode}/signevaluation/triggeremail

Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/signinfo
	GET	/v1.0/studies/{studyId}/{mode}/signinfo

Data Capture

Change	Method	Endpoint
New	GET	/v2.0/studies/{studyId}/{mode}/dataelements/formassociations/history/sourceForm/{sourceFormId}
	PUT	/v2.0/studies/{studyId}/{mode}/dataelements/subject/{subjectId}/event/{eventId}/form/{formId}/formassociations
	POST	/v4.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/subject/{subjectId}/code/{code}/orgId/{orgId}
	POST	/v10.0/studies/{studyId}/{mode}/dataelements
Deprecat ed	GET	/v1/studies/{studyId}/{mode}/subjects
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/events
	GET	/v3.0/studies/{studyId}/{mode}/subjects/history/all
	GET	/v2.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	GET	/v7.0/studies/{studyId}/{mode}/subjects/history/{subjectId}

Change	Method	Endpoint
	GET	/v8.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/{transferId}
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/dateRange/{subjectId}
	GET	/v2.0/studies/{studyId}/{mode}/subjecttransfers
	GET	/v3.0/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/odmsubmit/clinicaldata/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjects/odmsubmit/visitsMetadata/{subjectId}
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/all
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	GET	/v4.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	GET	/v8.0/studies/{studyId}/{mode}/dataelements
	GET	/v8.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}

Change	Method	Endpoint
	GET	/v1/studies/{studyId}/{mode}/formassociations
	GET	/v1.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/events/{eventId}/vendorCode/{vendorCode}/dataelements/withvendorcode
	GET	/v6.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	POST	/v2.0/studies/{studyId}/{mode}/visit/verify/history
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus/dateRange/{subjectId}
	GET	/v9.0/studies/{studyId}/{mode}/visitstatus
	GET	/v5.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusID}
	POST	/v9.0/studies/{studyId}/{mode}/visitstatus/subjects
	GET	/v1.0/studies/{studyId}/{mode}/codingstatus

Data Hub

Change	Method	Endpoint
New	POST	/v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/queries
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits

Change	Method	Endpoint
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/formItems
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/forms
	POST	/v5.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits
	GET	/v4.0/studies/{studyId}/{mode}/odm/clinicalData/unblinded
	GET	/v4.0/studies/{studyId}/{mode}/odm/clinicalData/blinded

Data Integration

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/asynch/report/{reportName}
	POST	/v1.0/studies/{studyId}/{mode}/report/{reportName}
	GET	/v1.0/studies/{studyId}/{mode}/signconfiguration/history
	GET	/v1.0/studies/{studyId}/{mode}/signeligibility/history
	GET	/v1.0/studies/{studyId}/{mode}/subjects/sitestudyversion

Designer

Change	Method	Endpoint	
New	PUT	/v1.0/studies/{studyId}/versions/{version}/status/{state}/async	
	GET	/v16.0/studies/{studyId}/versions/{version}/visits/{visitid}/forms	
	POST	/v2.0/studies/{studyId}/lockObjectDetails	
	POST	/v3.0/studies	
	GET	/v3.0/studies	
	GET	/v3.0/studies/library	
	PUT	/v3.0/studies/{studyId}	
	GET	/v3.0/studies/{studyId}/statusessummary	
	GET	/v5.0/studies/{studyId}/statuses	
	GET	/v5.0/studies/{studyId}/statuses/{version}	
	GET	/v6.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo	
	Deprecat ed	POST	/v1.0/report/{reportName}
		POST	/v1.0/studies

Change	Method	Endpoint
	GET	/v1.0/studies
	PUT	/v1.0/studies/{studyId}
	GET	/v1.0/studies/{studyId}/kits
	GET	/v1.0/studies/{studyId}/statuses
	GET	/v1.0/studies/{studyId}/statuses/{version}
	GET	/v1.0/studies/{studyId}/statusessummary
	GET	/v1.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v1.0/studies/{studyId}/versions/{version}/forms
	GET	/v1.0/studies/{studyId}/versions/{version}/forms
	GET	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v1.0/studies/{studyId}/versions/{version}/kits
	GET	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}

Change	Method	Endpoint
	PUT	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}
	GET	/v1.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v1.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	GET	/v1.0/studies/{studyId}/versions/{version}/randomizations/{randomId}/ratios
	POST	/v1.0/studies/{studyId}/versions/{version}/visits
	GET	/v1.0/studies/{studyId}/versions/{version}/visits
	PUT	/v1.0/studies/{studyId}/versions/{version}/visits/{visitId}
	DELETE	/v1.0/studies/{studyId}/versions/{version}/visits/{visitId}
	GET	/v1.0/studies/{studyId}/versions/{version}/visits/{visitId}/dispensings

Change	Method	Endpoint
	GET	/v1.0/visitschedules/{studyId}/{version}
	POST	/v2.0/report/{reportName}
	GET	/v2.0/studies/{studyId}/kits
	GET	/v2.0/studies/{studyId}/statuses
	GET	/v2.0/studies/{studyId}/statuses/{version}
	GET	/v2.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v2.0/studies/{studyId}/versions/{version}/forms
	GET	/v2.0/studies/{studyId}/versions/{version}/forms
	POST	/v2.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v2.0/studies/{studyId}/versions/{version}/kits
	GET	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}

Change	Method	Endpoint
	DELETE	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}
	GET	/v2.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v2.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v2.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	POST	/v2.0/studies/{studyId}/versions/{version}/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/visits
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}
	PUT	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}
	DELETE	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/dispensings
	GET	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms

Change	Method	Endpoint
	PUT	/v2.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms
	GET	/v2.0/studies/{studyId}/versions/{version}/visitschedules
	GET	/v2.0/studies/{studyId}/visits/{visitId}/validate
	GET	/v2.0/visitschedules/{studyId}/{version}
	GET	/v3.0/studies/{studyId}/statuses
	GET	/v3.0/studies/{studyId}/statuses/{version}
	GET	/v3.0/studies/{studyId}/versions/{version}/dispensings
	POST	/v3.0/studies/{studyId}/versions/{version}/forms
	GET	/v3.0/studies/{studyId}/versions/{version}/forms
	POST	/v3.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v3.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v3.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo

Change	Method	Endpoint
	GET	/v3.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v3.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v3.0/studies/{studyId}/versions/{version}/randomizations
	GET	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	PUT	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	DELETE	/v3.0/studies/{studyId}/versions/{version}/randomizations/{randomId}
	GET	/v3.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms
	GET	/v4.0/studies/{studyId}/versions/{version}/design
	GET	/v4.0/studies/{studyId}/versions/{version}/dispensings
	PUT	/v4.0/studies/{studyId}/versions/{version}/dispensings
	GET	/v4.0/studies/{studyId}/versions/{version}/forms
	GET	/v4.0/studies/{studyId}/versions/{version}/forms/randomizationfactors
	POST	/v4.0/studies/{studyId}/versions/{version}/forms/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}

Change	Method	Endpoint
	PUT	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v4.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}/blindedInfo
	GET	/v4.0/studies/{studyId}/versions/{version}/kits/{kitId}/dispensings
	POST	/v4.0/studies/{studyId}/versions/{version}/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/visits
	GET	/v4.0/studies/{studyId}/versions/{version}/visitschedules
	GET	/v5.0/studies/{studyId}/versions/{version}/design
	POST	/v5.0/studies/{studyId}/versions/{version}/forms
	PUT	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v5.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	POST	/v5.0/studies/{studyId}/versions/{version}/visits

Change	Method	Endpoint
	GET	/v5.0/studies/{studyId}/versions/{version}/visits
	POST	/v6.0/studies/{studyId}/versions/{version}/forms
	GET	/v6.0/studies/{studyId}/versions/{version}/forms
	GET	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}
	POST	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v6.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	POST	/v6.0/studies/{studyId}/versions/{version}/visits
	POST	/v7.0/studies/{studyId}/versions/{version}/forms
	GET	/v7.0/studies/{studyId}/versions/{version}/forms
	GET	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}

Change	Method	Endpoint
	POST	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	GET	/v7.0/studies/{studyId}/versions/{version}/forms/{formId}/visits
	POST	/v7.0/studies/{studyId}/versions/{version}/visits
	GET	/v7.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms
	POST	/v8.0/studies/{studyId}/versions/{version}/forms
	GET	/v8.0/studies/{studyId}/versions/{version}/forms
	GET	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	DELETE	/v8.0/studies/{studyId}/versions/{version}/forms/{formId}
	GET	/v8.0/studies/{studyId}/versions/{version}/visits/{visitId}/forms
	POST	/v9.0/studies/{studyId}/versions/{version}/forms
	GET	/v9.0/studies/{studyId}/versions/{version}/forms
	GET	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}
	PUT	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}

Change	Method	Endpoint
	DELETE	/v9.0/studies/{studyId}/versions/{version}/forms/{formId}

Randomization and Supplies

Change	Method	Endpoint
New	POST	/v2.0/studies/{studyId}/{mode}/reports/titration-summary
	POST	/v3.0/studies/{studyId}/{mode}/resupply/resupply

Rules

Change	Method	Endpoint
New	POST	/v2.0/rule/studies/{studyId}/copyrules
	PUT	/v3.0/rule/studies/{studyId}/bulkcopy
	PUT	/v4.0/rule/studies/{studyId}/{mode}/bulkupdate

Sites and Depots

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties
	PUT	/v1.0/studies/{studyId}/{mode}/sdfs/extendedProperties
	POST	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties
	PUT	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties

Change	Method	Endpoint
	DELETE	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propId}
	GET	/v1.0/studies/{studyId}/{mode}/sdfs/globalProperties/{propName}
	DELETE	/v1.0/studies/{studyId}/{mode}/sdfs/{sdfId}/properties/{propId}
	GET	/v2/studies/{studyId}/{mode}/sdfs/pinaddr
	GET	/v4/studies/{studyId}/{mode}/sdfcountry

Users, Permissions and Roles

Change	Method	Endpoint
New	GET	/v1.0/studyroles/{studyId}/rolesRights
Deprecated	GET	/v1.0/authroles/
	GET	/v1.0/authroles/{studyId}
	GET	/v2.0/authstudies/{studyId}/users
	GET	/v1.0/authusers/{userId}/studies/{studyId}
	GET	/v2.0/authusers/{userId}/studies/{studyId}
	PUT	/v1.0/authusers/{userId}/studies/{studyId}

Change	Method	Endpoint
	GET	/v2.0/globalroles/users
	POST	/v1.0/{studyId}/{mode}/report/{reportName}

6

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 22.3

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)
- [Rest API updates](#)
See what has been updated in the Oracle Clinical One Platform API.

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.3 release. None of these fixes affect the user work flow or the application's functionality.

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

Table 6-1 Patch log

Release Number	Release Date	Fixed Issues
Release 22.3.1.7	08-March-2023	The following issues were fixed: <ul style="list-style-type: none">• 35118802• 35120560 For more information, see Fixed issues for Oracle Clinical One Analytics.
Release 22.3.1.6	02-March-2023	For this release, we fixed an issue related to unscheduled and branch visits. For more information, see Fixed issues for Oracle Clinical One Analytics.
Release 22.3.1.5	25-January-2023	For this release, we fixed several issues related to data collection. For more information, see: <ul style="list-style-type: none">• Fixed issues for forms, visits, and rules for details on issues 34914490 and 34909567.• Fixed issues for randomization and kits for details on issue 34899167.• Fixed issues for reports, archives, extracts, and notifications for details on issue 34917672.

Table 6-1 (Cont.) Patch log

Release Number	Release Date	Fixed Issues
Release 22.3.1.4	18-January-2023	For this release, we fixed an issue related to the Oracle Clinical One Platform Support chat. For more information, see Fixed issues for all users .
Release 22.3.1.3	12-January-2023	For this release, we introduced a new live chat feature for you to easily get in contact with Oracle Support. For more information, see What's New .
Release 22.3.1.2	03-January-2023	For this release, we fixed an issue related to how questions with code lists were displayed in the Subject Data Extract. For more information, see Reports, archives, extracts, and notifications .
Release 22.3.1.1	27-December-2022	For this release, we fixed an issue related to code lists. For more information, see Fixed issues for code lists .
Release 22.3.1	18-December-2022	For this release, we fixed several issues related to forms, visits, custom rules, Oracle Clinical One Analytics, kits, and reports. For more information, see the list below: <ul style="list-style-type: none"> • Fixed issues for forms, visits, and rules for details on issues 34890170. • Fixed issues for Oracle Clinical One Analytics for details on issues 34865395, 34265433, 34059966, 34053211, and 34042915. • Fixed issues for randomization and kits for details on issue 34771269. • Fixed issues for reports, archives, extracts, and notifications for details on issue 34769175.
Release 22.3.0.1	02-December-2022	For this release, we fixed an issue impacting the scheduler functionality for the Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

What's new

- [Data collection](#)

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

Data collection

- [Create and manage code lists for all studies at your organization](#)
Sponsor users and CROs now have dedicated spaces within the application to manage their code lists for a single study or all studies at an organization.
- [Clear saved data for a subject](#)
You can now clear data saved for a subject to correct any known errors.
- [Update a subject number during the study conduct period](#)
- [Order studies using the company filters](#)
A filter to order studies based on sponsor affiliation is now included on the homepage.
- [Customize the welcome letters for users](#)
The welcome letter for new users can now be customized for all studies or a single study.
- [Greater flexibility for date/time questions](#)
Study designers can now modify the details of **date & time, date only, and time only** questions within forms to allow for unknown values, following the approval of the study design.

Create and manage code lists for all studies at your organization

Sponsor users and CROs now have dedicated spaces within the application to manage their code lists for a single study or all studies at an organization.

You can now create your very own library of code lists! By organizing your default and custom values, you offer all sponsor users at your organization the ability to effectively manage their own data library. For example, if your organization conducts a pediatric study and an oncology study, both groups of sponsors may need to use very different values within each study. This is where the library of code lists comes in handy. Having a set of default code list values and the ability to customize those values at a study level gives you the perfect blend of data consistency and integrity, and data customization across studies.

Before you work with this feature

This new feature can impact most study team members. The following users can manage code lists:

- The study designer, as long as they are assigned with the *Manage Study Code Lists* permission. Study designers can only manage code lists that are used in form design.
- Any user at a sponsor or CRO who is assigned the new *Codelist Manager* global role.

Details about system code lists and the global library of code lists

Here's what's new for you, as a code list manager:

- On the homepage, there is a new page called Library.

- The Library page is where you can create a global library of code lists that can be used across multiple studies at your organization.
- On the Library page, code lists are organized by groups: custom code lists and system default code lists. The system default code list group contains predefined code lists created by Oracle and you will see them on the User Interface (UI). The custom code list group contains all code lists that can only be used for form design or study filters. For more information on study filters, see [Order studies using the company filters](#) .
- The system default code list group contains code lists that exist in the system, by default. You can view and edit certain details of these default code lists, but you cannot delete them or create new ones. You can create new system code list groups, but those will only contain the default code lists (also included in the default group of code lists). You can edit certain elements of the code lists included in a system code list group that you've created yourself.
- The custom code list group contains all code lists that you create from scratch and that you can view and further edit. You can hide values in a custom code list, create new values in a code list, or create a new code list in the custom code list group.
- Code lists can be created in all languages available in the application. Upon selecting a code list, you can view the code list items by switching between language tabs in the library.
- Upon creating a study, you should assign a system code list group to that study. This way, your study uses the appropriate group of code values. You also have the option of assigning a system code list group to a study at any time during the study's development, whether it's during the design phase, the testing phase, or the conduct period of a study.

Figure 6-1 Access the Library

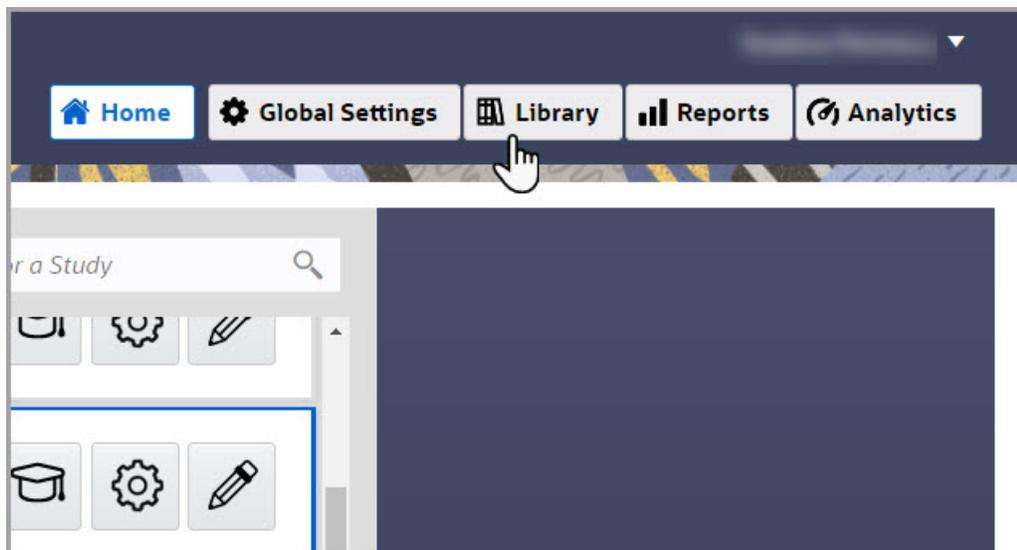
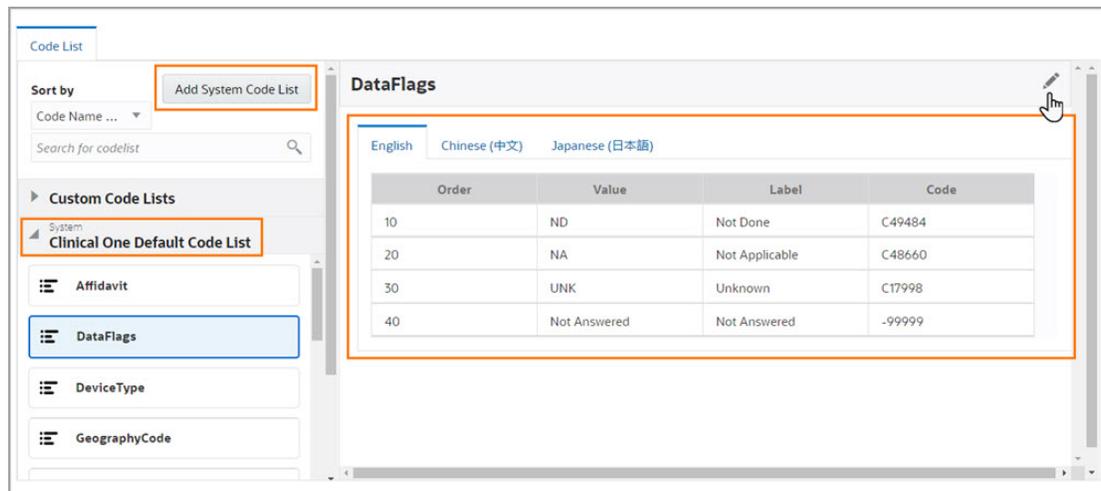


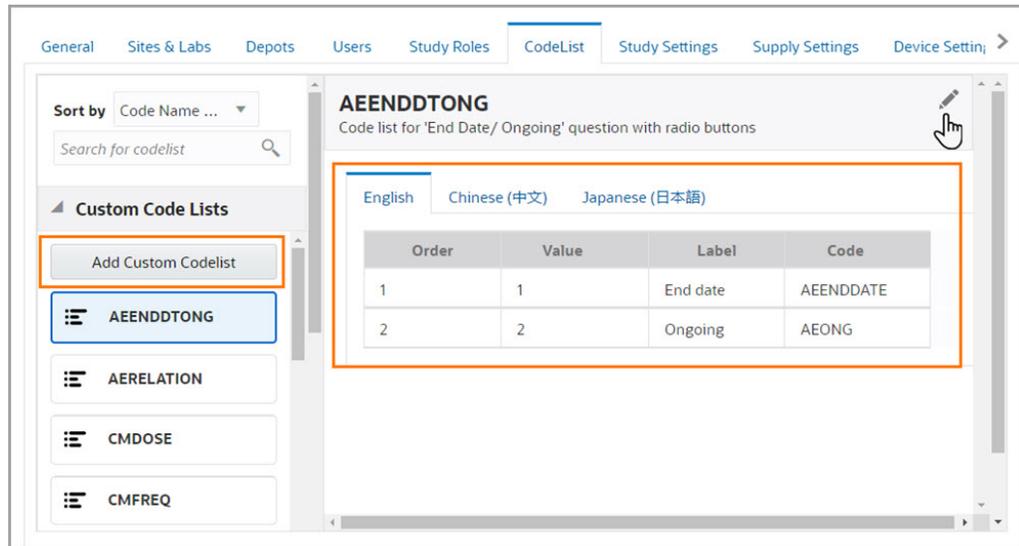
Figure 6-2 Create a system code list group



Details about study code lists and a study's individual library

Here's what's new for you, as a study designer who creates and manages code lists at a study level only:

- As a study designer, you can continue creating code lists specific for designing forms. A code list that can be used in form design can be found in the custom code list group on the Code list tab in a study's settings.
- All code lists in a single study can now be managed in a study's settings, on the new Code List tab. You can either edit certain elements in a code list from the system default code list group or you can create or delete a custom code list in the custom code list group.
- on the Code list tab, if you create a new custom code list, that newly-created custom code list is not available for all studies at your organization. If you edit elements of any system default code lists (from the system default code list group), these edits will only be available in the context of a single study.
- When new system code list groups are added at a global level (on the Library page), these new code list groups are also displayed on the Code List tab in the context of a single study.

Figure 6-3 Create a custom study code list**Already working in a live study?**

As soon as the upgrade for this release is complete, you can begin creating and managing code lists for specific studies or all studies at your organization. For existing studies, you can continue using the custom code lists you have created for form design and you do not have to update these code lists to accommodate the new feature. All of the existing custom code lists that were previously created for form design will now show up on the Code List tab for every study.

To assign a system code list group to an existing study, you can edit the study's details on the General tab, and select the appropriate system code list group to assign to that study.

Note:

When you attempt to update the custom code list called EDCYearRange, you may experience some unexpected behavior related to how labels are updated. This Known Issue may potentially impact the way partial dates are defined in a form. For more information, see issue **34783476** in the [Known Issues List](#).

Clear saved data for a subject

You can now clear data saved for a subject to correct any known errors.

Before you work with this feature

- Any permissions site users are assigned with to enter specific data allow them to also clear that data.

- **Site Edits Visit Date** must be enabled under Study Settings for the menu icon (☰) to appear for the particular visit type you would like users to be able to clear the visit date for.
- To remove data from a radio button question without returning it to a new state, you have the option to select **Reset** from the menu.
- When **Reset** is selected for a radio button question, the Answer History will show it has been reset, while the Answer History will reflect a question has been cleared when **Clear** has been selected.

Details for site users

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

- The option to clear data will only be available in the menu for an item once data has been entered and saved for that question.
- You can select **Clear** from the menu icon (☰) next to the item you would like to clear data from.
- You are prompted to select an option from the **Reason for Change** drop-down when you choose to clear data.
- Data entered for a question or visit cannot be cleared if that question or visit is locked or frozen.
- The option to clear data is available in all visit types (Scheduled, Unscheduled, Screening, Withdrawal, Completion, Dispensation, Randomization, and Adverse Events).

Report enhancements

You can now include or exclude cleared data from the Subject Data report and Subject Events report:

- When you select the Subject Data report under the Reports & Archives tab, the option to include or exclude cleared data is available in the Settings pane on the right.
- A new status, **Visit Date Cleared**, appears under the **Event Type** column in the Subject Events report.
- In addition, the Subject Data Extract will not include records of cleared forms.

Further details will be featured in the Subject Data Report, Subject Events Report, and Subject Data Extract.

Already working in a live study?

Once the upgrade for this release is complete, clearing subject data will be available for all existing studies. More information on data clearing and step-by-step instructions on how to do so will be featured in the *Site User Guide*.

Update a subject number during the study conduct period

With the appropriate permission, users at a sponsor or site now have the option of updating a subject number during the study conduct period.

If you ever need to update a subject number, there is now a simple way for you to do that! With the new ability of updating subject numbers, you can perform this update at any time and with only a few clicks. Rest assured, every change you make is saved in the system and

you, as well as other sponsor users, can view the audit trail of the subject numbers that you update.

Before you work with this feature

This new feature does not only impact site users. As a user administrator, you must make sure that the site user or sponsor user who updates a subject number has the appropriate permission to do so. We recommend that you only grant site users the permission to update subject numbers temporarily. After they are done with their updates, you should remove that permission associated with their role.

We also recommend that you create a custom study role for site users. The custom study role should contain the appropriate permissions for a site user, as well as the new permission called *Update a Subject's Number*. After a site user is done with the subject number updates, you can re-assign them with their original study role. For more information on how to create a custom study role at a study level, see [Create a study role for one study](#).

Details for sponsor users

There are no changes in the workflow within the application. However, there are certain things that you should know:

- When a subject number is updated during the study conduct period, the system validates the new subject number to ensure it adheres to the subject number format requirements. As a best practice, we recommend you review the planned update prior to having the user's permissions updated.
- After a user updates a subject number, we recommend you work with your user administrator to ensure that the user's permission to update a subject number is revoked.
- From the moment a subject number is updated it is displayed in reports, extracts, and all other areas within the application.
- If you are assigned the *Receive the Subject Number Update Notification*, you receive a notification whenever a subject number is updated. The notification includes relevant details such as the site number, the original subject number, and the updated subject number.

Details for site users

Here's what you need to know about this new feature:

- On the Subjects page, when you click **Manage Subjects**, you see a new option called **Update Subject Number(s)**. This option is only active if you have the appropriate permission assigned to your role and if you have previously selected a specific site (when you have access to multiple sites).
- Upon selecting a subject and clicking **Update Subject Number(s)**, a new dialog appears. On the Update Subject Number(s) dialog, you can perform the following actions:
 - View a subject's current subject number (under the **Selected Subject** column).
 - View the required subject number format.
 - Update a subject's current subject number (under the **Update To** column).
 - Add and remove subject numbers that you want or do not want to update.

- Enter a reason for the update that you are making.
- If you are assigned the *Receive the Subject Number Update Notification*, you receive a notification whenever a subject number is updated. The notification includes relevant details such as the site number, the original subject number, and the updated subject number.

Figure 6-4 How a user sees the Update Subject Number(s) dialog

Update Subject Number(s) ×

* Selected Subject * Update To +

MG16	MG1 24	🗑️
MG14	MG1 26	🗑️

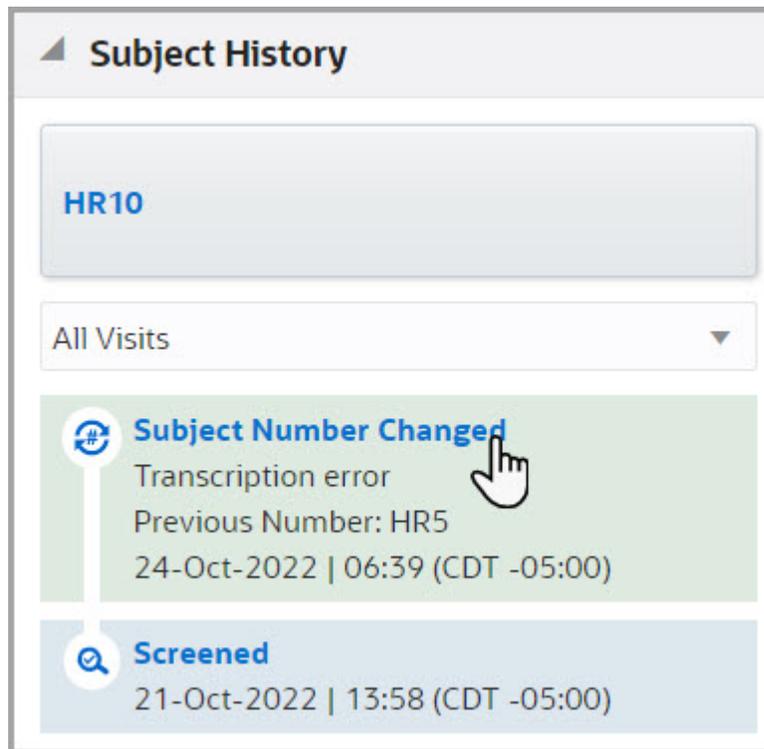
Please enter a value containing only numbers

* Reason for Change

Due to a transcription error, multiple subject numbers must be updated.

Cancel Update

Figure 6-5 A changed subject number in a subject's history



Reporting updates

The moment a subject number is updated, it is displayed in reports, extracts, and all other areas within the application. The Subject Events report contains the following specific updates:

- There is a new column called **Previous Subject Number**. This column displays the original subject number for a subject whose number was updated during the study conduct period.
- The column called **Current Subject Number** displays the newly updated subject number.
- The **Event Type** column displays a value of **Subject Number Changed** when an update has occurred.

Note:

Subject number updates will be reflected in the Oracle Clinical One Analytics custom reports and dashboards in a future release.

Impact to integrations

This feature is not compatible with all integrations configured with Oracle Clinical One Digital Gateway. If you want to change a subject's number, carefully consider how this change might impact your current integrations.

If a subject number change occurs after verbatim terms are sent to Oracle Central Coding, this will result in subject number discrepancies between the Oracle Clinical One Platform and Oracle Central Coding. Verbatim terms and coding results will still be associated with the correct subject number.

The ability to seamlessly update subject numbers without impacting your coding processes will be introduced in an upcoming Oracle Central Coding release. Until then, make sure you work with your Oracle Project Manager for additional information before changing a subject number.

Already working in a live study?

The new permissions called *Update a Subject's Number* and *Receive the Subject Number Update Notification* can be added to study roles for existing studies as soon as the upgrade completes. There is no other action for you regarding the compatibility of this feature with existing studies.

Order studies using the company filters

A filter to order studies based on sponsor affiliation is now included on the homepage.

Before you work with this feature

This new filter allows Clinical Research Organizations (CROs) to view information about all studies from the same sponsor. You are now able to:

- Only display studies associated with the user roles.
- Associate Company names with unique code lists in English and other languages.

To create and manage a custom code list that contains company names for all studies at your organization, you must be assigned either the Study Creator or the Code List Manager global role. Users see only study filters with their assigned studies. For example, a study designer can only see the granted studies for a specific company and not others. Filters are tied to the overall study permissions the user has.

Details for study creators and code list managers

When working with code lists this is what is new for you:

- For a CRO or sponsor user to filter studies for their organization, you must first create a custom code list that contains all company names on the **Library** page. This system code list with all company names can be used for all studies at your organization.
- Upon creating a study, there is a new **Company** field where you can select the organization that is associated with your study. The options available for the **Company** field are the organizations that you previously included as code values in the custom code list created on the **Library** page.
- In a study's settings, on the **General** tab, you can add a new selection for the **Company** field for an individual study at any point during the study conduct period.

Already working in a live study?

After the upgrade is complete, you can create a custom code list with all company names and begin using it for your existing study. For more information, see the *Sponsor and CRO User Guide*.

Customize the welcome letters for users

The welcome letter for new users can now be customized for all studies or a single study.

Existing studies now have the welcome letter populated automatically. However, the updated format in the welcome letter appears in newly generated emails.



Note:

To populate company names for existing studies you must set them up in the Companies code-list. For more information, see [Order studies using the company filters](#) and [Create and manage code lists for all studies at your organization](#).

Other study team members and study creators can now include relevant information in the welcome message about the study, training, or help center to guide new users. With this enhancement you are now able to:

- Customize the content to match for all studies at your organization or a specific study's details.
- Create a template that populates in all studies so you can modify as required.
- Employ a progressive disclosure of information using the roles that can edit the letter.

How you intend to use the custom letter to support team members will determine which role is more suitable. For example, some study team members might need to have information such as correct sponsor name and study scope, while others might need to identify specific studies when working with numerous data and names.

Details for study creators and study managers

The welcome message can be customized at two different levels: at the **global level** (for all studies at your organization) and the **study level**. At the global level, you must be assigned the Study Creator global role to edit the welcome letter. At a study level, you must be assigned the *Edit Welcome Details in General Study Settings* permission.

The following study template roles have the *Edit Welcome Details in General Study Settings* permission assigned by default:

- Study Manager
- Production Admin
- Rules Designer

As the study creator, you can only update the welcome message available at a global level (for all studies at your organization). You can do this on the Global Settings page, on the General tab.

As a study manager, you can only customize the welcome message at the study level. You can do this in the study's settings on the General tab.

Already working in a live study?

After the upgrade is complete, you can begin customizing welcome messages for your newly created studies. For existing studies, you can customize the welcome message, but only newly added study team members will see it. For more information see the *Sponsor and CRO User Guide*.

Greater flexibility for date/time questions

Study designers can now modify the details of **date & time**, **date only**, and **time only** questions within forms to allow for unknown values, following the approval of the study design.

Details for study designers

For date/time questions, study designers can now increase the number of unknown elements in a question, by modifying the **Minimum Answer**. The format of the date/time cannot be modified following approval, however, study designers can now modify the minimum acceptable answers site users provide for date/time questions.

The Date/Time selector is now a set of radio buttons. Selecting any of the following limits the range of **Format** options displayed: **Date & Time**, **Date Only**, **Time Only**. For instance, if **Time Only** has been selected, the following options will be available under **Format**: **HH**; **HH:MM**; **HH:MM:SS**.

Already working in a live study?

As soon as the upgrade is complete, you will be able to modify the minimum answer subjects can provide for date/time questions.

Data review

- [Lock a subject's data at the question, form, or visit level](#)
You can now lock a subject's questions, forms, or visits to prevent users from modifying that subject's data.

Lock a subject's data at the question, form, or visit level

You can now lock a subject's questions, forms, or visits to prevent users from modifying that subject's data.

By locking a subject's data at the question, form, or visit level, other users cannot insert new or update existing data for that subject, such as API loaded data or changing the subject number. Subjects can be locked at the form or visit level even if the visit or form is incomplete or has open queries.

Before working with this feature

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can now lock a subject's forms or visits to prevent new data from being added or updated by another user. Any user assigned this permission also has the ability to unlock a subject's data.

Any user assigned the *View Form Data for Subjects* permission will be able to see whether the subject, visit, form, and question are locked as long as they have permissions to view those elements.

Details for sponsor users

- When a subject is locked, all existing data becomes read-only.
- A Locked icon () appears next to a subject to indicate it is locked.
- Locking data at the form or visit level also locks any questions that are hidden to the user.
- The options to sign, freeze, unfreeze and verify are still available on locked questions, forms, and visits.
- Normal ranges on lab forms can still be updated even if the lab form is locked.
- Coding continues to run on locked data.
- The Subject Data Extract, Subject Data report, and Subject Queries report reflect the study's design at the time the report is run, even for locked questions.

More information and step-by-step instructions on subject data locking will be available in the *Sponsor and CRO User Guide*.

Details for site users

Site users can view locked and unlocked data, so long as they have the corresponding permissions to see that element.

- A Locked icon () is visible next to a locked question for a subject with open queries.
- An Unlocked icon () appears next to an unlocked question, indicating that the question has been unlocked by a sponsor user.

More information on locked and unlocked icons will be featured in the *Icon Reference*.

Impact to integrations

When it comes to your workflow for coded terms in Oracle Central Coding and locked data:

- When a subject's data is locked, site or sponsor users cannot enter new or modify existing Verbatim terms, Indication, and Route.
- Coding activities in Oracle Central Coding are still allowed even if the verbatim, context items, or coding target fields are locked.
- Updates to the coding are reflected in the audit trail.
- Queries cannot be raised, answered, or closed on locked coding items.

Note:

Data for locked questions, forms, and visits cannot be transmitted through integrations into or out of Oracle Clinical One Platform.

Impact to rules

- A custom rule will not re-run after its variables or targets are unlocked unless one or more of the questions entered as variables are updated. If a rule needs to be re-run, you must manually select the option to re-run from the Rule's menu.
- A custom rule cannot open queries or apply calculations to locked questions, forms and visits.
- A new notification called Rule Failure Notification for Locked Data is available. Users assigned the *Receive Rule Failure Notification for Locked Data* permission will receive this notification informing them that some targets were not updated due to them being locked.

Already working in a live study?

Once the upgrade for this release is complete, users will have the ability to perform subject data locking at the question, form and visit level, and view locked and unlocked data. More information on locking subject data will be featured in the *Sponsor and CRO User Guide*.

Randomization and trial supply management

- [Perform partial dispensation](#)
Site users can now partially dispense investigational product to adapt to a kit shortage at a site.

Perform partial dispensation

Site users can now partially dispense investigational product to adapt to a kit shortage at a site.

To allow partial dispensation, this setting must be activated and details must be defined for the partial dispensation of a particular kit type. The partial dispensation option is available when multiple kits of the same type must be dispensed during a visit, as long as you have at least one kit available of each kit type that must be dispensed.

Consider the following when working with partial dispensation:

- For kits with calculated doses, data changes after a partial dispensation will not result in the recalculation of the dose.
- The Do Not Dispense (DND) days requirement considers the initial dispensation date only.
- When a partial dispensation occurs, the Dispensation notifications now include details related to it.

Details for clinical supply managers and other sponsor users

You can now activate partial dispensation from the Supply Settings page. Settings must be defined for each kit type that is allowed for partial dispensation, but it is not necessary for all kit types to be defined for partial dispensation or to have matching settings. Additionally, you can turn the partial dispensation setting on and off as required, globally and individually defined for a given kit type at a specific visit range.

For each kit type, you must specify a visit range during which partial dispensation is allowed. Any dispensation visit, scheduled or unscheduled, will allow partial dispensation for the given

kit type, as long as it is within the defined visit range and regardless of whether there was a skipped visit or not.

To prevent subsequent shortage, predictive resupply strategies consider subjects with ongoing partial dispensation in the resupply orders.

**Note:**

Partial dispensation and dose holds cannot be simultaneously active in a study.

Details for site users

Site users are able to complete a visit when there are not enough kits available at the site to dispense. When performing a partial dispensation, you still need to follow the regular steps for dispensing the investigational product: complete the required forms, confirm the dispensation of kits, titrate, or dispense reusable kits, if applicable.

Details about performed partial dispensation display on the Subjects History pane. A partial dispensation must be completed before a subsequent dispensation visit, whether it is scheduled or unscheduled, otherwise visits will be left with incomplete dispensation. In this regard, the system warns you about pending partial dispensations whenever you attempt to dispense kits for a later visit. If the site still doesn't have enough kits upon the subject's return, you can perform another partial dispensation until the full amount of pending kits is available and the dispensation is complete. For titration studies, you can perform a later unscheduled titration to decrease the dose so that the subject doesn't need to come back for additional kits.

Already working in a live study?

As soon as this upgrade is complete, clinical supply managers can define partial dispensation settings. Once these settings are applied, site users will be able to perform partial dispensation and adjust to kit availability.

More information regarding partial dispensation will be featured in the *Sponsor and CRO User Guide* and the *Site User Guide*.

Reporting, archives, and analytics

- [Access customizable dashboards](#)
Clinical Research Associates (CRAs) and data managers (DMs) now have access to dashboard templates in Oracle Clinical One Analytics.
- [Enhancements for Oracle CRF Submit archives and reports](#)
The following details provide an overview of enhancements for Oracle CRF Submit archives and reports included in this release.
- [New notifications for scheduled reports](#)
You can now receive various notifications for scheduled reports depending on their configured setting.
- [New User Assignment Across Studies report](#)
Global user managers and study creators can now run a report that identifies the roles assigned to specific users across studies.

Access customizable dashboards

Clinical Research Associates (CRAs) and data managers (DMs) now have access to dashboard templates in Oracle Clinical One Analytics.



Tip:

Whether you are working in a live study (and already using Oracle Clinical One Analytics), a user working in a brand new study, or just starting work with analytics, reach out to your Oracle Project Manager to learn more about these new dashboards.

With the introduction of the new standard dashboard templates in Oracle Clinical One Analytics, you can get a better, more holistic view of your study's data. By leveraging the existing functionality of datasets, you now have access to customizable, interactive dashboards containing reports and visualizations that can help improve your decision-making and data management processes.

Because they are templates, you do not have to create dashboards from scratch, but you can customize them to meet your needs. All you have to do is simply tweak the data in each dashboard and adjust their filters to make sure you are viewing data relevant to your work.

Before you work with this new feature

Each predefined dashboard is built by leveraging an existing dataset in Oracle Clinical One Analytics. Because of this, you must have access to the respective dataset before you can properly view data in a corresponding dashboard. Access to a dataset is given based on a permission that you must be assigned in Oracle Clinical One Platform. For more information on these permissions, see [Descriptions of permissions in Oracle Clinical One Platform](#).

Details for Clinical Research Associates (CRAs)

With the new Clinical Research Associate (CRA) Dashboard, you can now monitor and control the data integrity and health of your study and sites. Built using the Subject and Queries datasets, this customizable dashboard offers you complex data on enrollment and query management, broken down into the following interactive reports:

- Study Overview
- Screening Overview
- Enrollment Report
- Subject Dropout Count by Reason
- Outstanding Queries by Site and Visit
- Query Ageing by Site
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Volume by Form
- Subject Counts with Outstanding Queries

The reports and visualizations grouped in this dashboard can help CRAs evaluate existing issues and identify the possible need of site training adjustments, as well as protocol and screening population redefinition.

Details for data managers

With the new Data Manager Dashboard, you can now view actionable visualizations and detailed listings of queries, subject states, and general subject data. Built using the Queries dataset, this customizable dashboard offers you the most relevant data that a clinical data manager could require in their work, exposed in the following interactive reports:

- Outstanding Queries by Site and Visit
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Ageing by Site
- Query Volume by Form

The reports and visualizations included in this dashboard can provide valuable information for workload prioritization and can help to identify the possible need of site training adjustments and monitoring visits.

Already working in a live study?

As soon as this upgrade is complete, CRAs and data managers can access the new customizable dashboard templates in Oracle Clinical One Analytics. If you have any trouble accessing specific data, reach out to your Oracle Project Manager or user administrator to check your permissions.

More information regarding dashboards will be featured in the *Analytics User Guide*.

Enhancements for Oracle CRF Submit archives and reports

The following details provide an overview of enhancements for Oracle CRF Submit archives and reports included in this release.

PDF headers now include the Locked form status

The Archives PDF header, specifically the **Form Status** row, now displays the status, **Locked**, for locked forms. The locked status is only present in the output files generated for Submission, Archival, and Custom PDF requests.

All date formats are now supported in Blank Form PDF active controls

Previously, only certain date/time formats were supported for the active controls included in blank PDFs. Now, all date formats that can be defined for a date/time item during design, including partial date restrictions, are supported in active controls. For more information, see [Create a date/time question](#)

Example: if YYYY-MM-DD was defined as the date/time format for an item, this format is represented in the blank form PDF active control.

**Note:**

Blank PDFs are included in Submission, Archival, Blank Form, and Custom PDF requests.

You can now view expected and completed file details during processing

Along with percent complete, the number of files expected and the number of files successfully generated are displayed on the Download Archives side panel during request processing. For more information, see [Generate an Oracle CRF Submit archive or report](#).

Archives are now available in Simplified Chinese

You now have the option to view the Archives user interface in Chinese. Additionally, the blank PDFs and subject PDFs included in the output zip file for Submission, Archival, Blank Form, and Custom PDF requests, including bookmarks, are now available in Chinese.

The default language is English, however, you can dynamically switch to any of the offered languages, Japanese and now Chinese by clicking your name in the upper right corner and choosing from the available languages in the **Change Language** control. For more information, see [Conduct studies in Simplified Chinese](#).

New notifications for scheduled reports

You can now receive various notifications for scheduled reports depending on their configured setting.

A variation of notifications are sent to the user who creates, activates, or deactivates a scheduled report.

Notifications

Users with the *Schedule Reports to Run* permission can now receive several new notifications for scheduled reports:

- The **Report Scheduled Created notification** is sent when a scheduled report has been created.
- The **Report Scheduled Activated notification** is sent when the **Scheduled Report** toggle for a report is turned on.
- The **Report Scheduled Deactivated notification** is sent when the **Scheduled Report** toggle is turned off.

Each notification includes the following details:

- Study name, ID, and mode
- Report name
- Report schedule
- sFTP location
- Date scheduled
- The user the report was scheduled by
- Notification recipients

New User Assignment Across Studies report

Global user managers and study creators can now run a report that identifies the roles assigned to specific users across studies.

About this feature

The User Assignment Across Studies report can help Clinical Research Associate (CRAs) with the following:

- Provide a dashboard to view users and their roles across studies.
- Compare permissions of the roles across studies.
- Recognize specific user activity to find a suitable replacement.
- Identify users from studies that had access temporarily or permanently removed.
- Find users that should be removed across studies.

Details for global user managers and study creators

Here's what's new for you:

- On the **Reports** tab, you will see a new report called **User Assignment Across Studies**.
- When you select that report, a **Settings** side panel will appear on the right, prompting you to filter data in your report. You can perform the following actions:
 - Select one or multiple user names, but never all.
 - Select the study mode in which the study user has access (under **Study Mode**)
 - Include or exclude permissions assigned to users in one or multiple study roles across studies.
 - Include or exclude decommissioned studies.
 - Select the file type of the report export whether it's **CSV**, **HTML**, or **PDF**).

Already working in a live study?

Use the report for existing studies as soon as the upgrade completes.

More information is featured in the *Reporting Guide* in User Assignment Report .

User experience

- [Chat in real time with your Support team](#)
With the new Oracle Clinical One Platform chat feature, you can now quickly get in touch with our Oracle Support team and discuss your issues in real time.
- [Conduct studies in Simplified Chinese](#)
Oracle Clinical One Platform now gives you the option to design studies and collect subject data using Simplified Chinese.

Chat in real time with your Support team

With the new Oracle Clinical One Platform chat feature, you can now quickly get in touch with our Oracle Support team and discuss your issues in real time.

The Oracle Clinical One Platform chat lets you engage directly with technical support and will be available starting with 16-January-2023, at 08:00 GMT.

Details for all users

On the home page, when you click Chat & Help, a new Chat & Help dialog is displayed. On that newly displayed dialog, you'll see several options to click:

- **View Documentation:** this opens the Oracle Clinical One Platform Oracle Help Center homepage where you can browse the application's documentation.
- **My Training Videos:** this displays the videos assigned to your user based on your permissions in the application.
- **Live Chat:** clicking this option displays several new mandatory fields that you can fill in to start your live chat session: First Name, Last Name, Email Address, and How may we help you? By default, the fields First Name, Last Name, and Email Address are automatically populated with the details associated with your Oracle Clinical One Platform account.

When you click Live Chat and fill in the details, a new dialog called Live Assistance is displayed. In there, you can either start your conversation with a Support agent or get a notice that informs you when there are no agents available to chat.

For more information on how to use this feature, see [Chat in real time with Oracle Support](#).

Conduct studies in Simplified Chinese

Oracle Clinical One Platform now gives you the option to design studies and collect subject data using Simplified Chinese.

As an end user, you now have the option to view and use the Oracle Clinical One Platform application in the Simplified Chinese language.

The first time you sign into the application, you will notice that the default language of the application is English. To switch to Simplified Chinese, click your user name on the Home page and choose **Chinese** from the **Choose Language** drop-down at any time. After you select the Chinese language, the user interface refreshes, allowing you to see the product and common functionality translated into Simplified Chinese. Your language preference is then preserved for the next login session.

Localizing the Oracle Clinical One Platform application to accommodate the needs of users who speak different languages is part of a broader project that our team is currently working on. For this release, the major focus is to translate all product areas that impact the site user's experience. These areas include core labels, titles, system messages, site-facing code lists, as well as support for form design, clinical data collection and specific site-facing reports, and notifications. The remaining reports and notifications will be translated as part of an upcoming feature.

 **Note:**

MEDDRAC and WHODDC Chinese dictionaries are going to be supported in Oracle Central Coding and in Oracle Clinical One Platform as part of an upcoming release.

Form design and clinical data collection

A study designer is now able to define form items using Simplified Chinese characters and the preferred date and time formats used in the Chinese language: YYYY-MM-DD and YYYY-MM-DD HH:MM. Similarly, the site user is able to enter form data using the same Simplified Chinese characters and respective date and time formats.

In order to maintain data integrity, the user language preference will not influence form design or collected data. Forms will remain as they were defined by the sponsor, as well as collected data will remain as entered by the site user, regardless of the application language preference. For example, if forms within a study are designed in English, site users will see English forms even if they select Chinese as their preferred language and vice versa. Similarly, if data is collected in English, it will remain as that even if the language preference changes.

Reports and archives

As a site user, if you select your language preference as Chinese, you can access the following reports and extracts in the Simplified Chinese language:

- Subject Data Extract
- Subject Visits
- Subject Visits (Unblinded)
- Kit Dispensation
- Subject Queries
- Study Design
- Titration Summary
- Titration Summary (Unblinded)
- Chain of Custody
- Chain of Custody (Unblinded)
- Clinical One Training

 **Note:**

Clinical data will never be translated and will be reported exactly as collected despite the user's language preference.

Notifications

When the preferred language is set to Chinese, the following notifications are translated:

- Code Break

- Randomization Failed
- Dispensation Failed
- Subject Randomization Complete
- Subject Dispensation Complete
- Unblinded Pharmacist dispensation
- New Shipment Request
- Cancel Shipment
- Insufficient Shipments, Shipment Failure notifications
- Cohorts Limits Reached
- New Shipment for Destruction created
- Kit Missing from Shipment for Destruction
- Disable Kit List
- Subject added
- Subject transferred
- Subject withdrawal
- Subject screening/ screen failure
- Subject visit complete
- Training complete (Oracle Clinical One Platform training only)
- Training status reminder
- Custom notifications
- User added to study
- State of a site has changed
- Rule re-run
- Report is ready
- Report failed to generate

**Note:**

- Notifications intended for non-Oracle Clinical One Platform users, such as depot email addresses, will always be sent in English.
- Oracle Health Learn course certificates and notifications for other applications are *not* translated.

User documentation

To make sure your user experience is complete, we have translated our entire Oracle Clinical One Platform documentation set to Simplified Chinese. From now on, not only can you conduct your study in Chinese, but if you ever need user assistance, you can browse the documentation in the same language.

To learn more, see the [translated documentation on the Oracle Help Center](#).

Other enhancements

Report enhancements

The following reports have been updated in this release:

- The Subject Queries report now includes information about three new fields- *Created By*, *Last Modified By*, and *Created By Role*. More information about the new fields will be featured in the Subject Queries report.
- The User Upload Error report has been reformatted to match the User Upload Template. This allows you to download the report, correct errors directly in the report, then simply import it to create user accounts. For more information, see the User Upload Error report.

Additional information on these reports will be featured in the *Reporting Guide*.

Kit lists can now contain special characters

Kit lists will now be stored as UTF-8, a standard which covers a broad range of characters. This means that dashes, decimals, along with other special characters ("|" "/" "\$" "&") will now be allowed within kit numbers.

On the Study Inventory and Site Inventory pages, users can now search for individual kits only if the list contains UTF-8 characters.

On the Study Inventory page, provided that kit numbers include non-numerical characters, these will be sorted based on numerical characters first, followed by alphabetical (i.e. non-digit) characters.

As on the Study Inventory page, a range filter is now available on the Site Inventory page which searches across kit types.

Randomize subjects only when kits are available at site

You can now let site users randomize subjects only if specific kits are available at a site. On the Supply Settings tab, there is a new setting called **Randomize Only when All Kits Are Available at Site**. With it, you can choose to either allow randomization regardless of site inventory or prevent randomization when kits are not available. If you choose to confirm kits' availability at randomization, you can select the specific kit types required in the inventory to be able to randomize a subject.

Before this feature was introduced, there was no configuration available to set this behavior. Existing studies will have the setting set to **No** by default, to preserve the existing configuration. This allows sites to randomize subjects regardless of site inventory. As soon as this upgrade is complete, authorized sponsor users will be able to modify this setting to either allow or prevent randomization after kits' availability confirmation.

Fixed issues

- [All users](#)
- [Facilities, settings, and user management](#)
- [Forms, visits, and rules](#)

- [Integrations](#)
- [Oracle Clinical One Analytics](#)
- [Randomization and kits](#)
- [Reports, archives, extracts, and notifications](#)
- [Site users and subject data](#)

All users

The Oracle Clinical One Platform chat landing page points to a different URL

Now, when you open the Oracle Clinical One Platform live chat in the application, the chat connects to the appropriate Oracle Support URL (which is <https://hsgbu.custhelp.com>). Previously, the live chat was pointing to a different instance of the same URL. (Issue **34982023**)

Login dialog title is not translated to Japanese

Now, when you sign out of the application and sign back in, the Login dialog title is translated to Japanese, as expected. Previously, even though your language preference was set to Japanese, the Login dialog title was still displayed in English. (Issue **32941159**)

Facilities, settings, and user management

Default label for a stratum group is now translated

Study designers: Now, when your application's language preference is set to Japanese, and you create a central stratified randomization, you will notice that the default label for the stratum group is displayed in Japanese. Previously, these default labels were still displayed in English (Issue **32902693**)

Some error messages related to custom enrollment groups are not translated

Study managers: Now, when your application's language preference is set to Japanese, validation error messages for custom enrollment groups are fully translated. Previously, on the Create Custom Enrollment Group dialog, when you entered incorrect text in fields or left them blank, you may have noticed that the validation error messages were not fully translated in Japanese. (Issue **32891833**)

Regions with similar titles are allowed in the system (former known issue)

Study managers: On the Study Settings tab, there is now a validation that prevents you from using duplicate titles for the regions in your study. Previously, you may have noticed that you were allowed to create regions with similar titles. For example, you could create a region called "Region A" and another region called "Region a". That is because the Title field was not case sensitive.

Retracted workaround: We recommend you do not use duplicate or similar titles for multiple regions in your study. (Issue **34251662**)

Oracle Help link for custom enrollment settings not working (former known issue)

Study managers: Now, the Oracle Help Center URL displayed in the Custom Enrollment Settings section works as expected. Previously, when you clicked the link, you may have noticed that it did not work.

Retracted workaround: None. (Issue **32956426**)

Certain columns on the Study Settings tab are not translated to Japanese

Study managers: In the Visit Settings table, the columns titled Site Enters Visit Dates and Site Edits Visit Dates are properly translated to Japanese. Previously, the titles of these columns were not translated to Japanese, even though you had selected Japanese as your preferred language.

Retracted workaround: None. (Issue **32908869**)

Local lab values not translated to Japanese

Sponsor users: Certain local lab values (such as years, months, days) are now properly translated to Japanese. Previously, these values were still displayed in English. Keep in mind that local labs may use custom code values that are added in English (and not translated by the system). The following values are now translated:

- **Lab Unit:** the default code value called "Sample";
- **Normal Text Result:** the default code value called "Sample";
- **Fasting:** The code value called "All";
- **Gender:** The code value called "All";
- **Race:** "The code value called "A".

(Issue **32910370**)

Delayed user creation when uploading duplicate files in parallel

User administrators: Now, all users are created without delay when you upload a template containing identical user and role details, while the first upload is still in progress. Previously, when you attempted to upload a duplicate file, while the first file was still in progress for a study or multiple studies at your organization, you could encounter a delay in user creation in Oracle Clinical One Platform. This was caused by a delay in the service responsible for user creation in Oracle Clinical One Platform. (Issue **34039516**).

Forms, visits, and rules

Send Notification rule doesn't work as expected

Study designers: Now, when you create a Send Notification rule and specify the study roles that should receive the notification, all users who are assigned that study role receive the appropriate notification when it is generated. Previously, users assigned a specific study role (specified in the Send Notification rule) didn't get a notification when expected. Instead, the rule only worked when you specified the recipients' email addresses. (Issue **34914490**)

Duplicate automated queries are unexpectedly created

Rule designers: Now, when a site user enters data manually into a form, the fields that have any automated query rules associated with them will work as expected. Previously, when a site user manually entered data into a field with an automated query rule created for it, that automated query rule may have created multiple queries. (Issue **34909567**)

Selecting a value from the Select Lab drop-down results in an error

Site users: Now, after selecting a lab value from the Select Lab drop-down on a lab form, you are no longer presented with an error. Previously, when you made a selection, you were presented with, An issue just occurred in the system. Try performing this action again.

Retracted Workaround: None. (Issue **34783047**)

Signing out is required to see updates to a live study (former known issue)

Site users and sponsor users: Now, when a study designer applies a study design update to a live study version (such as adding a new question to a form or adding a new form to an existing visit), that update is properly reflected in the updated study version for a site user to see. Previously, it would take up to 15 minutes for the change to be displayed for the site staff.

Retracted workaround: A site user no longer has to refresh the Subjects page or sign out and back in for the study design updates to become effective. (Issue **33418179**)

Removing lab unit or test from code list also removes it from normal ranges list (former known issue)

Study designers: Starting with this release, you no longer can or have to delete a code value from a code list, including lab units or tests. You can only hide a value from a code list. This will ensure that any lab unit or test that you hide from a code list does not remove it from the normal ranges list. For more information, see [Create and manage code lists for all studies at your organization](#).

From now on, on the Subjects page, in the visit view, the lab unit that you hide is still displayed in previously completed lab forms. This ensures that hiding a code value from a code list does not cause any normal ranges that were previously entered to become invalid.

Retracted workaround: You can no longer delete Test Names and Units from tagged code lists, you can only hide these values from the code list. (Issue **31938228**)

Icons on a duplicated form are no longer displayed (former known issue)

Study designers: Now, after you duplicate a form, you may notice that its icons are displayed, as expected. Previously, the appropriate icons were not displayed for duplicate forms. For example, if you copied form A, that contained questions related to randomization, calculated doses, rollover visits, and branches, you may have noticed that the copied form A did not display the expected icons that indicated the presence of those questions.

Retracted workaround: You no longer have to refresh your browser's page to have the duplication icons displayed. (Issue **34296461**)

A dialog's title is not translated to Japanese (former known issue)

Study designers: Now, with your preferred language set to Japanese, you will notice that the All Visits in Branches dialog title is properly translated to Japanese. Previously, after selecting individual cycles for assigning a form to a branch, this dialog's title was still displayed in English.

Retracted workaround: None. (Issue **33659421**)

Closed captions are not generated for a video in Japanese

Study designers: Now, the video called Create and Copy Forms is displaying Closed Captions (CC) in Japanese, as expected. Previously, this video in Oracle Clinical One Platform did not display Japanese Closed Captions (CC). This complicated the user's experience with their in-product training. (Issue **34474875**)

The hover text of a branch is not translated to Japanese

Study designers: While the application's preferred language is set to Japanese, when you hover your mouse cursor over a branch's title, the hover text is translated to Japanese, as expected. Previously, the displayed hover text was not translated and the English text also contained a typo. (Issue **32916654**)

The Rule Editor dialog title overlaps with a rule's title (former known issue)

Rule designers: Now, when the application language preference is set to Japanese, the rule's title (that you add in the Rule Name field) is properly displayed in the Rule Editor dialog. Previously, you may have noticed that a rule's title was overlapping with the Rule Editor dialog title.

Retracted workaround: None. (Issue **34224726**)

An error displays when completing a visit or event with a radio button in Testing Mode

Study Designers: Now, users are able to complete a visit or event with a radio button from a study live in **Testing Mode** without an error prompting. Previously, when study designers completed a visit or event, the error '*An issue occurred in the system. Try performing this action again*' displayed when saved. The error showed after saving a subject screening in a **Baseline** visit. (Issue **34890170**)

Integrations

A job is failing with an unexpected error message (former known issue)

Integration managers: For an integration between the Oracle Clinical One Platform and Oracle InForm, you can now send data on a subject who previously failed screening. Previously, after you successfully screened a subject and ran the integration, a job would fail with the following message: "The initial submit for a subject is not the screening form."

Retracted workaround: None. (Issue **34313755**)

An integration may not send screening data to Oracle InForm

Integration managers: Now, for an integration between Oracle Clinical One Platform and Oracle InForm, data related to screen failures is sent to Oracle InForm, as expected. Previously, you may have noticed that jobs associated with an integration were marked as successful in the system, even though the appropriate screen failure data wasn't even sent through the integration. (Issue **34145697**)

Oracle Digital Gateway Builder integrations cannot be properly configured

Oracle Services: Now, you can configure and run integration with the Oracle Digital Gateway Builder applica

Unable to properly view a job's details in Oracle Clinical One Digital Gateway (former known issue)

Integration managers: Now, while an integration is running, you can properly view details about its associated jobs on the Job side panel. Previously, the Jobs side panel did not expand enough for you to view any of the details of a job.

Retracted workaround: You no longer have to check your browser's resolution settings and adjust them in a way that will make the Jobs side panel expand. Job details display as expected already. (Issue **34276537**)

Treatment arm details cannot be integrated with Oracle InForm (former known issue)

Integration managers: Now, for an integration between the Oracle Clinical One Platform and Oracle InForm, you can integrate treatment arm details for a randomized subject, as expected. Previously, when you attempted to do this, an error message stated that it could not find certain parameters to synchronize the data between the two applications. This issue was caused by a misconfiguration between parameters in the integration configuration file.

Retracted workaround: You no longer need to use the GUID of the treatment arm to ensure that data is synchronized between the two applications. For more information on this fixed issue, contact your Oracle Project Manager. (Issue **34334378**)

Oracle Clinical One Analytics

Oracle Clinical One Analytics displayed two-section form data as deleted even though it wasn't

Now, the data from the flat and repeating sections of a two-section form is displayed correctly even if you delete the last entry in a repeating section of a two-section form or the last instance of a two-section form entirely.

Previously, data sets that contained data from two-section forms displayed all flat and repeating section data as deleted if the last entry in a repeating section was deleted or a two-section form was deleted entirely. This issue was observed after completing two-section forms in an unscheduled visit. (Issue **35118802**)

Oracle Clinical One Analytics displayed two-section form data incorrectly

Now, the last entry in the repeating section of a two-section form no longer appears in the flat section record in the data set. Previously, data collected in the last instance of a repeating section of a two-section form was displayed in the flat section within a data set when it should not have been. (Issue **35120560**)

Data for unscheduled visits and cyclic branch visits are overwritten in data extract form tables

Now, unscheduled visits are verified in data extract tables, and cyclic and non-cyclic branches are supported in runtime in Oracle Clinical One Analytics. Previously, after moving a study design with screening, non-cyclic branch, cyclic branch, and unscheduled visits from Draft to Testing mode, then adding data for each branch and unscheduled visit, data for each instance was overwritten in data extract form tables. (Issue **34981114**)

Edited data integrated with Oracle Clinical One Analytics does not reflect in reports

Sponsor users and services consultants: Users can now see the data edits reflected in the Oracle Clinical One Analytics reports. Previously, after modifying data, such as subjects or events in Clinical One, the edits did not show in the Analytics reports. For Clinical One studies integrated with Clinical One Analytics certain data were not integrated. For example, when users ended visits or changed the subject's data, the back end displayed a differed status. The error 'Error while inserting and updating form data row'. prompted. For more details on the back-end process, contact your Oracle Project Manager. (Issue **34865395**)

Data not displayed in data sets when dispensation occurs during screening (former know issue)

Users working with Oracle Clinical One Analytics: Now, the Analytics report shows that the screening visit has dispensed the kits. Previously, we reported that in Oracle Clinical One Platform, when you assigned kits for dispensation to the screening visit, those same kits did not appear in the **Kits and Randomization Design** data set in Oracle Clinical One Analytics

Retracted workaround: None (Issue **34042915**)

The Study Design Delta report does not show deleted visits or forms (former known issue)

Study designers: Now, the changes show in the correct columns in the Study Design Delta report. Previously we noted that the Study Design Delta report would not indicate any changes, such as deleting a form or visit from a study. Also, the report column did not record the details of events and forms in the appropriate columns.

Retracted workaround: None (Issue **34053211**)

Non-existent study changes are displayed in the Study Design Delta report (former know issue)

Study Designers: Now, the study versions display the correct data with no registered differences. Previously, we reported that when you attempted to build a report with the study differences in the Study Design Delta report, unsolicited changes in the **Item Details** table appeared in your study in Oracle Clinical One Platform. The report indicated changes between study versions, even when you made none. This behavior happened when moving the study to a different mode and running the Study Delta report.

Retracted workaround: None (Issue **34059966**)

The ACTION_RULES data element does not display the expected data (former know issue)

Study Designers: Now, the columns report displays the expected data in the correct order with no changes. Previously, we reported that in the Study Design Delta report, the **ACTION_RULES** column did not display data in the same order for different study versions when the forms contain multiple predefined rules. This behavior happened even when users made no changes.

Retracted workaround: None (Issue **34265433**)

Data related to subject visits may not be properly displayed in Analytics (former known issue)

Now, data related to all types of visits is properly displayed in all corresponding datasets in the Analytics app. Previously, because data between the Oracle Clinical One Platform and the Oracle Clinical One Analytics was not updated as expected, the same data wasn't properly displayed in datasets either. This behavior was observed with cycle and non-cycle visits, as well as branches. This was a backend issue caused by an unexpected error message that appeared when data is refreshed in the Analytics app.

Retracted workaround: None. (Issue **34284115**)

Expired user accounts in Oracle Clinical One Platform can still access Analytics (former known issue)

Now, a user in Oracle Clinical One Platform whose access has expired can no longer use the Oracle Clinical One Analytics application. Previously, even though a user's access may have expired, they could still access datasets and reports in Oracle Clinical One Analytics.

Retracted workaround: None. (Issue **34274952**)

The Study Design dataset displays confusing error message (former known issue)

Now, when you include a combination of the ITEM_NAME and READONLY data elements, in the Rows portion of a Data Canvas, you can view the newly introduced data as expected. Previously, you may have noticed that a confusing error message was displayed after adding these data elements to the canvas. The message stated "Unable to Display Table – Query Canceled".

Retracted workaround: None. (Issue **33742720**)

Data on upcoming visits is not properly displayed in certain datasets (former known issue)

Now, for a completed or withdrawn subject, data on upcoming visits in the study is no longer displayed in the Subject Forms datasets. Previously, whenever a subject was marked as **Complete** or **Withdrawn** in a study in Oracle Clinical One Platform, data on upcoming visits in Oracle Clinical One Analytics was displayed as missing from the study.

Retracted workaround: None. (Issue **34288471**)

The Templates folder should be read-only for sponsor users (former known issue)

In Oracle Clinical One Analytics, the Clinical One Report Templates (located underneath the Shared Folders) is now read-only. Any modified reports or dashboards need to be saved in other folders within the application for you to further edit them.

Sponsor users can perform the following actions related to these templates only when they're located in a different folder:

- Add filters.
- Update filter values.
- Export reports and dashboards as a DVA file and import them into a different folder in the application. This lets sponsor users perform any other changes and save them into the exported file.

Retracted workaround: None. (Issue **34241618**)

Data related to dispensation may not be properly displayed in Oracle Clinical One Analytics

Now, whenever a dispensation visit without prior randomization is complete, the data from Oracle Clinical One Platform is sent to Oracle Clinical One Analytics, as expected. Previously data related to dispensation visits was not properly displayed in certain datasets, such as the Blinded Subject Event, Unblinded Subject Event, and the Unblinded Kits dataset.

Retracted workaround: None. (Issue **34274613**)

Randomization and kits

A kit's expiration date is displayed incorrectly

Clinical supply managers: Now, kits that are present in a study or site inventory have their expiration date displayed as expected according to the lot that they belong to. Previously, you may have noticed that a kit may have had an earlier expiration date than the date specified in the lot. The kit's expiration date was displayed in both inventories (for a study or a site) on the Expiration Date column. (Issue **34899167**)

Japanese characters not allowed in the title of a list (former known issue)

Clinical supply managers and statisticians: Now, on the Supply Settings tab, you can upload a kit or randomization list that contains Japanese characters in their file name, without receiving any error messages. Previously, the system raised an error message whenever the filename of a list contained Japanese characters.

Retracted workaround: You no longer have to make sure your kit or randomization lists do not contain Japanese characters in their file name. (Issue **32577227**)

Receiving kits quarantined notification when kits were not in quarantine.

Users subscribed to Quarantined Depot or Site Shipments notifications: Now, when a site user registers a shipment that is not quarantined, other users with the *Receive the Quarantined Depot Shipment Notification* or *Receive the Quarantined Site Shipment Notification* permission do not receive unsolicited notifications. Previously, whenever site users generated a shipment without any quarantined kits, other subscribed users would receive unrequested notifications about raised shipments with no quarantined kits. (Issue **34771269**)

Reports, archives, extracts, and notifications

Questions with measurement units were not integrated as expected with Oracle DMW

Data managers and statisticians: When a question with numbers contains an associated measurement unit, that type of question is now displayed as NUMBER in the Type column, in the data extracts generated for the integration with Oracle DMW. Previously, a question with measurement units was displayed as VARCHAR2 (data that is varying) in the Type column. (Issue **34917672**)

Questions with code lists were not properly displayed in the Subject Data Extract

Data managers and statisticians: Now, in a Subject Data Extract, the following types of questions are displayed as expected:

- Questions with a code list applied to them where the code list's name contains special characters such as a forward slash (/).
- Questions with a code list applied to them where the code value is not defined.
- Questions with a code list applied to them where the code list was renamed prior to the 22.3 release.

Previously, these types of questions were not properly displayed in the Subject Data Extract. Moreover, there were times when generating this extract failed due to several validation issues. (Issue **34939373**)

The User Assignment report is not populating a user's username (former known issue)

User managers: Now, when you generate a User Assignment report with historical data, all usernames are displayed in the report, as expected. Whether a user is removed from a study, retired, active, newly created, or their account has been deactivated in Oracle Life Sciences IAMS, their username is properly displayed in the report. Previously, some usernames were displayed as "N/A". This happened when a user was deleted from the study and deactivated in Oracle Life Sciences IAMS.

Retracted workaround: Although this issue has been fixed, we still recommend you do not delete a user from a study. Instead, when required, set a specific End Date for their access to the study. That way, after the specified date, they will no longer be a part of your study and you can also maintain a record of their study association. (Issue **34483826**)

Date range issues in the Kit Chain of Custody (Blinded) report (former known issue)

Sponsor users: Now, the Kit Chain of Custody (Blinded) report displays the kit transitions that have occurred on a certain date in the system, as expected. For example, if you choose 27-June-2022 as one of the dates in the **Transaction Date** setting, you may notice that kit transactions from that date are displayed in the report. Previously, kit transactions for specific dates were not properly displayed in this report. This issue was caused by a time zone inconsistency occurring in your browser.

Retracted workaround: None. (Issue **34300162**)

A subject's status is displayed in English in a Japanese Kit Dispensation report

Site users: Now, when you generate the Kit Dispensation report, you will notice that a subject's status is displayed in Japanese, as expected. Previously, when your language preference was set to Japanese, you may have noticed that a subject's status was still displayed in English, despite the report having been generated in Japanese.



Note:

A subject's status is located in the header bar of the Kit Dispensation report.

(Issue **33087630**)

Shipment creation notifications are not sent to depots (former known issue)

Clinical supply managers and depot users: Now, if you're working in multiple studies at your organization, you may notice that depot facilities are receiving email notifications when a new shipment is created, as expected. Previously, the email associated with a customer depot did not receive shipment creation notifications when a new shipment was created.

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

Sequence numbers in the Submission PDF are not properly sorted

Sponsor and site users: Now, sequence numbers for repeating forms are sorted in numeric order only (for example: 1, 2, 3, 4, 5). Previously, sequence numbers were sorted in an alphanumeric order. For example, if a repeating form contained 10 instances, the 10th instance would be placed after the first and you would see 1, 10, 2, 3, 4. (Issue **34343692**)

The Subject Queries report does not properly display query-related data (former known issue)

Sponsor and site users: Now, when you transfer a subject at another site and you modify an existing query at the previous site, the query update is properly displayed in the Subject Queries report. Previously, when you transferred a subject at another site and then you updated an existing query associated with that subject and their initial site, this update was not displayed in the report. For example, you updated an existing query at site A (their initial site) and then you added a new query at site B (the site where they were transferred). In the Subject Queries report, on the Last Updated On Site column, you may have noticed that the initial site was displayed, instead of the site where the subject was transferred to.

Retracted workaround: None. (Issue **34271619**)

Lab ID and lab name only displayed for predefined lab rows (former known issue) **Note:**

Lab IDs and names will only be displayed for labs going forward. IDs and names of existing labs in your study will not be displayed in the extract.

Study designers: Now, for a lab form, when you switch the **Add Additional Rows** toggle on, several users will get to experience the appropriate impact in the User Interface (UI).

- Data managers and statisticians can now see all additional repeating rows in the Subject Data Extract. Columns in the extract are populated with data whether the additional rows are manually added by a site user (in the UI) or automatically through an integration.
- Data managers and statisticians can only see the lab name and ID associated with these additional rows. Lab normal values are not displayed in the Subject Data Extract or the UI for additional repeating rows.

Retracted workaround: None. (Issue **32079296**)

Inconsistent month format between blank and subject PDF (former known issue)

Sponsor users: Now, the month value in the Blank Form PDF file matches the month value in the subject PDF file. Previously, the month drop-down in the blank PDF file displayed Japanese characters which did not match the subject PDF output.

Retracted workaround: None. (Issue **32699964**)

Site Confirmation and Download Log incorrectly displays data when administrative data contains commas

Sponsor users: Now, if administrative data such as a site's name includes a comma, the CSV output for the Site Confirmation & Download Log archive reports display administrative data in the correct cells. Previously, if a comma existed in a site's name (for example 'Health Center, ABC') the 'ABC' portion was inserted in the next cell. (Issue **33139699**)

The Subject Data Extract does not display all code list values (former known issue)

Study designers, code list managers, and statisticians: The Subject Data Extract report now displays the code values in the expected format. Previously, we reported that for new and existing questions in a study, when you assigned a system default code list group to a study or a custom code list to a question, certain code values were not displayed properly in the Subject Data Extract. As an example, when you flagged a question with the "Not Applicable" option, the code value was not displayed in the Subject Data Extract.

Retracted workaround: None (Issue **34769175**)

Site users and subject data

Cannot update visit date for a reinstated subject (former known issue)

Site users: Now, after you reinstate a subject in the study (Undo Subject Completion or Undo Withdrawal), you can clear the previously entered visit date (in the Visit Start Date field) and continue with a subject's visits. Previously, whenever you had to reinstate a subject, you could not change a visit's date for the subject's next scheduled visit. An error message was displayed stating that the visit date that you entered must be on or after a certain date.

For more information on clearing data, see [Clear saved data for a subject](#).

Retracted workaround: A study designer no longer has to extend the start window of the Completion or Withdrawal event to enable a lengthier visit window for the subject's next visit (that appears after they are reinstated). (Issues **33839734** and **33839744**)

A repeating form tool tip is not properly translated

Site users: Now, in a repeating form table, when you hover over the status icon of a repeating form instance (or row), the tool tip is displayed in your application's preferred language. Previously, for example, if your language preference was set to Japanese and you hovered over a status icon in a repeating form, you may have noticed that the text was still displayed in English. (Issue **32920898**)

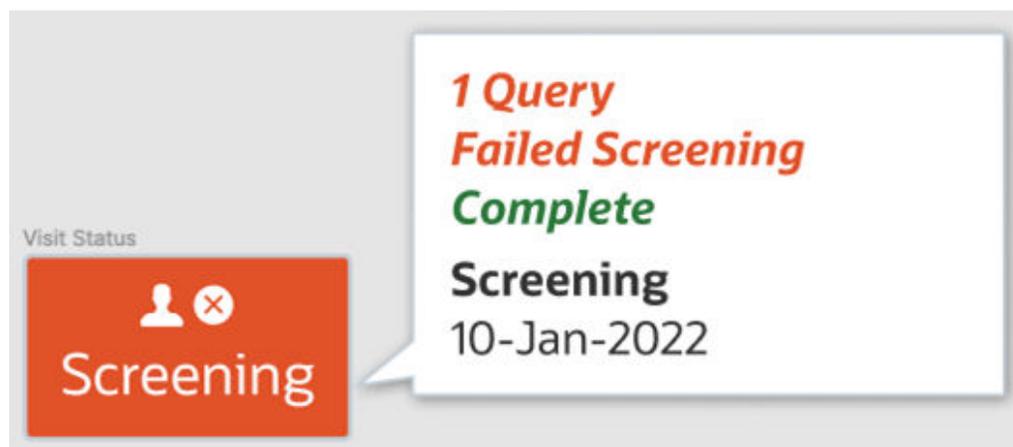
Failed screening visits must be displayed with a status of Incomplete (former known issue)

Site users: Now, when a subject fails their screening visit and that specific visit has any incomplete forms or opened queries, the visit's status is not only displayed as **Failed**

Screening. The hover text also indicates whether there are any opened queries, if the visit is considered incomplete (when there are incomplete forms), in progress, or complete.

Retracted workaround: None. (Issue [34290221](#))

Figure 6-6 How a visit's status is displayed



A query's age is not translated to Japanese

Data managers: On the Queries side panel, a query's age is now translated to Japanese. For example, if you just created a Candidate query a few seconds ago, the part "a few seconds ago" that is displayed next to the query is properly translated to Japanese. Previously, a query's age was displayed in English. (Issue [32920602](#))

A question's status of Signed is not translated to Japanese

Principal investigators and site users: Now, when your language preference is set to Japanese, a question's status of Signed is properly translated to Japanese, as expected. Previously, in the Answer History and Visit History sidebars, the Signed status was not translated to Japanese. (Issue [32916685](#))

Tooltip text for signed, verified, and frozen questions is not translated to Japanese

Site users: Now, when you hover your mouse cursor over a question's icon for Signed, Verified, or Frozen, the tooltip text that is translated to Japanese, as expected. Previously, the tooltip text was still displayed in English. (Issue [32919376](#))

The Subject Rollover dialog title is not translated to Japanese

Site users: Now, when you roll a subject over to another study, the Subject Rollover confirmation dialog title is translated to Japanese, as expected. Previously, once the Subject Rollover dialog was displayed, you may have noticed that the dialog's title was still displayed in English although the content of the dialog was translated to Japanese. (Issue [32934262](#))

Rest API updates

See what has been updated in the Oracle Clinical One Platform API.

The following services have been updated:

- [Code list](#)
- [Coding](#)
- [Data Action](#)
- [Data Hub](#)
- [Data Integration](#)
- [Data Capture](#)
- [Designer](#)
- [Notifications](#)
- [Randomization and Supplies](#)
- [Reporting](#)
- [Sites and Depots](#)
- [Users, Permissions and Roles](#)

Code list

Change	Method	Endpoint
New	DELETE	/v2.0/codelist/code/{codeId}
	PUT	/v3.0/codelist/code/{codeId}
Deprecated	GET	/v1.0/codelist/values/{fieldName}
	GET	/v2.0/codelist
	POST	/v2.0/codelist/code
	PUT	/v2.0/codelist/code/{codeId}
	GET	/v2.0/codelist/history/{name}

Change	Method	Endpoint
	GET	/v2.0/codelist/{name}
	GET	/v3.0/codelist
	GET	/v3.0/codelist/{name}

Coding

Change	Method	Endpoint
New	POST	/v1.0/studies/{studyId}/{mode}/subjectNumberChange

Data Action

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/lockedstatus
	POST	/v1.0/studies/{studyId}/{mode}/cleardatacheck/{scope}
	GET	/v1.0/studies/{studyId}/{mode}/subjects-with-locked-data
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/forms/{formId}/items/{itemId}/locks
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks/all
	GET	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/locks/visits

Change	Method	Endpoint
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/events/{eventId}/unlocks
	POST	/v1.0/studies/{studyId}/{mode}/subjects/{subjectId}/multipleitems/locks
	PUT	/v1.0/studies/{studyId}/{mode}/unsign-unverify

Data Hub

Change	Method	Endpoint
New	POST	/v3.0/tenant/{tenantId}/studies/{studyId}/{mode}/unblindedKits
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/blindedVisits
	POST	/v4.0/tenant/{tenantId}/studies/{studyId}/{mode}/subjects/unblindedVisits

Data Integration

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/lockedstatus

Data Capture

Change	Method	Endpoint
New	PUT	/v1.0/studies/{studyId}/{mode}/dataelements/clear/{scope}
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/visitdata
	PUT	/v1/studies/{studyId}/{mode}/subjects/subjectnumber

Change	Method	Endpoint
	GET	/v10.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v10.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v10.0/studies/{studyId}/{mode}/visitstatus
	POST	/v10.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v10.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/{dataelementId}
	GET	/v2.0/studies/{studyId}/{mode}/subjects/dateRange
	GET	/v2.0/studies/{studyId}/{mode}/subjects/history/all
	POST	/v2.0/studies/{studyId}/{mode}/subjects/visitschedule
	GET	/v3.0/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	POST	/v3.0/studies/{studyId}/{mode}/subjects/randomizeordispense
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v6.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
	GET	/v7.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}

Change	Method	Endpoint
	PUT	/v8.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/subjectnumber
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/subjectnumber
Deprecated	POST	/v1.0/studies/{studyId}/{mode}/dataelements/freeze
	POST	/v1.0/studies/{studyId}/{mode}/dataelements/verify
	POST	/v1.0/studies/{studyId}/{mode}/studyVersion/{studyVersion}/signSubject/ subject/{subjectId}/code/{code}/orgId/{orgId}
	POST	/v1/studies/{studyId}/{mode}/dataelements
	GET	/v1/studies/{studyId}/{mode}/dataelements
	PUT	/v1/studies/{studyId}/{mode}/dataelements
	GET	/v1/studies/{studyId}/{mode}/dataelements/all
	GET	/v1/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	POST	/v1/studies/{studyId}/{mode}/dataelements/multiple
	POST	/v1/studies/{studyId}/{mode}/dataelements/multirepeatingform
	GET	/v1/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}

Change	Method	Endpoint
	GET	/v1/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v1/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v1/studies/{studyId}/{mode}/forms/{formId}/dataelements
	GET	/v1/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v1/studies/{studyId}/{mode}/sites/{siteId}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/formassociations
	GET	/v1/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	DELETE	/v1/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/forms/{formId}/dataelements
	POST	/v1/studies/{studyId}/{mode}/subjects
	GET	/v1/studies/{studyId}/{mode}/subjects
	GET	/v1/studies/{studyId}/{mode}/subjects/dateRange/{subjectId}
	POST	/v1/studies/{studyId}/{mode}/subjects/randomizeordispense
	GET	/v1/studies/{studyId}/{mode}/subjects/sitestudyversion
	DELETE	/v1/studies/{studyId}/{mode}/subjects/state/{subjectId}

Change	Method	Endpoint
	GET	/v1/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak
	PUT	/v1/studies/{studyId}/{mode}/subjects/{subjectId}/codeview
	POST	/v1/studies/{studyId}/{mode}/subjectsettings
	GET	/v1/studies/{studyId}/{mode}/subjectsettings
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	GET	/v1/studies/{studyId}/{mode}/subjecttransfers/{transferId}
	POST	/v1/studies/{studyId}/{mode}/visitstatus
	GET	/v1/studies/{studyId}/{mode}/visitstatus
	GET	/v1/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v1/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v1/studies/{studyId}/{mode}/visitstatus/{visitStatusId}

Change	Method	Endpoint
	POST	/v2.0/studies/{studyId}/{mode}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	POST	/v2.0/studies/{studyId}/{mode}/dataelements/multiple
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/subjectId/{subjectId}
	GET	/v2.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v2.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v2.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v2.0/studies/{studyId}/{mode}/subject/{subjectId}/event/{eventId}/dataelements/formassociations
	GET	/v2.0/studies/{studyId}/{mode}/subject/{subjectId}/visit/{visitId}/deleted/dataelements
	POST	/v2.0/studies/{studyId}/{mode}/subjects
	GET	/v2.0/studies/{studyId}/{mode}/subjects
	GET	/v2.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
	POST	/v2.0/studies/{studyId}/{mode}/subjects/randomizeordispense

Change	Method	Endpoint
	GET	/v2.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}
	PUT	/v2.0/studies/{studyId}/{mode}/subjects/{subjectId}/codebreak
	GET	/v2.0/studies/{studyId}/{mode}/subjecttransfers/subjects/{subjectId}
	POST	/v2.0/studies/{studyId}/{mode}/visitstatus
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus/dateRange
	GET	/v2.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v2.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v2.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v3.0/studies/{studyId}/{mode}/dataelements
	GET	/v3.0/studies/{studyId}/{mode}/dataelements
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}

Change	Method	Endpoint
	GET	/v3.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v3.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v3.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v3.0/studies/{studyId}/{mode}/subjects/history/{subjectId}
	GET	/v3.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}
	POST	/v3.0/studies/{studyId}/{mode}/visitstatus
	GET	/v3.0/studies/{studyId}/{mode}/visitstatus
	GET	/v3.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v3.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v3.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v4.0/studies/{studyId}/{mode}/dataelements
	GET	/v4.0/studies/{studyId}/{mode}/dataelements
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}

Change	Method	Endpoint
	GET	/v4.0/studies/{studyId}/{mode}/dataelements/subjects/{subjectId}/items
	PUT	/v4.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v4.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements
	GET	/v4.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	POST	/v4.0/studies/{studyId}/{mode}/visitstatus
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus
	GET	/v4.0/studies/{studyId}/{mode}/visitstatus/history/{visitsStatusId}
	POST	/v4.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v4.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v5.0/studies/{studyId}/{mode}/dataelements
	GET	/v5.0/studies/{studyId}/{mode}/dataelements
	GET	/v5.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v5.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v5.0/studies/{studyId}/{mode}/forms/{formId}/subjects/{subjectId}/dataelements

Change	Method	Endpoint
	GET	/v5.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v5.0/studies/{studyId}/{mode}/visitstatus
	POST	/v5.0/studies/{studyId}/{mode}/visitstatus/subjects
	PUT	/v5.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	POST	/v6.0/studies/{studyId}/{mode}/dataelements
	GET	/v6.0/studies/{studyId}/{mode}/dataelements
	GET	/v6.0/studies/{studyId}/{mode}/dataelements/history/{dataElementId}
	PUT	/v6.0/studies/{studyId}/{mode}/dataelements/{dataElementId}
	GET	/v6.0/studies/{studyId}/{mode}/eventsCount
	GET	/v6.0/studies/{studyId}/{mode}/repeatInstanceNumbers
	GET	/v6.0/studies/{studyId}/{mode}/subjects/sitestudyversion
	GET	/v6.0/studies/{studyId}/{mode}/visitstatus
	PUT	/v6.0/studies/{studyId}/{mode}/visitstatus/{visitStatusId}
	GET	/v7.0/studies/{studyId}/{mode}/dataelements

Change	Method	Endpoint
	GET	/v7.0/studies/{studyId}/{mode}/visitstatus
	POST	/v8.0/studies/{studyId}/{mode}/dataelements

Designer

Change	Method	Endpoint
New	POST	/v1.0/studies/welcome
	GET	/v1.0/studies/welcome
	PUT	/v1.0/studies/welcome
	DELETE	/v1.0/studies/welcome
	GET	/v4.0/studies/{studyId}/statuses
	GET	/v4.0/studies/{studyId}/statuses/{version}
	POST	/v1.0/studies/{studyId}/lockObjectDetails

Notifications

Change	Method	Endpoint
New	POST	/v1.0/i18support/email/{templatetype}

Randomization and Supplies

Change	Method	Endpoint
New	GET	/v1.0/studies/{studyId}/{mode}/events/resume_dosehold_dispensation/{eventId}
	GET	/v1.0/studies/{studyId}/{mode}/events/resume_partial_dispensation/{eventId}
	GET	/v1.0/studies/{studyId}/{mode}/kits/{inventoryId}/historyById
	GET	/v1.0/studies/{studyId}/{mode}/kits/{inventoryId}/lastStatusById
	POST	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings
	GET	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings
	GET	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	PUT	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	DELETE	/v1.0/studies/{studyId}/{mode}/partial-dispensation-settings/{id}
	POST	/v1.0/studies/{studyId}/{mode}/reports/partialdispensations
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/historyById
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{inventoryId}/lastStatusById
	POST	/v1.0/studies/{studyId}/{mode}/subject-partial-dispensations

Change	Method	Endpoint
	POST	/v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	GET	/v14.0/studies/{studyId}/{mode}/visits/subjectvisit
	POST	/v15.0/studies/{studyId}/{mode}/visits/subjectvisit
	PUT	/v2.0/studies/{studyId}/{mode}/barcode
	GET	/v2.0/studies/{studyId}/{mode}/events/codebreak/{eventId}
	GET	/v2.0/studies/{studyId}/{mode}/kits/{kitNumberUTF}/lastStatus
	GET	/v2.0/studies/{studyId}/{mode}/shipments/{shipmentId}/eligible-kits
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumberUTF}/lastStatus
	POST	/v2.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits
	GET	/v3.0/studies/{studyId}/{mode}/inventory/kit-types/{kitTypeId}/kits
	GET	/v3.0/studies/{studyId}/{mode}/kits/{kitNumberUTF}/history
	GET	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumberUTF}/history
	GET	/v3.0/studies/{studyId}/{mode}/sites/{siteId}/shipments/{shipmentId}/kits
	POST	/v3.0/studies/{studyId}/{mode}/subjects/{srcSubjectId}/replacekits

Change	Method	Endpoint
	GET	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/doseheld
	POST	/v3.0/studies/{studyId}/{mode}/subjects/{subjectId}/reuse-kits
	GET	/v4.0/studies/{studyId}/{mode}/inventory/kit-types
	GET	/v5.0/studies/{studyId}/{mode}/inventory/kit-types
	GET	/v7.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits
	GET	/v8.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
	PUT	/v8.0/studies/{studyId}/{mode}/supply/settings
	GET	/v9.0/studies/{studyId}/{mode}/subjects/{externalSubjectId}/dispensation-history
Deprecat ed	GET	/v1.0/studies/{studyId}/{mode}/kits/{kitNumber}/history
	GET	/v1.0/studies/{studyId}/{mode}/kits/{kitNumber}/lastStatus
	GET	/v1.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumber}/lastStatus
	GET	/v2.0/studies/{studyId}/{mode}/kits/{kitNumber}/history
	GET	/v2.0/studies/{studyId}/{mode}/sites/{siteId}/inventory/kits/{kitNumber}/history

Reporting

Change	Method	Endpoint
New	POST	/v1.0/notification/{notificationType}

Sites and Depots

Change	Method	Endpoint
New	DELETE	/v1/studies/{studyId}/{mode}/sdfs/deleteDepotEmail
	GET	/v2/studies/{studyId}/{mode}/country/{countryId}/states
	GET	/v2/studies/{studyId}/{mode}/sdfs/countries
	GET	/v3/studies/{studyId}/{mode}/regions
	GET	/v3/studies/{studyId}/{mode}/regions/{regionId}
	GET	/v3/studies/{studyId}/{mode}/regions/{regionId}/countries
	GET	/v3/studies/{studyId}/{mode}/sdfcountry
	GET	/v4/studies/{studyId}/{mode}/country

Users, Permissions and Roles

Change	Method	Endpoint
New	POST	/v1.0/report/globalstudyrole/{reportName}
	POST	/v2.0/{studyId}/{mode}/report/uploadererror/{reportName}

7

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 22.2

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.2 release. None of these fixes affect the user work flow or the application's functionality.

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

Table 7-1 Patch log

Release Number	Release Date	Notes
Release 22.2.3	20-October-2022	For this release, Oracle Clinical One Platform renewed its Statistical Analysis System license. The ongoing SAS technology facilitates compliant study data analysis for data managers and statisticians. The SAS yearly update doesn't impact users working with Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
Release 22.2.2	10-October-2022	For this release, we fixed several issues related to subject visits, integrations, and Oracle Clinical One Analytics. For more information, see: <ul style="list-style-type: none">• Other enhancements to review details for enhancement 31374245 related to the integration with Fisher Clinical Services.• Site users and subject data to review details for fixed issue 34625379. For this release, we also improved the performance of Oracle Clinical One Analytics by dedicating a server group, creating a more stable environment.

Table 7-1 (Cont.) 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">• Reports, archives, extracts, and notifications to review details for fixed issues 34307434 and 34399461.• Forms, visits, and rules to review details for fixed issues 34287424 and 34314729.• Integrations to review details for fixed issue 34376688. <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

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.

The screenshot displays the Clinical One interface for Study ORS-456. The main area shows a table of subjects with columns for Subject, Adverse Event, Next Visits, and Previous Visits. The Subjects table includes rows for CA2-0011, CA2-0010, CA2-0009, CA2-0008, and CA2-0007. The Queries sidebar on the right shows a list of queries, with a context menu open over one of them, displaying options: View, Re-Open, and Close.

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*.

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 a Show Form rule is applied

Site users: Now, the form saves the data and the visit is complete when a dynamically displayed form is present in that visit. Previously, the subject visit showed incomplete or unsaved data, even when the subject already completed the screening or did not select the question that dynamically displayed a form.



Note:

This issue occurred when the Show Form rule was modified and applied to a new study version, as an advanced study versioning change.

(Issue **34314729**)

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

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

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

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

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

Inconsistent rule behavior for automated queries

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

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**)

API endpoints can now be used for adding subjects in a study**For integration managers who use Oracle Clinical One Digital Gateway**

Now, the API endpoint typically used to add subjects can be used to add subjects through an integration with Oracle Clinical One Digital Gateway, as expected. This task can be performed even when the corresponding setting is set to **No** in a study. Previously, when a study manager had configured the study to prevent site users from manually adding subjects (setting the value for **Allow Subjects to be Manually Added to No**), that study setting would also apply to the API endpoint. This prevented both site users from adding subjects in a study, as well as adding them through an integration. (Issue **34376688**)

For API users who only operate in Oracle Clinical One Platform

Now, if you need to add subjects through the APIs, while the **Allow Subjects to be Manually Added** setting is set to **No**, you can do so by using the *Add transferred subject* API endpoint.

This API endpoint does not validate the command of adding subjects against the **Allow Subjects to be Manually Added** setting, as well as other subject-related settings in Oracle Clinical One Platform. To ensure that no duplicate subject numbers are created in a study, the API endpoint does validate the newly added subject against existing subject numbers.

For specific details related to the API endpoint, see [Add a transferred subject](#).

Oracle Clinical One Analytics

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

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

Retracted workaround: You no longer need to reach out specifically to your Oracle 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 Archival PDF is not generated properly when a site user is deleted

Sponsor users: In the Archival PDF, the Subject Archives PDF is now generated appropriately even though the site user who entered data for a subject is deleted from a study. Previously, when the site user who collected data for a subject was deleted from a study, the Subject Archives PDF did not generate as expected. (Issue **34412995**)

The Subject Events report takes longer to generate than expected

Site and sponsor users: Now, when you run the Subject Events report you will no longer notice that it takes longer than expected to generate the report (in any mode or format). Previously, running the Subject Events report either took longer than usual or you could not generate the report at all. This was a database issue that has now been fixed by implementing a clearing mechanism to ensure that the performance of reports is optimal going forward. (Issue **34399461**)

The Archival PDF takes a long time to generate

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

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

Kit Dispensation report displays data from all sites

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

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

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

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

Sponsor and site users: Now, when you generate the Subject Events report, you will notice that data related to event instance numbers is properly displayed, even if you run this report at the same time with other reports in the system. Previously, you may have noticed certain data 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 endpoint could not be used for adding subjects through an integration

Integration managers: Now, the API endpoint typically used to add subjects can be used to add subjects through an integration with Oracle Clinical One Digital Gateway, as expected. This task can be performed even when the corresponding setting is set to **No** in a study. Previously, when a study manager had configured the study to prevent site users from manually adding subjects (setting the value for **Prevent Site Users from Manually Adding Subjects** to **No**), that study setting would also apply to the API endpoint. This prevented both site users from adding subjects in a study, as well as adding them through an integration. (Issue **34376688**)

 **Note:**

This fixed issue only impacts integrations created through Oracle Clinical One Digital Gateway.

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**)

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Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 22.1

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)

Patch log

This topic briefly describes the history of small fixes we have applied to the 22.1 release. None of these fixes affect the user work flow or the application's functionality.

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

Release number	Release date	Notes
Release 22.1.0.7	10-June-2022	For this release, we fixed an issue related to tenant on boarding in the identity management system.
Release 22.1.0.6	16-May-2022	For this release, we fixed several issues related to rules, integrations, and randomization and trial supplies. For more information, see: <ul style="list-style-type: none">• Fixed issues for forms, visits, and rules to review details for bug 34151802 .• Fixed issues for integrations to review details for bug 34142164.• Fixed issues for randomization and kits to review details for bug 33899730 .

Release number	Release date	Notes
Release 22.1.0.5	09-May-2022	<p>For this release, we fixed several issues related to data collection, integrations, reports, analytics, and notifications.</p> <p>For more information, see:</p> <ul style="list-style-type: none">• Fixed issues for forms, visits, and rules to review details for bugs 34098859 and 34052489.• Fixed issues for integrations to review details for bug 34064421.• Fixed issues for reports, archives, extracts, and notifications to review details for bugs, 34087670, 33920237, 34062042, 34058969, and 33985315.• Fixed issues for Oracle Clinical One Analytics to review details for bug 34084687.• Fixed issues for all users to review details for bugs 34120146 and 34086950.
Release 22.1.0.4	28-Apr-2022	<p>For this release, we disabled the cache size limit in the application to improve the product's performance. No functionality has been changed and no testing is required.</p>
Release 22.1.0.3	26-Apr-2022	<p>For this release, we fixed an issue related to extracts and reports. For more information, see Fixed issues for reports, archives, extracts, and notifications to review details for bug 34109490.</p>
Release 22.1.0.2	22-Apr-2022	<p>For this release, we fixed an issue related to extracts and reports. For more information, see Fixed issues for reports, archives, extracts, and notifications to review details for bug 34087227.</p>
Release 22.1.0.1	16-Apr-2022	<p>For this release, we fixed several issues related to data collection. For more information, see Fixed issues for forms, visits, and rules to review details for bugs 34036119 and 34056494.</p>

What's new

- [Integrations](#)
- [Notifications](#)
- [Randomization and trial supply management](#)
- [Reporting and analytics](#)

- [Rules management](#)
- [User experience](#)
- [User management](#)
- [Other enhancements](#)

Integrations

- [Integrate screening and randomization data](#)
Oracle Clinical One Digital Gateway now supports a web service based, two-way integration between iMednet EDC and Oracle Clinical One Platform RTSM.
- [Oracle Clinical One Integration Hub is now Oracle Clinical One Digital Gateway](#)
Oracle Clinical One Integration Hub has been rebranded. The new name, Oracle Clinical One Digital Gateway, now appears throughout the product. The functionality is unchanged.
- [Load lab data into Oracle Clinical One Platform forms](#)
Oracle Clinical One Digital Gateway now supports the automatic loading of data in the CDISC lab model format into Oracle Clinical One Platform forms using American Standard Code for Information Interchange (ASCII) files.
- [Load data into hidden fields in Oracle Clinical One Platform](#)
Oracle Clinical One Digital Gateway now supports the automatic loading of data into Oracle Clinical One Platform in hidden fields using American Standard Code for Information Interchange (ASCII) files.
- [Enhanced template for the Oracle InForm to Oracle Argus Safety integration](#)
The integration between Oracle InForm and Oracle Argus Safety now has an updated configuration template.

Integrate screening and randomization data

Oracle Clinical One Digital Gateway now supports a web service based, two-way integration between iMednet EDC and Oracle Clinical One Platform RTSM.

How is data integrated between the systems?

Subjects are first screened in iMednet EDC. A schedule, configured in Oracle Clinical One Platform, calls Mednet APIs to retrieve a list of screened subjects who are marked as Ready for Randomization. Screening data is then sent to Oracle Clinical One Platform to automatically screen subjects.

Subjects can then be randomized in Oracle Clinical One Platform, resulting in randomization data being sent back to the iMednet EDC system.

How can I get more information about this integration?

Additional details about this integration can be found at [Access Your Data](#), under *Use a pre-built data integration*.

Notifications

- [New rule for follow-up notifications on data changes](#)
Study designers can now configure rules in form design to send email notifications. These notifications can be sent upon specific response entries and for data changes in choice type questions, with the option to set follow-up notifications.

New rule for follow-up notifications on data changes

Study designers can now configure rules in form design to send email notifications. These notifications can be sent upon specific response entries and for data changes in choice type questions, with the option to set follow-up notifications.

What are the benefits?

Email notifications are frequently sent to specific sponsor users based on custom JavaScript rules. With this new feature, study designers can additionally set rules to send notifications while designing a form. These rules can generate email notifications based on choice type questions for a specific answer or for changes to a specific question. To follow an initial notification sent based on a specific answer, you can configure follow-up notifications for data changes in multiple selected questions.

Even though these new rules settings are limited, as opposed to custom JavaScript rules, this process makes it easier for study designers to configure important notifications related to choice type questions and makes it possible to monitor data changes and send follow-up notifications upon an initial email. For example, this feature can help in monitoring Adverse Events after they have been identified as serious. After specific data points are updated, the follow-up notifications are sent for any changes in the questions specified by the study designer.

Details for study designers

Here is what is new for you if you want to start including this type of rule in your form:

- When creating or editing a form, upon selecting a question, you now see a new type of rule that you can configure for that question. This new rule is called **Send Notification**.
- There are two conditions available to generate a notification. If you select **Is**, then you must specify the answer of the selected question that generates the notification. If you select **Changes**, an email notification will be sent every time the answer to that specific question is updated.
- If you choose to send an initial notification for a specific answer (using **Is** option), you can activate **Notify when response changes to the selected questions** and then select the questions that, when modified, will send follow-up notifications after the initial email.
- A link to **Specify recipients and messages** will open a dialog window where you can set user roles and email addresses or distribution lists as recipients, as well as the subject line and body message of the notification and follow-up notifications, when applicable.

Details for rule developers

While you can still use custom rules to send notifications to other study team members, you may want to consider working with your study design team to implement these notifications using the built-in functionality when possible. This reduces your need for custom code. However, keep in mind that rules in form design to send notifications can only be based on choice type questions and set for specific answers and data changes. Contrastingly, while in the Rule Editor you can reference any type of question to send notifications in different scenarios, notifications and follow-up notifications on data changes are not feasible.

In addition, the email notification template has been updated to unify notifications, whether they are configured based on custom JavaScript rules or based on rules in Study Design. Work with your study design team to avoid sending duplicate notifications and make the most out of this feature.

Working with reports?

Data on notification rules in Study Design mode are included in the Rules report.

Already working in a live study?

As soon as this release is available, study designers can begin configuring rules in Study Design mode to send email notifications and follow-up notifications on data changes.

To make your new rules and updates effective, the Draft version must be moved to the appropriate mode container: Testing, or Approved. For step-by-step instructions on how to manage study versions, see [Make a study version available in Testing mode](#) and [Make a study version available \(for Production and Training mode\)](#).

Randomization and trial supply management

- [Allow depots to supply other depots](#)
Clinical supply managers can now create depots that will supply other depots with kits throughout the study conduct period.
- [Improved shipment receipt process](#)
You can gather detailed information on the state of a received shipment with an improved receipt process.

Allow depots to supply other depots

Clinical supply managers can now create depots that will supply other depots with kits throughout the study conduct period.

Details for user administrators and global user managers

Your workflow hasn't changed, but there are some new permissions that you need to be aware of. We recommend you add these new permissions to study roles created (or existing) at a study level. Assigning new permissions to an organization study role is allowed, but the updates are not reflected in study roles at a study level.

Permission	Study role (predefined by Oracle)
Create Shipments to Depots	<ul style="list-style-type: none"> • Clinical Supply Manager • Production Admin • Unblinded Depot User

Permission	Study role (predefined by Oracle)
Assign a Resupply Strategy to a Depot	<ul style="list-style-type: none"> Clinical Supply Manager Production Admin
Receive New Shipments at the Depot	<ul style="list-style-type: none"> Clinical Supply Manager Production Admin Unblinded Depot User
Release Shipments from Quarantine	<ul style="list-style-type: none"> Clinical Supply Manager Production Admin
Receive Notification of Depot Shipments	<ul style="list-style-type: none"> Clinical Supply Manager Production Admin Unblinded Depot User

Details for clinical supply managers

Here's what's changed in your workflow when it comes to creating a depot:

- In the Create Depot dialog, when you specify the kit types that a depot can include in a shipment, you can also specify the supplying depot. In the new Supplying Depot column, you can select the depot that will be supplying the depot you are creating.
- On the Depots tab, depots now have different corresponding columns including Depot Location, Contact, Supply Countries, and Resupply Strategy. In the Resupply Strategy column, you can choose to specify a resupply strategy for the supplying depot.
- Use the new **Create Resupply Group** button to access the Create Min/Max Resupply Group dialog. In this new dialog, you can configure a new resupply group for the supplying depot by specifying whether the resupply strategy is for a site or a depot, and specifying the minimum and maximum buffer for each kit type. Resupply strategies that you create using this dialog are displayed in the Min/Max Resupply side panel on the Supply Settings tab.
- In the Create Shipment dialog, you can specify the exact destination of a shipment, to a site or to a depot.
- Whenever changes occur in the supply chain between two depots, you may receive several notifications, depending on the permissions that you have in the system. There is also a new notification called Depot Shipment, that you receive whenever a depot shipment is created.

Details for depot users

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

- On the Shipments tab, when you create a depot shipment, you can specify the destination depot and the source depot.
- The receiving depot must confirm that they have received supplying shipments from another depot.
- As with shipments for sites, a depot user can indicate if kits are missing or damaged in the depot order form. You can also indicate if a temperature excursion occurred and if the kits associated with the order should be quarantined.
- You can mark kits as Pending Destruction in the inventory and then add them to a depot shipment for destruction.

- On the Shipments tab, when you click **Create Shipment**, a second option is displayed called Shipment for Destruction. That shipment automatically includes all kits marked as Pending Destruction.
- Every shipment now indicates its source and destination.

Already working in a live study?

As soon as the upgrade for this release is complete, you can create depot-to-depot shipments in your live study. Existing depots are not impacted by this new feature.

Improved shipment receipt process

You can gather detailed information on the state of a received shipment with an improved receipt process.

The updated prompts during intake allow you to collect in depth information on received shipments, facilitating a more detailed shipment receipt process. Before you can capture further details on the state of a shipment, you must record information about the temperature monitors within the shipment. Step-by-step instructions on how to identify temperature excursions in your kits will be featured in the *Sponsor and CRO User Guide* guide.

Details for sponsor users

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

- Users with the *Release Shipments from Quarantine* permission can move shipments or individual kits out of quarantine and update their status to either Damaged or Available.
- When you select Yes for the Allow for Temperature Excursions setting, the system displays a new setting called **Shipments Received without a Temperature Monitor Should Be**. For this setting, you must specify the process to follow when receiving a shipment without a temperature monitor at a site.

Details for site users

Here's what's changed in your workflow:

- After receiving a shipment, when you click **Add Shipment to Inventory** a new Add Shipment to Inventory dialog appears to guide you through the normal process of setting kit statuses to Quarantined, Missing, Damaged, and Available.
- You may be required to enter information about the temperature monitors in your shipment in the Add Shipment to Inventory before proceeding with your receipt confirmation. Depending on what is configured in the supply settings, you can continue the normal receipt process or update the whole shipment and kits' statuses to Quarantined.

Already working in a live study?

As soon as the upgrade for this release is complete, you can record detailed information about the state of your shipments when they are received. These enhancements apply to all studies with the default value for **Allow Temperature Excursion** set to No, therefore, it will not affect current data in ongoing trials.

For more information on inventory management, see Inventory management and dispensation FAQs (for clinical supply managers). Step-by-step instructions on how to configure and release from temperature excursions, and quarantine single kits and shipments will be featured in the *Sponsor and CRO User Guide* guide.

Reporting and analytics

- [New data fields added to Oracle Clinical One Analytics datasets](#)
Data fields are being added to Oracle Clinical One Analytics datasets to support different features available in Oracle Clinical One Platform.
- [New Study Design Delta report in Oracle Clinical One Analytics](#)
Study designers can now identify study configuration differences between study versions.
- [New Kit Chain of Custody \(Blinded\) report](#)
Site users and blinded study team members can now view kit transitions from *In Transit* through their return to depots by running the Kit Chain of Custody (Blinded) report.
- [Reports can now be scheduled](#)
Some reports can now be scheduled to run automatically based on a schedule that you define in the Oracle Clinical One Platform user interface.

New data fields added to Oracle Clinical One Analytics datasets

Data fields are being added to Oracle Clinical One Analytics datasets to support different features available in Oracle Clinical One Platform.

Support for two-section form data

In order to easily identify *repeating forms*, *lab forms*, and *two-section forms* data, new fields have been added to the following datasets in Oracle Clinical One Analytics:

- Subject Forms Dataset
- Subject Form Items Dataset
- Queries Dataset
- Data Collection Design Dataset
- Kits and Randomization Design Dataset

These new fields let you see all data collected through repeating sections and repeating forms. Also, this new organized structure facilitates identifying when repeating data is present and differentiating non-repeating section data from repeating section data.

Support for form associations

New fields have been added to the Subject Forms Dataset in Oracle Clinical One Analytics to support form associations. This lets data managers identify related information that is collected in two or more forms. This is particularly relevant, but not limited to, Adverse Events (AE) and Concomitant Medications (CM) forms.

For more information on form associations, see [Create and manage links between forms](#). Details on these new fields are available in the Subject Forms Dataset description.

Already working in a live study?

As soon as this release is available, data managers can use these new data fields in Oracle Clinical One Analytics for custom reports on any new or existing studies, and in

any mode. For more information review the Dataset descriptions in the *Analytics User Guide*.

New Study Design Delta report in Oracle Clinical One Analytics

Study designers can now identify study configuration differences between study versions.

The Study Design Delta report allows you to identify study configuration differences between study versions, creating an easier review process and reducing the amount of validation required when implementing changes to your study. The Study Design Delta report includes the following sections:

- Study Design Differences
- Branch Details
- Event Details
- Form Details
- Item Details

This report can be found in the Report Templates folder in Oracle Clinical One Analytics. Any user assigned the *Run the Data Collection Design Dataset* is able to view, but not save over this report.

Already working in a live study?

Once the upgrade for this release is done, you will be able to run the Study Design Delta report in Oracle Clinical One Analytics for any live study. More information about this report will be featured in the *Sponsor and CRO User Guide* guide.

New Kit Chain of Custody (Blinded) report

Site users and blinded study team members can now view kit transitions from *In Transit* through their return to depots by running the Kit Chain of Custody (Blinded) report.

You are now provided with the Kit Chain of Custody (Blinded) report, which allows you to follow every kit transition throughout the study. When run at the site level, the report reveals details on every change to a kit, both virtual and physical. It also includes information on the user who created the change, when the change occurred, and any comments that may have been provided.

Note:

You are only able to run the report for kits that are assigned to the site you have access to. Site users cannot see kits in the report that are in transit from the depot to the site until the kits are received at the site. Kits appear on the report even after they've been returned to the depot as part of the reconciliation process.

Users assigned the *Run the Blinded Chain of Custody Report* permission can generate this report. Once you've successfully run this report, you receive an email that lets you know that the Kit Chain of Custody (Blinded) report is available to view and download in Oracle Clinical One Platform. For more information on this notification, see Report is ready notification.

Already working in a live study?

Once the upgrade for this release is complete and you have been assigned the required permission, you can run the Kit Chain of Custody (Blinded) report for a live study. More information about this report will be featured in the *Sponsor and CRO User Guide* guide.

Reports can now be scheduled

Some reports can now be scheduled to run automatically based on a schedule that you define in the Oracle Clinical One Platform user interface.

On the Reports tab, several reports now feature a new side panel, called **Schedule Reports**, where authorized users can define a schedule to generate reports automatically.

Additional reports will be available for scheduling in future releases. For this release, the following reports can be scheduled:

- Subject Data Extract
- Subject Data
- Kit Chain of Custody (Blinded)
- Kit Chain of Custody (Unblinded)
- Subject Events
- Subject Visits (Blinded)
- Subject Visits (Unblinded)

Before you work with this feature

The permission **Schedule Reports to Run** are included in the following template study roles: Clinical Supply Manager, CRA, Data Manager, ODM Extract, Production Admin, Study Manager, Unblinded Depot User, User Administrator, and View Only for Unblinded Support User.

As a user administrator or global user manager, you will need to add the permission manually to custom roles to take advantage of this feature.

New settings for scheduling reports

The following settings can be configured when scheduling reports:

- Start date
- Time Zone
- Frequency
- Notifications
- File Type

You can still configure existing report settings (such as File Name, Study Version, User Name, Event Type, and more) for every selected report.

Information on the report output

Once generated, all reports will be available for download in the **Download Reports** side panel in Oracle Clinical One Platform. If needed, reports can also be delivered to a pre-determined sFTP folder. In order to use this option, additional setup steps are required.



Note:

Scheduled reports set to be delivered to sFTP cannot exceed seven (7) scheduled reports per day, per study.

Additional information on this enhancement will be featured in the *Sponsor and CRO User Guide* guide.

Rules management

- [Debug custom rules](#)
Rule designers can now use logs and debug custom JavaScript rules when editing to understand the logic behind rule behavior.

Debug custom rules

Rule designers can now use logs and debug custom JavaScript rules when editing to understand the logic behind rule behavior.

What are the benefits?

Now, in the Rules Editor, you can create and debug a rule at the same time, allowing you to understand a rule's behavior and to identify and correct failures before testing. The new debug functionality is used by calling the `logMsg()` helper function when running a rule in debug against existing subject's data. Adding log statements at different key points of the rule expression allows you to get relevant information on the rule's performance, by displaying values of defined variables and messages that reveal the logic behind rule behavior. Additionally, you get error descriptions whenever an exception occurs.

Details for rule designers

Here's what's new for you when creating or editing rules in Testing mode:

- While working in the Rule Editor, you can place log statements where needed in the JavaScript expression to reveal how data is being processed at specific points of the code when the rule is running.
- A new **Debug** button is introduced in the Rule Editor screen. When clicked, changes to the JavaScript expression are saved and executed against the current subject's existing data.
- When the debug process starts, a log window appears at the right of the Rule Editor dialog and outputs log information. In the event an exception occurs, the stack trace details and error messages are displayed along with the logs, providing additional information about the rule's failure or unexpected behavior.
- After reviewing log information, you can change the rule expression and repeat the process for further debugging until the rule works as expected.

All rule saving requirements must be fulfilled prior to clicking **Debug**, which saves the JavaScript expression. Any compilation error or missing requirement will not allow the debug process to complete.

To make the most out of this new feature, don't forget to review the `logMsg()` helper function documentation and usage tips.

Already working in a live study?

As soon as this release is available, rule designers can begin to debug any newly created or existing custom rule for all studies in Testing mode. The debug functionality is not available for live studies in Production mode due to security constraints.

More information about this functionality will be featured in *Information for CRO and Sponsor Users*. See *Create and manage custom rules*.

User experience

- [Get a filtered view of your subjects](#)
Site and sponsor users can now get a more granular view of subjects in a study, using the brand new subject filters.

Get a filtered view of your subjects

Site and sponsor users can now get a more granular view of subjects in a study, using the brand new subject filters.

On the Subjects tab, depending on your study role and site assignment, you may see any of the new subject filters introduced in this release. As a site or sponsor user, you can use these filters to get a more precise view of subjects in your study and get faster access to specific data.

You can use these filters individually or they can be combined. The filters you select are preserved until you sign out of the application, but they are not preserved if you switch to another study. Filters can also be cleared.

The new filters introduced in this release are:

- The **Countries** filter: This filter includes the countries that you have access to. By default, the filter is set to All countries.
- The **Sites** filter: This filter includes the sites that you have access to. By default, this filter is set to All sites.
- The **Subjects** filter: This filter includes all of the statuses a subject can have. By default, this filter is set to All subjects.
- The **Review Status** filter: This filter includes all of the review-related statuses that a visit can have. By default, this filter is set to All reviews.

Already working in a live study?

As soon as the release upgrade is complete, you can view and use the new subject filters, whether you are already part of a live study or about to start working in a brand new study.

User management

- [Create user accounts in Oracle Clinical One Platform](#)
Create Single Sign-On (SSO) user accounts, assign roles, sites, and depots directly in Oracle Clinical One Platform.

Create user accounts in Oracle Clinical One Platform

Create Single Sign-On (SSO) user accounts, assign roles, sites, and depots directly in Oracle Clinical One Platform.

In addition to the ability to assign an individual user to a role, sites, and depots, user administrators can now create and manage SSO user accounts in bulk directly in Oracle Clinical One Platform using the new **User Upload** template.

Details for user administrators

- The User Upload template can be downloaded from the **Users** tab.
- The User Upload template can be used to update the end date for existing users.
- Users are created at the global level in Oracle Clinical One Platform

 **Note:**

If an account already exists, the user will be assigned to the study, and the role, sites, and depots defined in the template.

- User accounts are automatically created in Oracle Life Sciences Identity and Access Management Service (IAMS).
- Users are loaded in Production mode by default. The setting, **Upload users to Training mode** can be enabled if you want to import users to both Production and Training mode.
- New users will receive the **New Study Assignment** notification.
- The **User Upload Error** report is available to easily identify and address user upload errors..

More information on this enhancement will be featured in About creating user accounts using the upload template in the *Add Users Guide* guide.

Already working in a live study?

Once the upgrade for this release is complete, users assigned the *Upload Users in Bulk* permission will be able to download the Upload Users template, upload users in bulk for existing studies, and access to the User Upload Error report.

Other enhancements

New permission for updating a depot order form

Clinical supply managers are assigned the new *Update the Shipment Order Form* permission, allowing them to restrict sites' ability to resend the depot order form. This permission is designed to eliminate errors when receiving shipments and fulfilling orders.

 **Note:**

The template study role will be automatically updated. User administrators must update any custom study roles required with this new permission.

More information will be featured in *Add Users Guide* in the following topics:

- Clinical supply manager
- Descriptions of permissions in Clinical One

New notifications on subjects

As a sponsor user, you can now be notified when a subject completes an unscheduled visit, when they are enrolled into a rollover study, and when they complete a study. To receive these notifications, you must be assigned new permissions.

Permission	Study roles
<i>Receive the Subject Completion Notification</i>	<ul style="list-style-type: none"> • CRA • Data Manager
<i>Receive the Subject Rollover Notification</i>	<ul style="list-style-type: none"> • Clinical Supply Manager • CRA • Data Manager
<i>Receive the Unscheduled Visit Notification</i>	<ul style="list-style-type: none"> • Clinical Supply Manager • CRA

New reports available in Japanese

When you set your language preference as Japanese, the following reports are now available in the Japanese language in all formats:

- Titration Summary report (CSV, HTML, PDF)
- Titration Summary (Unblinded) report (CSV, HTML, PDF)

Keep in mind, clinical data will never be translated and will be reported exactly as collected, regardless of the user's language preference.

New options in Oracle CRF Submit to enhance your work flow

Sponsor and site users can now monitor the progress of an archive request, as well as pause, resume, and cancel requests while they are generating. Also, failed requests can now be resubmitted.

Also, sponsor users can now generate a Custom PDF. The Custom PDF request type gives you access to all settings available in Oracle CRF Submit.

For more information, see Oracle CRF Submit archives and reports in the Oracle Clinical One Platform Reporting Guide.

New integration with SAP system for additional kit identifiers

Sponsor users can now include additional identifiers for kits in the Oracle Clinical One Platform database. These fields are accessible through the SAP system and are populated via an integration.

Although this information will not be available through the Oracle Clinical One Platform interface, kit identifiers will be available to data managers in Oracle Clinical One Analytics as part of an upcoming release.

Introducing the new Redwood design!

The Oracle Clinical One Platform user interface has been refreshed to align better with Redwood, Oracle's new user experience design language. Redwood represents an effort to develop a new Oracle UI to bring natural elements into our products, including Oracle Clinical One Platform. A darker global header with the new Redwood stripe is introduced, as well as sharper fonts and icons.

What is not changing: The Oracle Redwood theme is a UI change only and **does not** impact:

- System performance.
- The underlying database.
- Data within the application.
- Your ability to perform daily tasks and functions.
- Integrations or external systems.

User interface behavior when the data intake integration populates a future visit

When data is automatically loaded in forms through a data intake integration, the data may be populated in visits out of chronological order as defined in a study's visit schedule. If data is loaded in a future visit, the user interface logically displays any preceding visits available for data entry.

For example, data entry has been completed for visits **Week 1** and **Week 2** but has not yet been started for visits **Week 3** through **Week 7**. When the data intake integrations, defined for **Week 8** and **Week 9** are processed:

- **Week 3** through **Week 7**, the preceding, not-yet-started visits are displayed in order, as defined in the visit schedule, have a dotted outline and are labeled *(Not Started)*.
- **Week 8** is displayed as the last entry under Previous Visits.
- **Week 9** is displayed under Next Visits.

Subject	Adverse Events	Next Visits	Previous Visits
016-015 Active	0 Total	Week 9 (04-Apr - 11-Apr)	Week 8 Week 7 (Not Started) Week 6 (Not Started) Week 5 (Not Started) Week 4 (Not Started) Week 3 (Not Started) Week 2 Week 1

More information will be featured in the Icon Reference Guide, section What statuses can a visit have?.

Fixed issues

- [All users](#)
- [Forms, visits, and rules](#)
- [Integrations](#)

- [Oracle Clinical One Analytics](#)
- [Randomization and kits](#)
- [Reports, archives, extracts, and notifications](#)
- [Sites, labs, depots, settings, and user management](#)
- [Site users and subject data](#)

All users

Notification rule should not trigger on initial entry when it is set as 'Change'

All users: Now, the notification email is not sent upon initial data entry but is sent only after the initial value entered has been changed. Previously, the notification email was sent upon initial data entry as the rule triggered under the assumption that initial data entry constituted a change.

Retracted Workaround: None. (Issue [34120146](#))

Audit trail – answer history showing wrong user performing action

All users: Now, the correct user ID is logged in the audit trail regardless of the number of actions performed in a visit or on a form. Previously, in certain instances, the audit trail logged a different user ID than that of the user who performed the action.

Retracted Workaround: None. (Issue [34086950](#))

Sign in dialog displayed randomly (former known issue)

All users: Now, the Log In dialog no longer appears in the application either while you're working or you've stopped using the application for some time. If you've stopped working in the application, the expected timeout dialog is displayed. Previously, you may have noticed that a Log In dialog was displayed in your browser asking you to enter your username and password to sign in even though you were working in the application.

Retracted workaround: None. (Issue [33803206](#))

Forms, visits, and rules

Rule re-run fails due to changes for notification rules

Rule designers: Now, rule re-run completes successfully when publishing a rule in Testing mode and re-running the rule in Active mode. In both cases, no errors are encountered in the UI and the Rule re-run complete emails are received. Previously, rule re-run and debugging would encounter failures when rule re-run and debugging were null.

Retracted workaround: None. (Issue [34151802](#))

Signing subject visit fails when data is captured for the same visit under different study versions

Sponsor and Site users: Now, you no longer encounter the error, *Due to an unexpected error, subject xxxxxx couldn't be signed*, when signing a subject visit where data entry occurs prior to and after a new study version is applied. Previously,

the error would be encountered in those cases where data entry was started at a visit and additional data was entered after a new study version was applied to a site.

Retracted workaround: None. (Issue **34098859**)

Dynamic section of a two-section form cannot be saved (former known issue)

Site users: Now, when you enter data using the dialog and not by inline editing of the repeating table of a two-section form, you can save all data. Previously, when you attempted to save data that was added in the dynamic section of a two-section form, you could not save the data. This occurred when data was entered using the dialog and not by inline editing a repeating table of a two-section form.

Retracted workaround: You no longer have to fill out and save the questions before the table, then enter and save data for the second section (the questions in the repeating table). (Issue **34052489**)

Visit details are not returned as expected by the getValues JavaScript expression (former known issue)

Rule designers: Now, when you run a rule using the getValues JavaScript expression, you will see visit data returned according to the visit schedule. The issue was originally caused by the presence of dynamic visits in a visit schedule.

Retracted workaround: None. (Issue **33088502**)

You cannot assign a locked form to a visit

Study designers: Now, you can assign a locked form to a visit in a study. Previously, while a form was edited and locked by one study designer, another study designer could not assign that form to a visit in the study. (Issue **33773027**)

A copied study's title is truncated (former known issue)

Study designers: Now, when you copy a design from one study to another, and the study's name is too long, an ellipses is displayed to indicate that there is additional text that is not shown. Previously, after copying a study's design, the study's title was truncated on the Home page.

Retracted workaround: You can still hover over the study title and you'll see the complete study title. (Issue **33605369**)

Another study designer can delete a locked form (former known issue)

Study designers: Now, you can no longer delete a locked form, as expected. Previously, you could delete a locked form while another study designer was editing that form. After deleting the locked form, when the other study designer attempted to save their changes, an error message was displayed.

Retracted workaround: None. (Issue **33664784**)

Questions are not properly ordered in a lab form (former known issue)

Study designers: Now, in a lab form, when you re-order questions in the repeating form table, questions preserve the order you just created and are also numbered consecutively, as expected. Previously, when you attempted to re-order questions in a lab form repeating table, upon saving your changes, you may have noticed that those questions were not properly numbered in the table.

Retracted workaround: None. (Issue **33699473**)

A Show Form dynamic rule is still effective despite being removed (former known issue)

Study designers: Now, when you remove a Show Form rule from a question and you apply that change to a live study version, the form that was previously displayed dynamically is now displayed all of the time, as a static form. Previously, in Draft mode, when you removed a Show Form rule from a question for a live study version, you may have noticed that the dynamic form was still displayed dynamically, when it should have been displayed as a static form.

Retracted workaround: None. (Issue **33736682**)

Getvalues helper function does not work for flat forms (former known issue)

Rule designers: In a standard form (a form that is not repeating), whenever you run a Getvalues rule on an empty field, the rule returns the expected null value. Previously, running the Getvalues rule helper function only returned a null value when the field was specifically cleared.

Retracted workaround: None. (Issue **33067140**)

A question is removed from a question group when dynamic rules are added

Study designers: Now, when the determining question of a dynamic form is placed within a question group, the question preserves its place within the group when you move the study from Draft to Testing. Moreover, all questions in the respective question group are properly ordered. Previously, the determining question of a dynamic form, if placed in a question group, was removed from the group whenever you moved the study from Draft to Testing. (Issue **33821413**)

GetCurrentCycle helper function does not retrieve the proper result

Rule designers: Now, when you attempt to modify an operand for a GetCurrentCycle custom rule for cycle visits, the appropriate result is displayed. Previously, upon modifying the rule's operand, you may have noticed that the rule was retrieving data for another cycle than the one that you just indicated. (Issue **33825640**)

The Visit Status API is not working properly (former known issue)

API users: Now, when attempting to configure a Show Visit dynamic rule and running a POST API command, you may notice that the API is working as expected. This fix is also available for inserting visits into the schedule of a live study. Previously, when a site user answered the determining question in a way that did not display the dynamic visit, and you ran the API command, you may have noticed that the response indicated a successful command. Instead, the API should have returned an error response because the determining question was not answered in a way that would display the dynamic visit.

Retracted workaround: None. (Issue **33615686**)

Associated form does not properly display data (former known issue)

Site users: Now, when you associate two forms in study design, all details of the question generating the link between the two forms are displayed, as expected. Previously, in Testing mode, when answering the determining question that would link

a repeating form to another, you may have noticed that only the row number and visit label were displayed.

Retracted workaround: None. (Issue **33856160**)

Dynamic form does not work when assigned to cycle visit (former known issue)

Site users: Now, when you assign a dynamic form to a specific visit cycle, that dynamic form is working as expected and the status of the impacted visit is properly updated. Previously, in Testing mode, whenever a dynamic form was displayed as associated with a visit cycle, the status of the impacted visit was not updated properly in the selected cycle.

Retracted workaround: None. (Issue **33733658**)

API returns empty array instead of returning null when study design includes at least two items in a repeating form

API users: Now, when a study design includes a repeating form with two or more items, and data is only entered for the first item, null data-elements are being created for the second item as part of the API response. Previously, null data-elements were not being created as part of the API response when there was no data entered for the second item.

Retracted workaround: None. (Issue **34036119**)

API returns extra records when study design includes a repeating form and data is entered in a specific manner

API users: Now, when a study design includes a repeating form and data is entered in a specific manner, the correct records are returned in the API response. Previously, the API response would include extra records in the return. This was addressed by adding additional conditions to ensure there is no duplication.

Retracted workaround: None. (Issue **34056494**)

Integrations

Fisher Clinical Services integration is failing after upgrade of Apache Mina to version 2.7.0

Integration managers: To address this issue, the SHA1 algorithm has been added to the newer version of Apache Mina 2.7.0.

Retracted workaround: None. (Issue **34142164**)

Generic error message displayed when Oracle Central Coding Return Codes job fails

Oracle Central Coding administrators: Now, if the Oracle Central Coding Return Codes job fails when attempting to return medical coding data to a Oracle Clinical One Platform study, Oracle Central Coding displays an error message that is relevant to the error. Previously, Oracle Central Coding would display a generic error message making it difficult to troubleshoot the issue.

Retracted workaround: None. (Issue **34064421**)

Multiple answers to a question are not supported in an integration (former known issue)**Note:**

This fixed issue does not impact the Oracle InForm to Oracle Argus Safety integration.

Integration managers: Now, you can integrate multiple answer options for a drop-down or a question with checkboxes (options introduced through a code list) without running into any issues. Previously, you could not select several answer options to integrate for a multiple-choice question.

(Issue **33520631**)

Out-of-range data can still be loaded into Oracle Clinical One Platform forms (former known issue)

Integration managers: Now, when you attempt to load data that does not match the criteria specified in Oracle Clinical One Platform, an appropriate validation error is displayed in the application. Previously, you may have noticed that the integration could load data that was out of range. For example, when a text field's limit for the number of characters was 3, and you loaded a data point that contained more than 3 characters, the job was successfully completed. Moreover, the Oracle Clinical One Platform UI did not highlight the field. Instead, anything that exceeded the 3-character limit was truncated and not displayed in the text field.

Retracted workaround: None. (Issue **33367269**)

Oracle Clinical One Analytics

Improved dashboard response time when using the Subject Queries dataset

Now, when including Subject Queries Dataset elements, the Oracle Clinical One Analytics dashboard loads in a more acceptable time. Previously, users may have experienced a longer than acceptable load time.

Retracted workaround: None. (Issue **34084687**)

Unexpected values displayed for a data element (former known issue)

The value NOT_APPLICABLE and NEVER_VERIFIED are no longer displayed for the FREEZE, VERIFIED, or SIGNED data elements in the following datasets:

- The Queries dataset
- The Subject Forms dataset
- The Subject Form Items dataset
- The Blinded Subject Events dataset
- The Unblinded Subject Events dataset

Retracted workaround: None. (Issue **33815975**)

Cannot export reports in a CSV format (former known issue)

Now, when attempting to export a report as CSV, columns are displayed as expected. Specifically, values in the Comments column are no longer displayed in different columns within the CSV report. Previously, values in the Comments column were not integrating new line characters and, as a result, values from that column may have appeared in a different column instead.

Retracted workaround: None. (Issue: **32976885**)

The Suppress Repeating Values feature is now available

You can now turn the Suppress Repeating Values setting on and off for your datasets. When the setting is turned off, expected values are displayed for each row in the report and no table cells are merged. When the setting is turned on, certain cells of the table may be merged for data records that have the same value.

For example, if the value for the REPEAT_SEQUENCE_NUMBER is the same for all forms, then the cells in that column can be merged to display the same value for all forms in a study.

Workaround: None. (Issue **32797889**)

Randomization and kits

The minimization algorithm currently uses the probability factor as the final calculation for a treatment arm to be assigned (former known issue)

Clinical supply managers and statisticians: Previously, the minimization list used the probability factor to determine how subjects are assigned to each treatment arm in a study. Now, the minimization algorithm uses the probability factor to determine the final calculation to balance out the number of subjects on each treatment arm.

Retracted workaround: None. (Issue **33899730**)

Open label randomization type available for randomization with cohorts (former known issue)

Study designers: Now, on the Create Randomization dialog, when you select **Unblinded** for the randomization type, and **Adaptive or Demography** for the Cohorts field, the **None – Open Label** option is no longer available for selection, as expected. Previously, on the Randomization drop-down, you could see the **None – Open Label** available for selection even though, for a randomization with cohorts, this option should not have been available

Retracted workaround: None. (Issue **33082175**)

Randomization and kit lists must not contain randomization or kit numbers as decimals (former known issue)

Clinical supply managers and statisticians: Now, when you attempt to upload a kit or randomization list that contains randomization or kit numbers with decimals, the system displays an error message that describes this specific issue. Previously, if you ever uploaded a randomization or kit list with decimal numbers in it, the system did not warn you about the issue.

Retracted workaround: None. (Issue **32565975**)

Reports, archives, extracts, and notifications

Study Design report displaying incorrect treatment group description after edit

Study designers: Now, the correct description appears in the Study Design report after editing the description. Previously, both the original and the updated descriptions were appearing in the report. This issue was encountered due to a missing study version constraint in the reporting query that is used to join the treatment arms. This resulted in the query picking up both the old and new descriptions in the report.

Retracted workaround: None. (Issue **34087670**)

The Subject Visits (Unblinded) report does not predict drug needs properly (former known issue)

Site users: The Subject Visits (Unblinded) report now includes study drug prediction data for all applicable visits in the study. Previously, you may have noticed that there was no study drug prediction for certain visits in the study. Specifically, those visits that have the option for a site user to down titrate a subject to a lower dose. Based on the study's design, you must be able to view the study drug prediction in this report.

This issue was specifically occurring when the first dispensed kit in a study was a kit type titration.

Retracted workaround: None. (Issue **33920237**)

The Unblinded Kits Dataset returns duplicate records

Clinical Supply Managers: Now, the Unblinded Kits Dataset returns unique records only. Previously, records were being stored in two separate database tables and were considered unique. This resulted in duplicate records being inserted into the dataset.

Retracted workaround: None. (Issue **34062042**)

Report-related emails are not sent to valid email addresses (former known issue)

Sponsor and site users: Now, when you include a list of email addresses in the scheduled reports configuration, all users receive the notifications. Previously, no one included in the email notification configuration received the email. This was caused by additional spaces in the email list resulting in both valid and invalid email addresses included in the configuration not receiving the completion notification.

Retracted workaround: You no longer have to specifically look for extra spaces between email addresses in the scheduled report configuration, although we still recommend that you make sure the email addresses you specify are correct. (Issue **34058969**)

Blank PDFs do not match study design when forms are copied

Sponsor and site users: Now, when a Sponsor or site user generates an Archival PDF in Testing mode, for a study that includes copied forms, the blank PDFs included in the Archival package include the correct question labels. Previously, the blank PDF would display the label of the question copied from, and not the renamed, new question label.

Retracted workaround: None. (Issue **33985315**)

Subject Data Extract report fails using SAS format when a decimal contains leading zeros

Sponsor users: Now, when generating a Subject Data Extract report that includes form items containing a decimal with leading zeros, you no longer receive an error indicating a report failure. Previously, when you attempted to generate a report, the report failed if an item contained a decimal with leading zeros (0.5 for example). This failure was caused by a newer version of the org.json library that incorrectly removed leading zeros from a decimal value.

Retracted workaround: None. (Issue **34109490**)

Subject Data Extract report fails when using SAS format due to leading zeros

Sponsor users: Now, when generating a Subject Data Extract report that includes numeric form items containing data with leading zeros, you no longer receive an error indicating a report generation failure. Previously, when you attempted to generate a report, the report failed if a numeric form item included leading zeros (05, or 005, for example). This failure was caused by a newer version of the org.json library that did not correctly remove leading zeros from numeric form items.

Retracted workaround: None. (Issue **34087227**)

Options in the Study Version dropdown are not all displayed for a Blank Form PDF (former known issue)

Sponsor users: For a Blank Form PDF request, when you attempt to configure the Select Versions filter, all available study versions are displayed in the dropdown list. The number of displayed study versions has now increased from 15 to 30. If more than 30 study versions exist for your study, a More results available, please filter further prompt is displayed.

Retracted workaround: None. (Issue **33531303**)

Subject PDFs now display a note for subjects who once exited the study

Sponsor users: In a Subject PDF, for subjects who were once withdrawn or who completed their study (but their completion or withdrawal was undone), a note is displayed that indicates that a form's status as either:

- Superseded due to Withdrawal reversal
- Or Superseded due to Study Complete reversal (Issue **33861203**)

Some notifications must be site-specific (former known issue)

Site users: From now on, you will only receive notifications for the sites that you are assigned to and for which you have the corresponding permissions. Previously, you may have received certain notifications that were not specific to the site that you were assigned to.

For example, you may have received the following notifications without you being assigned to any of the related sites:

- Not Dispensed to Subject (Unblinded)
- Not Dispensed to Subject
- Not Dispensed to Subject (Unblinded Pharmacist)

Retracted workaround: None. (Issue **33775119**)

Numeric data not properly displayed in the Subject Data Extract (former known issue)

Data managers and statisticians: Now, in the Subject Data Extract, all numeric data is displayed as expected. Previously, null numbers interfered with the way other numbers were displayed in the extract. This issue was observed for extracts generated in a sas7bdat. format only.

Retracted workaround: None. (Issue **33860587**)

Data flags are not properly displayed in the ODM-XML extract (former known issue)

Sponsor users and API developers: Now, data flags that a user applies to a field in Oracle Clinical One Platform are displayed as expected in the ODM Clinical Data XML extract. Previously, data flags in the ODM-XML extract did not match the data flags in Oracle Clinical One Platform. This issue was caused by an API error that is now fixed.

Retracted workaround: None. (Issue **33722382**)

Sites, labs, depots, settings, and user management

The statistician role includes unnecessary rights (former known issue)

Global user managers or user administrators: Now, the predefined statistician template role provided by Oracle no longer includes additional rights that are not required for this type of user. Because these additional rights are no longer associated with the study role, a statistician can no longer see features that they should not see on the User Interface (UI). Previously, they encountered inconsistent behavior throughout the application, such as:

- On the Subjects tab, although the option for reconciling kits was available in the user interface, a statistician could not select and update a kit's status. An error message appeared stating that they didn't have enough permissions to perform this task. Now, a statistician can no longer see the option for reconciling kits.
- On the Study Inventory tab, a statistician received multiple Oops error messages when attempting to update a kit's location or status. Now, a statistician can no longer see the options for updating a kit's location or status.
- On the Confirm Dispensation dialog, when a statistician attempts to confirm the dispensation of a kit, the kit number disappears and the kit cannot be confirmed. Now, a statistician can no longer see the **Confirm Dispensation** button.

Retracted workaround: None. A statistician was not supposed to perform the above-mentioned tasks. However, seeing these options available in the user interface caused confusion as to what tasks a statistician can or cannot perform in the application. (Issues **31624774**, **31628276**, **31624449**, and **31624589**)

A pharmacy user cannot create DDF shipments (former known issue)

Global user managers or user administrators: Now, when you create a custom study role for a pharmacy user and assign the permissions typically associated with that user type, they can create shipments for destruction (also known as DDF shipments). Previously, even though the pharmacist role may have had the appropriate permission assigned to them (and in the template, as well), a pharmacist could not raise shipments for destruction.

Retracted workaround: When creating a study role for a pharmacy user, you no longer have to include the Perform Source Data Verification and Reconcile Inventory permissions to ensure that the user can create DDF shipments. (Issue **31610928**)

A Production Admin can create a shipment without the required permission (former known issue)

Global user managers and user administrators: Now, when you create a Production Admin user who is assigned the corresponding Oracle template study role, they can no longer see the Create Shipment button, on the Shipments tab, as expected. Previously, a Production Admin could create manual shipments in the system without having the required Create Manual Shipment permission assigned to their study role.

Retracted workaround: None. (Issue **33326742**)

A user account's effective dates may change in the UI and reports (former known issue)

User administrators: Now, on the Users tab, when you attempt to change a user's study role, its effective start and end dates remain the same, as expected, in both the user interface and the User Assignment report. Previously, when you edited a user, its start and end dates were both modified. This issue was caused by the difference between the time zone during which the user was created and the time zone during which the user was edited.

Retracted workaround: None. (Issue **33362166**)

A study role cannot be updated in the Japanese application (former known issue)

User administrators: Now, while the application's language is set to Japanese, you can update a user's study role at any time. Previously, whenever you attempted to update a user's study role, on the Edit User dialog, the drop-down for each study mode displayed a message that said: "The text which matches your search is not found." instead of the study role options.

Retracted workaround: None. (Issue **33767546**)

Site users and subject data

Visit details not displayed on Site Inventory page (former known issue)

Site users: Now, when a kit is reused and dispensed in another visit, the visit details associated with the newly dispensed kit are displayed on the Site Inventory page, as expected. Previously, the visit details were not displayed on the Site Inventory page.

Retracted workaround: Although the information is now displayed on the Site Inventory page, you can still run the Kit Dispensation report to view these details, as well. (Issue **33713547**)

A subject's ID and visit ID are displayed as "null" in an error message

Site users: Now, when you attempt to dispense kits to a subject outside of their visit window, the error message that is displayed indicates the appropriate subject ID and visit ID. Previously, when you wanted to dispense kit to a subject outside of their visit window, the error message that followed displayed the subject's ID and the visit ID as "null". (Issue **32917100**)

A dynamically displayed visit interferes with a dynamic form (former known issue)

Site users: Now, when you modify the answer to a determining question for a dynamically displayed visit it no longer interferes with other determining questions for dynamic forms and it does not modify the status of previously completed visits.

Retracted workaround: None. (Issue **33703557**)

The Tab key does not work for a date field (former known issue)

Site users: Now, when you use the Tab key on your keyboard to navigate between date fields, the cursor moves in the right direction when it lands on a date field with a format of YYYY-MM-DD. Previously, when you used the Tab key on your keyboard to navigate between date fields, the cursor moved in the opposite direction in the date field.

Retracted workaround: None. (Issue **33633003**)

9

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 21.4

- [Patch Log](#)
- [What's new](#)
- [Fixed issues](#)

Patch Log

This topic briefly describes the history of small fixes we have applied to the 21.4 release. None of these fixes affect the user work flow or the application's functionality.

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

Release number	Release date	Notes
Release 21.4.0.1	25-Jan-2022	For this release, we fixed several issues related to forms, visits and reports.
Release 21.4.0.2	29-Jan-2022	For this release, we fixed several issues related to Oracle Clinical One Analytics.
Release 21.4.0.3	10-Feb-2022	For this release, we fixed several issues related to data collection, Oracle Clinical One Analytics, and reporting.
Release 21.4.0.4	19-Feb-2022	For this release, we fixed an issue related to a security vulnerability.
Release 21.4.0.5	02-Mar-2022	For this release, we fixed an issue related to the Oracle Clinical One Digital Gateway.
Release 21.4.0.6	14-Mar-2022	For this release, we fixed issues related to data collection performance. This included a fix for issue 32606237.
Release 21.4.0.7	17-Mar-2022	For this release, we fixed an issue related to in-product training. For more information, see issue 33969082.

What's new

- [Data collection](#)
- [Integrations](#)
- [Randomization and trial management system](#)

- [Reporting and analytics](#)
- [Other enhancements](#)
Sponsor and site users can now follow better workflows with these new enhancements.
- [Data collection](#)
- [Data extraction](#)
- [Integrations](#)
- [Randomization and trial supply](#)
- [Rules management](#)
- [Other enhancements](#)

Data collection

- [Encourage collaborative design for your forms](#)
Multiple designers can now work together in a single study to create or edit forms. A new automatic lock prevents you from overwriting another designer's work. This allows multiple form designers to work simultaneously to design forms in a study.
- [Configure dynamic forms in multiple visits](#)
Using the Show Form dynamic rule, study designers can now configure a question to display a dynamic form in visits across the schedule. Study designers can also assign forms to individual cycles in a visit branch from a single interface.
- [Visit Date field must be manually completed](#)
The system is now enhanced to no longer automatically set a visit's date to the current date, so site users must make sure they always complete the Visit Date field. This option is set based on the study settings configuration.

Encourage collaborative design for your forms

Multiple designers can now work together in a single study to create or edit forms. A new automatic lock prevents you from overwriting another designer's work. This allows multiple form designers to work simultaneously to design forms in a study.

What are the benefits?

With this feature, you can save time designing forms and empower collaboration. While study designers cannot work on the same form at the same time, one study designer can edit a form while another study designer is creating a new form in the same study.

Details for study designers

You can now perform several actions simultaneously with other study designers on your team.

- While the study is in the Draft container, you can access it simultaneously with other study designers.
- You can create and edit forms in the study concurrently with other study designers.

 **Note:**

You are not allowed to work on the same form simultaneously. Once a study designer starts editing a form, that form is automatically locked and can only be viewed by another user.

- If a form is locked by another study designer, you can still copy the latest saved version of that form.

Before you work with this feature

- When a study designer is editing other elements of a study (such as visits, kits, or randomizations), you and other study designers can only create and edit forms simultaneously. You cannot access or make changes in any study areas other than forms. Once the study designer who is editing other parts of the study has saved their work, the study is unlocked and you can make changes to other areas.
- Every time you attempt to open a form or another area in the study that is being edited by a different study designer, the system displays a message informing you that another user is editing that specific area of the study at the moment and that you can only view it. Once the form or other study area is saved and unlocked, it becomes accessible again. For a form, the study designer will be seeing the last saved version of it.

Already working in a live study?

As soon as this release is available, multiple study designers can start working on different forms in the study concurrently.

Configure dynamic forms in multiple visits

Using the Show Form dynamic rule, study designers can now configure a question to display a dynamic form in visits across the schedule. Study designers can also assign forms to individual cycles in a visit branch from a single interface.

What are the benefits?

This enhancement to the dynamic form configuration allows you to control the display of multiple forms in multiple visits and individual cycles throughout the study by using one determining question associated with a different visit in the study.

For example, in a Demography form assigned to the Screening visit, apply the Show Form dynamic rule to the single-choice question regarding the child bearing potential of the female subject. Answering the question with Yes will display the Pregnancy form at all subsequent visits where the form has been added to the visit schedule.

Details for study designers

There are several changes in your workflow associated with this feature:

- On the Forms tab, when you select a form and click **Manage Forms**, a new option called **Visit Assignment** is displayed. Selecting this option displays the Add Form to Visit or Event dialog. Dragging and dropping a form onto a visit still displays the Add Form to Visit or Event dialog.
- On the Add Form to Visit or Event dialog you can now select individual (or multiple) cycles and visits where a form must be displayed. You can also assign a form (whether dynamic or not) to a specific starting cycle, indicate how many times the form should be

repeated across cycle visits, and when the system should stop displaying the form to users. You can use the same dialog to continue assigning forms to other visits in the schedule.

- On the Rules pane within a form, when you define a Show Form dynamic rule, a new section is displayed called **Show Form on**. In that section, you can choose between two options: **Current Visit/ Event Only** or **Current & Future Visits/ Events**.
- When a question with a Show Form rule applied to it is included in a visit in the initial schedule and the dynamic form is configured to be displayed in a cycle visit (in a visit branch), that dynamic form appears in all cycles for the visit, by default. You can select or deselect individual cycles for that dynamic form, so that it is displayed only on certain cycles of the visit.
- In the Show Form field, you can now select forms that are assigned to other visits, too. Previously the question that contained the Show Form rule and the dynamic form had to be assigned to the same visit.
- You can dynamically display any kind of form in any kind of visit, as long as the determining question is included in a non-repeating form. For forms, this includes one-section forms, repeating forms, lab forms, or two-section forms. For visits, this includes scheduled, unscheduled, required, or optional visits, cycle visits or non-cycle visits.
- The determining question of a dynamic form can be hidden or read-only as long as there is an automated way of populating the answer field for that question. Moreover, the question and the dynamic form must be assigned to different visits for this configuration to work.

Already working in a live study?

As soon as this release is available, you can begin configuring dynamic forms to be displayed in other visits in the schedule. Remember that any change you make to a question in the Draft version of a study must be applied to the live study version, if you want the change to apply to all subjects. For step-by-step instructions on how to update a question in a live study version, see [Update a form during the study conduct period](#).

Visit Date field must be manually completed

The system is now enhanced to no longer automatically set a visit's date to the current date, so site users must make sure they always complete the Visit Date field. This option is set based on the study settings configuration.

Now, based on study settings configuration, it is mandatory for a site user to enter a visit start date before saving the forms proceeding with the completion of the visit. The Visit Date field is no longer automatically completed, by default, with the current date and it cannot be left blank, otherwise it will mark the visit as Incomplete.

Previously, when left empty, the Visit Date field was automatically set to the current date, which wasn't always accurate. In turn, this may have caused confusion among users consulting the audit trail of this field.

Take for example a situation where a subject's lab results are collected before they begin their visit at a site. On 21 December 2020, a site user collects lab data in Visit A, but leaves the Visit Start Date field empty because the visit hasn't started yet. Two days later, on 23 December 2020, the same site user must begin the subject's visit to collect their vital signs and any other required data. When entering the lab data on 21

December 2020, the Visit Start Date field should be left empty, so a site user can complete it with the actual starting visit date, which is 23 December 2020. The field should not automatically default to 21 December 2020. Instead, a site user must enter that visit date themselves when they begin the visit. This way, in the audit trail, the field will appear as correctly updated by the respective user.

We recognize visit data is often entered after the visit has occurred, therefore, we have removed the dialog message that used to appear when data entry was performed outside the visit window.

Already working in a live study?

As a site user, as soon as the release is available, you will see the Visit Date field as an editable field that you can complete based on study settings configuration.

Integrations

- [Integrate screening and randomization data](#)
Oracle Clinical One Digital Gateway now supports a web service based, two-way integration between iMednet EDC and Oracle Clinical One Platform RTSM.
- [Oracle Clinical One Integration Hub is now Oracle Clinical One Digital Gateway](#)
Oracle Clinical One Integration Hub has been rebranded. The new name, Oracle Clinical One Digital Gateway, now appears throughout the product. The functionality is unchanged.
- [Load lab data into Oracle Clinical One Platform forms](#)
Oracle Clinical One Digital Gateway now supports the automatic loading of data in the CDISC lab model format into Oracle Clinical One Platform forms using American Standard Code for Information Interchange (ASCII) files.
- [Load data into hidden fields in Oracle Clinical One Platform](#)
Oracle Clinical One Digital Gateway now supports the automatic loading of data into Oracle Clinical One Platform in hidden fields using American Standard Code for Information Interchange (ASCII) files.
- [Enhanced template for the Oracle InForm to Oracle Argus Safety integration](#)
The integration between Oracle InForm and Oracle Argus Safety now has an updated configuration template.

Oracle Clinical One Integration Hub is now Oracle Clinical One Digital Gateway

Oracle Clinical One Integration Hub has been rebranded. The new name, Oracle Clinical One Digital Gateway, now appears throughout the product. The functionality is unchanged.

What's changed?

In addition to the rebranding within the product, you will also see changes in email notifications, SDLC, and PVP templates.

Already working in a live study?

As soon as this release is available, all documentation and training for users will be updated to reflect the name change of Oracle Clinical One Integration Hub.

Load lab data into Oracle Clinical One Platform forms

Oracle Clinical One Digital Gateway now supports the automatic loading of data in the CDISC lab model format into Oracle Clinical One Platform forms using American Standard Code for Information Interchange (ASCII) files.

**Note:**

This feature does not affect existing integration types.

How does loading lab data work?

Lab data that is loaded into the application follows the Clinical Data Interchange Standards Consortium (CDISC) standard, ensuring any type of data that you enter in the application is in accordance with the industry standards for transmitting electronic data related to drug development.

**Note:**

This feature does not support the automatic loading of data into local lab forms.

After the expected forms are created in Oracle Clinical One Platform and you configure the integration in Oracle Clinical One Digital Gateway, you must prepare an ASCII file that you will then upload in the Oracle sFTP. The ASCII file must contain the expected data to be loaded in the Oracle Clinical One Platform forms.

How can I configure my integration to load data in the CDISC lab model format data into Oracle Clinical One Platform?

To configure integrations for properly loading data in the CDISC lab model format into Oracle Clinical One Platform, reach out to your Oracle project manager.

Load data into hidden fields in Oracle Clinical One Platform

Oracle Clinical One Digital Gateway now supports the automatic loading of data into Oracle Clinical One Platform in hidden fields using American Standard Code for Information Interchange (ASCII) files.

**Note:**

This feature does not affect existing integration types.

How does loading hidden data work?

Data that is loaded into Oracle Clinical One Platform forms (in hidden fields) must be sent through an ASCII file uploaded in the Oracle sFTP. The process for loading hidden data is similar to the process for loading lab data into forms.

This feature is particularly useful for protecting the study's blinded or classified data while operating integrations. Loading data into hidden fields in Oracle Clinical One Platform can be used for both types of data intake integrations.

How can I configure my integration to load hidden data into Oracle Clinical One Platform?

To configure integrations for properly loading hidden data into Oracle Clinical One Platform, reach out to your Oracle project manager.

Enhanced template for the Oracle InForm to Oracle Argus Safety integration

The integration between Oracle InForm and Oracle Argus Safety now has an updated configuration template.

The existing configuration template for this integration is now updated to accommodate a new feature of Oracle InForm Publisher called partial narrative. Currently, Oracle Clinical One Digital Gateway can only send a full safety case narrative from Oracle InForm Publisher to Oracle Argus Safety. With the new partial narrative feature, we are implementing a new job recovery mechanism to ensure that Oracle Clinical One Digital Gateway can successfully re-execute a failed job before a subsequent job is executed. This ensures that no data is missed from the safety case narrative when the integration is running.

How does this work?

In the current configuration template, a new tag is introduced called `<ProceedOnFailures>`. When the tag is set to true (this is the default setting), a job runs its usual course as it currently happens in the application. When the tag is set to false, any partial narratives coming from Oracle InForm Publisher will be processed during the execution of a job.

To update and validate your configuration template, reach out to your Oracle project manager.

Randomization and trial management system

- [Additional options for dose holds](#)
Managing dose holds in complex studies has been improved for users.

Additional options for dose holds

Managing dose holds in complex studies has been improved for users.

If you choose to perform dose holds in your study, there are new options available to you.

Before you begin building or modifying your dose holds, you should understand the limitations. For more information, see [Understand how dose holds work](#).

Details for sponsor users

Sponsor users have the option to enable or disable the dose hold setting for all studies. The toggle next to the dose hold settings on the Supply Settings page is available once the study designer defines kits. Clinical supply managers can then choose whether or not they want to allow dose holds in the study. You can also choose to delete a dose hold or implement additional dose holds.

For more information, see [Learn the details of performing a dose hold](#).

Details for site users

Enhancements to kits have been implemented to improve your overall workflow for dose holds. The Subject Dispensation notification has been modified to provide you with information about kits and their associated dose holds, along with a new notification that alerts you when a site user performs a dose hold. For more details about these notifications, see the Notifications and Permissions Guide.

Already working in a live study?

As soon as this release is available, you can begin applying these additional options when creating your dose holds. For step-by-step instructions on how to configure dose holds, see [Create or edit a dose hold](#).

Reporting and analytics

- [New Study Design dataset in Oracle Clinical One Analytics](#)
Study designers can now work with a new dataset in Oracle Clinical One Analytics.
- [New Kits and Randomization Design dataset in Oracle Clinical One Analytics](#)
Study design users can now work with a new dataset in Oracle Clinical One Analytics.

New Study Design dataset in Oracle Clinical One Analytics

Study designers can now work with a new dataset in Oracle Clinical One Analytics.

The new Study Design dataset allows study designers to generate custom reports that identify visit schedule and form design of any study version available in any mode. You can use this dataset to verify your changes before moving a study version to production.

Details for user administrators and global user managers

To work with the Study Design dataset, you must be assigned a new permission *Run the Data Collection Design Dataset*. As a user administrator or global user manager, you can assign this permission to any sponsor user that needs to work with this dataset in Oracle Clinical One Analytics.

This new permission is included by default in the following predefined template study roles:

- Template - Study Designer

Details for study designers

The Study Design dataset contains metadata about the study, branches, visits and events, forms, and questions. With this new dataset, you can create a time and events table of any study version available in any mode and use it to identify the differences between modes.

For study versions in draft mode, you have a new button in the draft mode dropdown that allows you to manually publish data so that it is available for use with this dataset in Oracle Clinical One Analytics. Use this button whenever you want to work with data collection design details of a study version that is in draft mode. Testing and approved versions' data will automatically be available in Oracle Clinical One Analytics.

For more details on the exact data elements included in this dataset check the *Oracle Clinical One Platform Analytics User Guide*.

Already working in a live study?

As soon as this release is available, you can use this dataset in Oracle Clinical One Analytics to generate custom reports for any new or existing studies in any mode. For more information reach out to your Oracle project manager.

New Kits and Randomization Design dataset in Oracle Clinical One Analytics

Study design users can now work with a new dataset in Oracle Clinical One Analytics.

With this new dataset, study designers can now work with custom reports to identify kits and randomization configurations. This is particularly useful when a study designer needs to understand kit definitions as well as randomization definitions to identify dispensation schedules.

Details for user administrators and global user managers

To work with the Kits and Randomization Design dataset, you must be assigned a new permission *Run the Kits and Randomization Design Dataset*. As a user administrator or global user manager, you can assign this permission to any sponsor user that needs to work with this dataset in Oracle Clinical One Analytics.

This new permission is included by default in the following predefined template study roles:

- Template - Study Designer

Details for study designers

The Kits and Randomization Design dataset includes metadata that provides additional information on treatment arms, randomization, kits, calculated doses, visits and events. This lets you have a better control over the dispensation schedule and identify any necessary modifications so that it properly fits the study protocol definition.

For more details on the exact data elements included in this dataset check the *Oracle Clinical One Platform Analytics User Guide*.

Already working in a live study?

As soon as this release is available, you can use this dataset in Oracle Clinical One Analytics to generate custom reports for any new or existing studies in any mode. For more information reach out to your Oracle project manager.

Other enhancements

Sponsor and site users can now follow better workflows with these new enhancements.

Support for date questions with the format YYYY-MM-DD

YYYY-MM-DD is the most common date format used in Japan. Study designers can now use the YYYY-MM-DD and YYYY-MM-DD HH:MM format when configuring dates and time on forms in their Japanese studies, or any other studies they desire to use this format in. Partial dates are also supported in this format.

As soon as the upgrade for this release is done, the YYYY-MM-DD and YYYY-MM-DD HH:MM date and time format options will be available to study designers to support their study designs.

Support for notifications in Japanese

As a user who can set their language preference as Japanese, you can now view notifications in the language that you selected.

Apart from the already supported notifications, the following notifications are now translated in Japanese:

- Subject added
- Subject transferred
- Subject withdrawal
- Subject screening/ screen failure
- Subject visit complete
- Training complete (Oracle Clinical One Platform training only)
- Custom notifications
- User added to study
- State of a site has changed
- Rule re-run
- Report is ready
- Report failed to generate

Note:

- Notifications intended for non-Oracle Clinical One Platform users, such as depot email addresses, will always be sent in English.
- Oracle Health Learn course certificates and notifications for other applications are *not* translated.

Oracle CRF Submit: Inclusion or exclusion of blank forms in the Archival PDF output is now configurable

The **Archival** request type for sponsor and site users now allows for the inclusion or exclusion of blank forms in PDF output files. To control this, a new setting, **Include Blank Forms**, has been added with a default setting of **Yes**. Going forward the setting **Blank Form Format** will only appear when the new setting is set to **Yes**.

Oracle Central Coding: Dictionary Version has been removed under Coding Item Type

The **Dictionary Version** option that appeared under **Coding Item Type** in the **Advanced** pane when creating a form that is to be integrated with Oracle Central Coding has been removed. This option is not needed as the Oracle Central Coding system combines the dictionary name, i.e., MedDRA and the version, i.e., 24.0 into a

single data point prior to sending the details back to the study. The single data point is mapped to and stored under **Dictionary Name**.

Dose holds can now be placed on Unblinded Pharmacist kits

Clinical supply managers can now configure a dose hold for an Unblinded Pharmacist kit. Additionally, an unblinded site user can place a dose hold for that kit during the study conduct period. When it comes to blinded site users, if there is an Unblinded Pharmacist kit that they must pause dispensation for, a notice is displayed on the screen to indicate that they should contact their pharmacist to perform this action. More details coming soon in:

- Understand how dose holds work
- Learn the details of performing a dose hold

Find additional information about kits

Clinical supply managers can now simplify their workflow in Oracle Clinical One Platform by locating additional information about their kits under the Study Inventory tab. An updated table within the interface provides you with new columns and details about your kit's status.

In addition to improving the management of kits for sponsor users, site users can now view kit information under the Site Inventory tab and in site-related reports after kits have been selected for a reconciliation shipment and returned to the depot. If a kit has been selected as a replacement, details of the newly dispensed kit are displayed under the Inventory Management pane.

You can also see information about a kit under the Inventory Management tab after changing the status of a kit to *Misallocated* and updating its details. Once the status of a kit has been changed to *Misallocated*, a new notification is sent to subscribed users.

If you choose to update a kit's status to *Not Dispensed to Subject*, the details will appear under the Inventory Management tab and the kit will be removed from the subject's history. When a site user updates the status of a kit to *Not Dispensed to Subject*, a notification is sent to users who are assigned permission to receive it.

Fixed issues

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- [Forms, visits, and rules](#)
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Fixed issues affecting all users

Training pop-up prompting users to redo trainings (intermittent issue)

In certain cases, even though the training toggle was disabled at the tenant level, users were being prompted with trainings. To address this, a new configuration property was introduced at the tenant level which overrides this behavior resulting in trainings being shown correctly to users. (Issue: **33969082**)

Integrations

Certain data elements are not properly sent to Oracle InForm (former known issue)

Integration managers: Now, for an integration between Oracle Clinical One Platform and Oracle InForm, all data is properly sent out to Oracle InForm. Previously, some data elements were considered data classifications by the system and therefore not sent to Oracle InForm, as expected.

Retracted workaround: None. (Issue **33559974**)

Forms, visits, and rules

Validation rule update does not work for updated Age field (former known issue)

Study designers: Now, when you update the validation rule of an age question and apply that change to an existing live study version, the updates are displayed in Production mode, as expected. Previously, whenever you performed this type of advanced study versioning update, you may have noticed that the changes were not appearing in the live study version.

Retracted workaround: None. (Issue **32591313**)

Certain visit types are missing from older versions of the Visit Status API (former known issue)

Users working with REST APIs: Now, you can use any version of the Visit Status API endpoint and you will get an expected response of 200 (if the parameters are correctly specified). Previously, when using the Visit Status API endpoint (versions 2, 3, and 5), you may have noticed that the response was missing certain visit types. The missing visit types were: `unscheduled`, `unscheduled_dispensation`, `optional`, `adverse_event`, and `randomization` (specifically for version 2 of the Visit Status API).

Retracted workaround: You no longer have to exclusively use the latest version of the Visit Status API endpoint. (Issue **33545732**)

Decimal number can be entered in Count of Cycles field (former known issue)

Study designers: Now, on the Create Branch and Edit Branch dialog, you can only enter a whole number in the Count of Cycles field, such as 12 or 5. Previously, the application let you add decimal numbers.

Retracted workaround: You no longer have to double check the Count of Cycles field to make sure that you didn't enter a decimal number. The application does not save the changes unless you enter a whole number. (Issue **32096978**)

Effective range validation rule must be defined first (former known issue)

Study designers: Now, when defining the details of a number type of question that must be used in a randomization design, it does not matter if the range validation rule is placed first in the list of validation rules, for your randomization design to work. Previously, if the number type of question had to contain other types of validation rules, but the range validation rule wasn't first in the list, the question could not be selected when defining the stratified or demographic cohort randomization. Other times, on the Randomizations tab, the cohorts were not even displayed properly.

These issues are now fixed.

Retracted workaround: You no longer have to make sure that the range validation rule is defined as the first rule for the number type of question. (Issues **32279735**, **32279746**)

Inserted and updated visit is not displayed for subjects (former known issue)

Study designers: Now, whenever you update an inserted visit, a proper Confirmation message is displayed. The message indicates that instances of this visit may be added or removed for all subjects, whether they already completed an instance of this visit or not. Previously, you were not given any warning as to what might happen when you updated an inserted visit. This is why the newly updated visit was not properly displayed for subjects during the study conduct period. Specifically:

- When you update an inserted visit to have it displayed for future subjects only (after it was previously displayed for both future and past subjects), this could result in the visit that was previously displayed for a subject to disappear, as a result of this update.
- When you update an inserted visit to have it displayed for future and past subjects (after it was previously displayed only for future subjects), this may result in the visit appearing for subjects when it wasn't previously displayed.

Retracted workaround: None. (Issue **33179207**)

A screening visit's status is affected by a newly added form (former known issue)

Study designers: Now, when you add a new dynamic form to a Screening visit in a live study (through advanced study versioning), the status of that updated Screening visit remains Complete. Previously, after performing this update, you may have noticed that the screening visit to which that form was assigned had a different status, even though the form was not even displayed.

Retracted workaround: None. (Issue **33497799**)

Dynamically displayed visit incorrectly placed in the schedule (former known issue)

Study designers: Now, when you dynamically schedule a visit, that visit is properly displayed in a subject's schedule. Previously, there were issues with a dynamic visit was included in a subject's schedule.

Retracted workaround: You no longer have to enter a visit start date for the dynamically displayed visit. The visit is already correctly placed in the study schedule. (Issue **33625797**)

Slower than expected response time for an aeCount API request

Users working with REST APIs: Now, you will no longer experience increased response times when using the aeCount REST API to retrieve a list of adverse event visit counts for a given list of subjects. Previously, when using the aeCount REST API you may have noticed it was taking longer than expected, sometimes minutes to receive a reply.

Retracted workaround: None (Issue **32606237**)

Fix Version: 21.4.0.6

Reports, archives, extracts, and notifications

Renaming a study using special characters does not work in Oracle CRF Submit (former known issue)

Sponsor users: Now, when the study rename command is run on the Oracle CRF Submit shared server the command is executed as expected. Previously, if you performed this update and then the command was run, a 404 not found error was displayed.

Retracted workaround: In Oracle Clinical One Platform, you no longer have to avoid using special characters when renaming your study. (Issue **33001503**)

Oracle CRF Submit archive requests do not appear to be removed (former known issue)

Sponsor and site users: Now, when you attempt to delete an archive request from the Download Archives section, the request is removed, as expected. Previously, when you attempted to delete an archive request you may have noticed that the request was not removed from the User Interface (UI).

Retracted workaround: You no longer have to refresh the browser page or collapse and expand the Download Archives pane to reflect the removal of the archive requests. (Issue **33306063**)

Kit Chain of Custody (Unblinded) report does not properly display a subject's number (former known issue)

Clinical supply managers and statisticians: Now, in the Kit Chain of Custody (Unblinded) report, the Subject Number column is no longer populated with a subject's number for a kit that has a status of **Available**. The subject number is still displayed for a kit that has a status of **Not Dispensed to Subject** for troubleshooting purposes. Previously, a subject number was always displayed in the Subject Number column, even for kits that should not have that number associated with them, such as kits that

were previously in a state of **Not Dispensed to Subject** and then updated to **Available**.

Retracted workaround: None. (Issue **33406968**)

Oracle CRF Submit archive requests do not appear to be removed (former known issue)

Sponsor and site users: Now, when you attempt to delete an archive request from the Download Archives section, the request is removed, as expected. Previously, there were instances when you could not remove an archive request from the UI.

Retracted workaround: You no longer have to refresh the browser page or collapse and expand the Download Archives pane to reflect the removal of the archive requests. (Issue **33306063**)

Date validation rule not displayed as expected in reports (former known issue)

Sponsor users: Now, when you run the Study Design report or the Annotated Case Forms report, date validation rules are properly displayed. Specifically, when a date field in a form allows for a partial date (with a validation rule applied to it such as On or After), the reports show the date the field was added by the study designer. Previously, these reports displayed the date the field was last edited.

Retracted workaround: None. (Issue: **33421485**)

Duplicate lab names displayed in Subject PDF (former known issue)

Sponsor users: Now, when generating an Archival PDF, in the Subject PDF, you will notice that there are no duplicate lab name fields in the lab form. Previously, you could identify duplicate lab name fields in the lab form, whether the lab name was populated or not.

Retracted workaround: None. (Issue **33047606**)

Calculated values do not work in the table of a two-section form (former known issue)

Rule designers and testers: Now, when the target field of a calculated value is included in a two-section form (in the repeating form table), the custom rule is running as expected and the target field is populated. Previously, a calculated value did not work and the target field included in a two-section form was not populated at all.

Retracted workaround: You no longer need to refresh the browser's page to display the calculated value. (Issue **33135305**)

Saving drop-down value is not working during subject visits for question groups in two section forms (former known issue)

Study designers: Now, when you create a two-section form with question groups, and drop-down questions within the question group, a site user can save those drop-down values, as expected. Previously, a site user could not save the data that they selected for a drop-down question included in a question group.

Retracted workaround: None. (Issue **33306238**)

Duplicate randomization events displayed in the Subject Events report (former known issue)

Sponsor users: Now, in the Subject Events report, the randomization event is displayed a single time for every subject. Previously, the randomization event was displayed multiple

times for the same subject, making you think that the system randomized a subject multiple times.

Retracted workaround: None. (Issue **33545211**)

Missing statuses in the Subject Events report (former known issue)

Sponsor users: In the Subject Events report, you now see all of the expected visit statuses regardless of how you combine the filters for this report. Previously, you may have noticed that the Event Type column was missing several visit statuses. The report only displayed three common statuses: Visit Complete, Visit Date Changed, and Visit Started.

Retracted workaround: None. (Issue **33555141**)

The Subject Visits report does not work without a Subject status filter (former known issue)

Sponsor and site users: Now, you can generate the Subject Visits report (blinded or unblinded) without specifying an option for the Subject Status filter. Previously, without the filtering option, you could not generate a Subject Visits report. Clicking the **Run Report** button did not start the generation of the report.

Retracted workaround: Make sure you always specify details for the Subject Status filter. (Issue **33572955**)

The Subject Queries report does not work (former known issue)

Sponsor users: Now, you can generate the Subject Queries report without encountering any issues. Previously, when attempting to generate the Subject Queries report, you may have noticed that the report could not be generated at all. Other times, it took too long for the report to be generated.

Retracted workaround: None. (Issue **33626740**)

A SAS or CSV data extract does not display deleted data (former known issue)

Data managers and statisticians: Now, when you extract subject data in a SAS or CSV format, the extract specifies when a section from a two-section form is removed. Previously, this detailed was not displayed in the extract.

Retracted workaround: None. (Issue **33537242**)

Sites, labs, depots, settings, and user management

The statistician study role cannot view shipments (former known issue)

Global user managers or user administrators: Now, a statistician can view details about a shipment, but they no longer see the **Create Shipment** button as though they could create a shipment. Previously, the predefined statistician template role provided by Oracle included some rights that weren't generally required for this type of user. Due to these extra rights, a statistician role could see the **Create Shipment** button, but they could not actually click it due to a conflict of permissions.

Retracted workaround: None. (Issue **31624507**)

Shipment displayed with an incorrect status in the system (former known issue)

Clinical supply managers: Now, you can only change the ship date or tracking number of a shipment while it has a status of Pending, In Transit, or Confirmed, avoiding any incorrect information displayed in the user interface (UI). Previously, you could make these updates while a shipment also had a status of Received. In turn, this caused issues with how shipments were displayed in the application. For example, if an integration changed the ship date and tracking number of a received shipment, its status may have been updated to In-Transit, despite the shipment having been received at a site.

Retracted workaround: None. (Issue **33251976**)

Introductory fields are not cleared in the Create Custom Enrollment Group dialog (former known issue)

Study managers: Now, when you create a custom enrollment group and you click **Save & Add Another**, you will notice that the top fields in the dialog are cleared, as expected. Previously, data was not cleared and the data that you added for a previous enrollment group was still displayed.

Retracted workaround: None. (Issue **32891543**)

Source Data Verification settings do not work for a Japanese user (former known issue)

Study managers: Now, when you switch your language preference from English to Japanese during the configuration of a study's Source Data Verification (SDV) settings, the settings that you initially configured are preserved. Previously, whenever you switched your language preference from English to Japanese, you may have noticed that SDV settings were set back to their default values. Moreover, when switching back to English, you may have noticed further inconsistencies with the way SDV settings were displayed.

Retracted workaround: None. (Issue **33451089**)

Navigation buttons are not displayed when creating a depot (former known issue)

Site administrators: Now, on the Depots tab, when your Zoom In setting is configured to 100%, and you begin creating a depot, the navigation buttons are properly displayed on the screen. Previously, with the specified display settings, you may have noticed that the navigation buttons were not properly displayed on the screen.

Retracted workaround: None. (Issue **33549659**)

Site user can see child question of hidden dynamic parent question (former known issue)

Site users: Now, you can no longer view a dynamic question when its determining question is not answered and, furthermore, that determining question is also hidden. Previously, while being assigned the Site User predefined study role, you were able to see a dynamic question in a form, even though its determining question was not answered, and that question was also hidden in the form.

Retracted workaround: None. (Issue **32004247**)

The SDV strategy does not exclude withdrawn subjects (former known issue)

CRAs and study managers: Now, your source-data verification strategy will not count withdrawn subjects, as expected. Even though a subject was previously verified, once that

subject is withdrawn, it will not be counted in the percentage of verified subjects. Previously, when your type of source-data verification strategy was set to 100%, and subjects who were already verified were withdrawn from the study, you may have noticed that the system did not exclude the withdrawn subjects from the source-data verification strategy.

Retracted workaround: None. (Issue **33605142**)

Site users and subject data

Unscheduled visit is not displayed in the Previous Visits column (former known issue)

Site users: Now, an unscheduled visit that is started right after a screening visit is displayed in the Previous Visits column, as expected. Previously, in a study where the first visit was both a screening and a dispensation visit, after starting and completing an unscheduled visit, you may have noticed that the unscheduled visit was not displayed in the Previous Visits column.

Retracted workaround: None. (Issue **33174859**)

Visit start date field for a new visit should not be editable (former known issue)

Production admins: Now, you cannot edit the Visit Start Date field and save the update, as expected. Previously, you could edit the Visit Start Date field but you could not save the update. After clicking outside of the field, an Oops error message was displayed.

Retracted workaround: None. (Issue **32304010**)

Visit date format is displayed incorrectly for a Japanese user (former known issue)

Site users: Now, when the language in the application is set to Japanese, and you attempt to complete a Visit Start Date field in a form, you will notice that the date you enter is displayed in the expected format which is YYYY-MMM-DD. Previously, you may have noticed that the format in which the date was displayed was incorrect. The date you entered was displayed in the following format: DD-MM 月-YYYY.

Retracted workaround: None. (Issue **32820521**)

Automated query rule is not updated after two-section form update (former known issue)

Rule designers, rule testers, and site users: Now, in a two-section form that contains an automated query rule, when you add or remove an instance of the two-section form, queries raised throughout the instances are updated as expected. Previously, automated queries were not properly displayed throughout the instances of a two-section form and you had to refresh the browser page to see them.

Retracted workaround: You no longer have to refresh your browser's page to display automated queries in a two-section form. (Issue **33350046**)

Dynamic visit is not displayed after an updated answer (former known issue)

Site users: Now, during a dispensation visit, when you answer a determining question in a way that does not display a dynamic visit, and then update its answer to make the dynamic visit appear, the visit is displayed, as expected. Previously, when you

switched between answers for the determining question, you may noticed that the visit was not displayed at all.

Retracted workaround: None. (Issue **33482285**)

Cannot clear a radio button's answer for a Show Visit dynamic rule (former known issue)

Site users: Now, in a form, you can clear or modify the answer of a determining question that can dynamically display or hide an unscheduled visit. Previously, when you attempted to clear the answer of a question with radio buttons, you may have noticed that the application displayed an error.

Retracted workaround: You no longer have to refresh your browser's page to display the cleared answer. (Issue **33630884**)

Visits that are not dynamically scheduled do not appear during schedule (former known issue)

Site users: Now, in a cycle with three visits, the Continuation visit is displayed, as expected, when you answer the Continuation question with Yes. Previously, when you answered the Continuation question with Yes in a previous visit, the next visit in the cycle did not appear. The next visit in the cycle appeared only if you answered the Continuation question with No.

Retracted workaround: None. (Issue **33412311**)

Cannot navigate to other visits after entering data in a two-section form (former known issue)

Site users: Now, you can navigate to other visits in the study, using the menu above the visit forms, after adding data into a two-section. Previously, this navigation was not possible, and you had to go back to the Subjects page to access a different visit.

Retracted workaround: You no longer have to click **Save**, **Save & Close**, or **Return to All Subjects** to get to the Subjects page and navigate to a different visit. (Issue 33377945)

A query is not displayed for a site user in a baseline visit (former known issue)

Clinical Research Associates (CRAs) and site users: Now, all queries raised by a Clinical Research Associate (CRA), in a baseline visit, can be seen by both the CRA and other site users. Previously, after raising queries in a baseline visit, users noticed that the queries were not displayed in forms.

Retracted workaround: You no longer have to refresh your browser's page or sign out and back in to properly view the queries. (Issue **33496783**)

A visit is incorrectly marked as complete with errors (former known issue)

Site users: Now, when there are several unanswered mandatory questions and validation errors in a non-dispensation visit, that visit is marked as Incomplete in the system. Previously, this type of visit was incorrectly marked as Complete with Errors in the system.

Retracted workaround: None. (Issue **33508227**)

Dispense button not displayed for an unskipped visit (former known issue)

Site users: Now, when you skip and undo the skipping of a dispensation visit, the **Dispense** button is displayed in the visit, as expected. Previously, when you skipped a dispensation visit

and then undid the skip action , you may have noticed that the **Dispense** button for that visit was not displayed.

Retracted workaround: None. (Issue **33549520**)

Subject status issues displayed after clicking the Undo Study Complete button multiple times (former known issue)

Site users: Now, if you click **Complete Study** multiple times a subject is updated with a status of Complete and no additional error message is displayed. Previously, if you clicked **Complete Study** multiple times, the subject was updated with a status of Screened. You could not randomize the subject again or attempt to complete their visits. You could only screen fail or withdraw the subject from the study.

Retracted workaround: None. (Issue **33630389**)

10

Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.3.2

- [Patch Log](#)
- [What's new](#)
- [Fixed issues](#)

Patch Log

This topic briefly describes the history of small fixes we have applied to the 21.3.2 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.3.2.1	15-Dec-2021	For this release, we fixed a security vulnerability.
Release 21.3.2.2	17-Dec-2021	For this release, we fixed issues related to copying rules.

What's new

- [Enhanced Subject Data Extract and other reports](#)
Data managers and statisticians can now extract more relevant subject data in the application. Moreover, other users at a sponsor and site staff can generate better standard reports in the application.
- [New dataset in Oracle Clinical One Analytics](#)
Sponsor users can now work with a brand new dataset in the Oracle Clinical One Analytics application.
- [Other Enhancements](#)
Read more about new enhancements for study designers and rule designers.

Enhanced Subject Data Extract and other reports

Data managers and statisticians can now extract more relevant subject data in the application. Moreover, other users at a sponsor and site staff can generate better standard reports in the application.

Details for data managers and statisticians

When it comes to the Subject Data Extract, here's what you will see new in the data that you extract:

- In the existing column called REPEATNUMBER, a value of 1 is displayed for lab forms. Additionally, this column will continue indicating the repeating form instance number.
- A new column called SREPEATID. This is a unique number representing the ID of each repeating form included within a two-section form instance.
- A new column called SREPEATNUMBER. This indicates a row's unique number for the repeating form table in a two-section form and a lab form.

 **Note:**

The values for REPEATNUMBER and SREPEATNUMBER indicate different values for lab forms. The REPEATNUMBER value will always be 1 and the value for SREPEATNUMBER indicates the value that used to be displayed in the REPEATNUMBER column.

Additionally, you must know that data collected in the Questions Before the Table section of a two-section form and data collected in the Questions In the Table section is presented in a merged format within the extract, to provide you with a comprehensive view of the repeating form data for analysis. For a lab form, data from the Date of Collection and Fasting Status questions is also merged onto each row, for the same reasons.

Details for site users and other users at a sponsor

- When it comes to the Subject Data report, you must know that the existing Repeating Form Number column will display different types of data, depending on what type of form it relates to. For example, it can indicate the unique number of a repeating form instance in a two-section form or a row's unique number for every repeating form (whether it is located in a two-section form or not).
- The Subject Queries report also indicates the instance number of a repeating form to provide more clarity for queries raised in a two-section form.
- The Randomization (Unblinded) List report can now be filtered by historical or current data in the study and it includes a new column that indicates the site, country, or region when a study is blocked.
- Lastly, the Subject Visits report (for both the Blinded and the Unblinded version) can now be filtered by active subjects or all subjects within your study.

Already working in a live study?

If you're already working in a live study, you must know that - as soon as the upgrade for this release is complete - you will see the new reporting and data extraction enhancements in the standard reports and the Subject Data Extract, respectively.

New dataset in Oracle Clinical One Analytics

Sponsor users can now work with a brand new dataset in the Oracle Clinical One Analytics application.

Particularly useful to clinical supply managers, the brand new Unblinded Kits dataset offers users the ability to create custom reports based on all the kits-related data that is collected within Oracle Clinical One Platform. This way, a clinical supply manager (or

any other sponsor user with the appropriate permission) can track shipments, lots, and kit statuses within their studies.

Details for user administrators and global user managers

The new permission (*Run the Unblinded Kits Dataset*) is associated with the ability to work with the Unblinded Kits dataset. As a user administrator or global user manager, you can assign this permission to any sponsor user who must have the ability to work with this dataset in Oracle Clinical One Analytics. Additionally, you must know that this new permission is included, by default, in the following predefined template study roles:

- Clinical Supply Manager
- View Only for Unblinded Support Users
- Statistician

Details for clinical supply managers and other sponsor users

The Unblinded Kits dataset contains additional metadata about your study, sites, depots, and kits, giving you not only the ability to have better control over your supply system, but also the opportunity to answer numerous questions related to supply elements within your studies (kit inventory statuses, shipment statuses, kit dispensation or lot data, and many more).

More details on the exact data elements included in this dataset can be found in the *Oracle Clinical One Platform Analytics User Guide*.

Before working with this new feature

If you're a sponsor user working with Oracle Clinical One Analytics, there's another change that you should be aware of. To properly use and filter data into a custom report, you must know that we are now identifying the required folder of each specific dataset. This way, you can determine what data element of a given dataset is required to create a proper report in Oracle Clinical One Analytics.

Here is a list of all required folders corresponding to each dataset:

- The Blinded Subject Events dataset: The Event folder.
- The Queries dataset: The Query folder.
- The Subject dataset: The Subject folder.
- The Subject Forms dataset: The Form folder.
- The Subject Form Items: The Item folder.
- The Unblinded Subject Events dataset: The Event folder.
- The Unblinded Kits dataset: The Kits folder.

Already working in a live study?

As soon as the upgrade for this release is complete, whether you are working in a new or existing study, you can start your work with this new data set (as long as your organization is enabled and ready to use Oracle Clinical One Analytics). For more information on this new data set, reach out to your Oracle project manager.

Other Enhancements

Read more about new enhancements for study designers and rule designers.

Validate rules when copying a study design

The Copy Study feature has been updated to minimize the effort to re-validate custom rules and makes it easier to identify copied custom rules with validation errors. Only published rules in the copied study version will be validated in the new study version.

Once the validation of the custom rules is complete, every user who is assigned the Design Custom Rules permission receives a Rules Validation Complete notification.

Once the upgrade for this release is complete, the Copy Study feature will re-save and validate rules when you move the study version from Draft to Test mode.

Fixed issues

- [Forms, visits, and rules](#)
- [Integrations](#)
- [Reports, archives, extracts, and notifications](#)
- [Sites, labs, depots, settings, and user management](#)

Forms, visits, and rules

You cannot complete a visit

Site users: Now, you can complete any visits without any issues or errors in the application. Previously, when you attempted to complete a visit, you may have noticed that the visit was not properly registered as a completed visit. Moreover, the system displayed an error message stating that it was unable to complete visit for a subject, even though the data collected during that visit was registered in the system. (Issue **33473211**)

You cannot complete a dispensation visit

Site users: Now, when you attempt to complete a randomization or dispensation visit, the application behaves as expected, and your visit is marked as complete. Previously, when you attempt to complete a randomization or dispensation visit, even though all required data was collected, the visit was still marked as being in progress in the system. (Issue **33521814**)

Integrations

You cannot load multiple values into a question in Oracle Clinical One Platform

Integration managers: Now, when you attempt to load multiple values for questions with checkboxes or drop-down questions, the job for loading this type of data no longer fails in Oracle Clinical One Digital Gateway. Previously, you were not able to load multiple values into the application. (Issue **33369297**)

The executeRule API does not work properly

Users working with REST APIs: The executeRule API endpoint now returns an error status for each corresponding element in your request. Previously, the API endpoint returned one single error status for all elements in the request, causing the users interacting with the user interface to believe that the same error is displayed for multiple fields in a form, even though only one field was impacted by the error. (Issue **33428689**)

Reports, archives, extracts, and notifications

Dates are displayed in an English date format in the Japanese Subject Queries report

Sponsor users: Now, in the Japanese version of the Subject Queries report, dates in the Last Transaction Date column are displayed in the expected Japanese format (MMM-DD-YYYY). Previously, dates were displayed in the typical English format, even though the report was translated to Japanese. (Issue **33130841**)

Sites, labs, depots, settings, and user management

Manual shipments take longer to create (former known issue)

Clinical supply managers: Now, when you attempt to create a manual shipment in a larger study, the shipment is created quickly, without having to wait a little over a minute or more to have it displayed in the system. Previously, it took longer than expected to create a manual shipment in the application.

Retracted workaround: None. (Issue **33361237**)

Custom country DNS values are not effective (former known issue)

Clinical supply managers: Now, when you specify a custom value of 0, and then 1, for the Do Not Ship (DNS) field, the update is properly reflected in the user interface when you create a shipment. Previously, when you specified a custom value of 0, and then 1, for the Do Not Ship (DNS) field, you may have noticed that the country update was not effective when you created a shipment. Specifically, when you attempted to add kits to a pending shipment, you should not have seen any available kits from the blinded lot when the Do Not Ship (DNS) value was set to 0. However, you did see kits that could be added to the shipment. This issue occurred when you attempted to make these changes and the expiry date was the current date.

Retracted workaround: None. (Issue **33325952**)

Query-related data is incorrectly displayed for a subject (former known issue)

Clinical Research Associates (CRAs): Now, on the Subject page, after you view the associated queries of a selected subject, and you then select another subject, the query-related data for that subject is displayed as expected. Previously, you may have noticed that the query-related data for a subject was displayed for other subjects, too.

For example, after viewing the queries of a selected subject, when you attempted to navigate to the visit of a different subject, and expanded the Queries pane, you may have noticed that data for another subject was displayed in that section.

Retracted workaround: None. (Issue **33399119**)

A lab form is generating errors during the study conduct period (former known issue)

Site users: Now, when you attempt to select a lab and complete a lab form, the application works as expected. Previously, there were issues with the way lab data was being loaded into the system for all labs in your study. In turn, this generated several errors anytime you attempted to select a lab or complete all rows in a lab form.

Retracted workaround: None. (Issue **33495033**)

Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.3.1

- [Patch log](#)
This topic briefly describes the history of small fixes we have applied to the 21.3.1 release. None of these fixes affect the user workflow or the application's functionality.
- [What's new](#)

Patch log

This topic briefly describes the history of small fixes we have applied to the 21.3.1 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.3.1.1	30-October-2021	This release is a patch to turn on additional logging.
Release 21.3.1.2	04-November-2021	This release is a patch to enhance additional logging in the application.
Release 21.3.1.3	12-November-2021	This release is a patch to enhance additional logging in the application.

What's new

- [Verify incomplete data](#)
Clinical Research Associates (CRAs) can now verify questions or forms associated with incomplete visits.

Verify incomplete data

Clinical Research Associates (CRAs) can now verify questions or forms associated with incomplete visits.

Additionally, a Clinical Research Associate (CRA) can also re-verify these questions at any time during the progression of a visit, whether that visit is just started, incomplete, in progress, or completed).

On the Subjects page, the search filter used to display subjects whose visits are ready to be verified will continue to filter for complete visits, but Clinical Research Associates (CRAs) must know that they can verify and re-verify incomplete visits regardless of what the filter displays.

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Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.3 (October 2021)

- [Patch log](#)
- [What's new](#)
- [Fixed issues](#)

Patch log

This topic briefly describes the history of small fixes we have applied to the 21.3 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.3.0.1	23-October-2021	For this release, we fixed several issues related to Oracle Clinical One Analytics and the Subject Data Extract.

What's new

- [Data collection](#)
- [Integrations](#)
- [Randomization and trial supply management](#)
- [Reporting and analytics](#)
- [Rules management](#)
- [Other enhancements](#)

Data collection

- [Copy a study design in a new study](#)
Study designers can now copy the latest approved study design version within the same organization to create a new study.
- [Dynamically show a table in a two-section form](#)
Study designers can now dynamically display a table in a two-section form.

Copy a study design in a new study

Study designers can now copy the latest approved study design version within the same organization to create a new study.

What are the benefits?

Study designers can save a lot of time when creating a new study by copying and re-using a previous study as a template. Study data (such as collected data during the study conduct period) is not copied along.

This feature is extremely helpful for study designers who must design very similar studies within the same organization or for commonly used study designs.

For more information on how to copy a study's design to a new study, see [Copy a study's design](#).

Details for study designers

Before reading the details of this new task, you must know that you can only copy an existing study's design if you're associated with that study. In other words, you're created as a user, on the Users tab. Only the latest approved version of an existing study can be copied to a new study.

- When you click the Study Settings button () , a new option is displayed called **Copy Study**.
- The Create Study dialog appears when you select **Copy Study**. You must enter the **Study Title** and **Study ID**. All other fields (**Study Phase**, **Therapeutic Area**, **Open Label / Blinded**, **Contract Code**) will contain default values from the existing study. These values can be modified.
- When copying the latest approved study version into a new study, all attributes of the study design and rules for the study are copied.
- Regarding rules when copying a study design:
 - Custom rules remain valid in the copied version of the study.
 - Only published rules are copied into the new study.
 - All rules from the original study will be copied, including all dynamic rules for showing questions, forms, or visits.
- You can then edit the copied study design under the initial new draft version.
 - Under the General settings tab, **Original Study Design Copied From** indicates the study the new study version was copied from, if you're associated with the original study, as a study designer.
- If an error occurs while a study is in process of being copied, a standard message is displayed for you to either cancel the process or try copying the study again.
- When it comes to Advanced Study Versioning, if the latest approved study version to copy has changes that are applied from another study version, then the latest changes will be copied over.
- The **Apply Changes to Study Version** definition on all questions from the source study will not be copied.

- While you're in the process of copying a study, the original study remains locked and no other users can edit that study until the copying process is either over or you cancel it.

Already working in a live study?

As soon as the upgrade for this release is complete, you can begin copying approved study versions to create new studies. To approve a study version, see [Make a study available](#).

Dynamically show a table in a two-section form

Study designers can now dynamically display a table in a two-section form.

What are the benefits?

You can now dynamically show the repeating table of a two-section form when the leading question has been answered in a manner such that data is required to be entered into the table. Conversely, when the leading question is answered such that data is not expected, the repeating table does not appear.

With the new **Show Section** dynamic rule, you can define which question and answer display the repeating table section of the two-section form type.

For more information about two-section forms, see [Create a form with two sections](#).

Details for study designers

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

- The **Show Section** rule is only applicable to two-section form types and can only be defined for leading questions, located in Questions Before the Table section. This cannot occur within a question group.
- Only one question in Questions Before the Table section can be used to determine the display of a repeating section on the same form.
- If there is a **Show Section** rule defined, the repeating table section of a two-section form is not displayed unless the question before the table is answered with what is defined in the **Show Section** rule.
- To make sure a repeating table is displayed in a two-section form as expected, you must use a question with checkboxes, radio buttons, or a drop-down (so long as it has Exactly 1 applied as a validation rule) as the determining question. If you use a drop-down question, and more than one option is selected for an answer, even if one of those options determines the display of a repeating table, that table is not displayed. If checkbox questions are used and one of the selections made is the trigger for the repeating section, the repeating section will be shown.

Details for CRAs, principal investigators, and data managers

When it comes to this new feature, nothing impacts your workflow. Just know that you can continue signing, verifying, and freezing data in a dynamic repeating form, as usual.

Details for site users

Once the data is collected and saved in the dynamically displayed repeating form, the repeating form table cannot be hidden unless all data is removed and the answer to the question that determines its display is changed.

Already working in a live study?

As soon as the upgrade for this release is ready, you can begin defining Show Section rules for questions in your two-section forms. To properly make these updates in a live study version, see how to update a form during the study conduct period and how to add a new form to a live study version.

Integrations

- [Load data into Oracle Clinical One Platform forms](#)
Oracle Clinical One Digital Gateway now support the automatic loading of data into Oracle Clinical One Platform forms using American Standard Code for Information Interchange (ASCII) files.

Load data into Oracle Clinical One Platform forms

Oracle Clinical One Digital Gateway now support the automatic loading of data into Oracle Clinical One Platform forms using American Standard Code for Information Interchange (ASCII) files.

How does this work?



Note:

This feature does not affect existing integration types.

You can load data into any type of form: a one-section or two-section forms, a lab form, or a repeating form that is assigned to a scheduled visit, unscheduled visit, or cycle visit.

After the expected forms are created in Oracle Clinical One Platform and you configure the integration in Oracle Clinical One Digital Gateway, you must prepare an ASCII file that you will then upload in the Oracle sFTP. The ASCII file must contain the expected data to be loaded in the Oracle Clinical One Platform forms.

How can I configure my integration to load data into Oracle Clinical One Platform?

To configure integrations for properly loading data into Oracle Clinical One Platform, reach out to your Oracle project manager.

Randomization and trial supply management

- [Customize DNS and DNC values](#)
Clinical supply managers can now customize specific values for each country and specify the amount of time before kits from a lot can no longer leave the depot or be used in resupply strategies.
- [New fields for creating a depot](#)
Clinical supply managers now have new fields to fill in when creating a depot in their study.

Customize DNS and DNC values

Clinical supply managers can now customize specific values for each country and specify the amount of time before kits from a lot can no longer leave the depot or be used in resupply strategies.

What are the benefits?

With this new feature, clinical supply managers can create a more precise resupply strategy for every study in their organization. With the newly introduced ability of customizing Do Not Ship (DNS) Days and Do Not Count (DNC) Days in the system, clinical supply managers can set these values differently for each country where their study operates. This way, they can set exceptions for certain countries with tougher regulations that may need more lead time to get through customs, for example.

Details for clinical supply managers

When it comes to this new feature, here is what's changed in your workflow:

- On the Study Inventory tab, when you choose to create a blinded lot, the dialog displayed afterwards now has a Do Not Ship/ Do Not Count Settings section.
- In the table underneath this new section, you must either configure the DNS and DNC Days for the default settings (all countries in your studies) or you can click the plus (+) icon and add a new row where you can define DNC and DNS Days for a specific country in your study.
- Any default settings you define for all countries in a study are overridden by the settings you define for one or multiple specific countries.

Already working in a live study?

DNS and DNC values that you already specified for an existing blinded lot remain the same. As soon as the release upgrade is complete, you can specify DNS and DNC values at a country level for existing blinded lots in your study. This update can be performed in either Testing, Training, or Production mode.

New fields for creating a depot

Clinical supply managers now have new fields to fill in when creating a depot in their study.

What are the benefits?

As a clinical supply manager, using these three fields can help you review or add depots in other supply systems that your study is integrated with. For example, you may want to integrate a depot that is associated with a certain manufacturing facility to make sure the appropriate investigational product is always delivered to your sites.

Other times, you may want to create the same depots across multiple studies at your organization. To ensure that you have an easy way to identify these depots and that the relevant supply data matches across systems or studies, you can use these newly introduced fields and always look for the combination of Plant ID, Storage Location, and Shipping Location values.

Details for clinical supply managers

When it comes to your workflow for creating depots, on the Create Depot dialog, the Depot Setup section, you will notice the following new fields:

- **Plant ID:** The value for this field can be the same for several depots at your organization. This is the ID of the location where the investigational product is manufactured.
- **Storage Location:** This is the location of the storage where the investigational product is stored until it is shipped to the depot or the site.
- **Shipping Location:** This is the shipping point from where the investigational product will be shipped as kits. It can be another depot or a site.

Already working in a live study?

As soon as the upgrade for this release is ready, you can create a depot with these new fields defined, in any of the three study modes: Testing, Training, or Production. You can also edit an existing depot and specify data for these new fields.

Reporting and analytics

- [New settings and fields for Oracle CRF Submit archives and reports](#)
New settings and fields are now available for sponsor and site users generating Oracle CRF Submit archives.
- [New Minimization report](#)
Clinical supply managers and statisticians can now run the new Minimization List report in Oracle Clinical One Platform.

New settings and fields for Oracle CRF Submit archives and reports

New settings and fields are now available for sponsor and site users generating Oracle CRF Submit archives.

These new settings and fields help you further customize your Oracle CRF Submit archives and ensure that you generate archives with the most relevant and precise study data.

The following new settings and fields are introduced on the Archives tab, on the Settings pane, for the Archival, Blank Form, and Submission PDFs:

- **Header Text** field: By default, this field contains the study name.
- **Footer Text** field: By default, this field contains placeholder text "***Confidential***".
- **Advanced** button: Clicking this button displays the Advanced Settings dialog where you can configure the following settings:
 - **Prevent Form Changes:** This setting lets you apply a password protection to the PDF archive so no user can edit it, unless they know the password of this document. For the Archival PDF, this setting is set to Yes, by default. For the Blank Form and Submission PDFs, this setting is set to No, by default.
 - **Prevent Form Comments Changes:** This setting lets you apply a password protection to the PDF archive so no user can add comments or any kind of

annotations, unless they know the password of this document. By default, this setting is set to No.

- **Prevent Content Extracts and Copying:** This setting lets you apply a password protection to the PDF archive so no user can copy the contents of this PDF, unless they know the password. By default, this setting is set to No.

Already working in a live study?

You can generate any of these three Oracle CRF Submit archives anytime during the study conduct period, in any of the three modes: Testing, Training, or Production.

New Minimization report

Clinical supply managers and statisticians can now run the new Minimization List report in Oracle Clinical One Platform.

With this new report, clinical supply managers and statisticians can download and analyze data for the minimization they created and implemented for their current study.

No new permission is required for running this report. The existing *Run the Unblinded Randomization Report* permission can be assigned to a user, so they can run this new report.

Already working in a live study?

As soon as the upgrade is ready and you are assigned the appropriate permission, you can run this report for any study (both new and existing) in any of the three modes: Testing, Training, and Production.

Rules management

- [Helper functions for two-section forms](#)
Using the new helper functions for two-section forms, rule developers can now use the same helper functions available in repeating forms for two-section forms.

Helper functions for two-section forms

Using the new helper functions for two-section forms, rule developers can now use the same helper functions available in repeating forms for two-section forms.

What are the benefits?

With these new rule helper functions, you can now search and filter data from two-section forms for a multitude of use cases, from finding the minimum value in a number item across all instances of a two-section form to getting the current two-section form instance.

How does this new feature work?

Using a set of available Oracle Clinical One Platform helper functions, you can make use of functions tailored for users and maximizing productivity while creating custom rules. The new helper functions are:

- `list2SInstances()`
- `get2SValues()`
- `getCurrent2SFormInstance()`

- `getCurrent2STableInstance()`
- `findDuplicate2SForm()`
- `findMatching2SForm()`

Already working in a live study?

As soon as the upgrade is complete and this feature is available, you can get started on using the new helper functions. This feature is compatible with all existing and new studies.

Other enhancements

Extend a visit window beyond 365 days

Visit windows and cycle visit schedules are no longer limited to 365 days. Visit windows for new and existing study designs can now exceed 365 days, allowing a longer study duration.

As soon as the upgrade for this release is complete, study designers can begin designing studies with visit windows that extend beyond 365 days. Study designers can also edit existing schedules to extend a visit's window beyond 365 days.

Annotated Forms report now enhanced in Study Design mode

Study designers can now generate the eCRF in Study Design mode to review the design prior to moving to Testing mode, improving the accuracy and efficiency of their study validation efforts.

No new rights or permissions are required. Users with the *Run the Draft Study Design Report* permission have access to the Annotated Forms report in Study Design mode.

As soon as the upgrade of this release is done, you can begin running this report in Study Design mode.

Fixed issues

- [Fixed issues affecting all users](#)
- [Forms, visits, and rules](#)
- [Integrations](#)
- [Randomization and kits](#)
- [Reports, archives, extracts, and notifications](#)
- [Site users and subject data](#)
- [Sites, labs, depots, settings, and user management](#)

Fixed issues affecting all users

Users with special characters in their names must not be uploaded (former known issue)

In Oracle Clinical One Platform, when you add a user, you are now prevented from using certain special characters for those users' names. Here's a list of special characters that you can use:

- Underscore (_)
- Hyphen (-)
- Spaces between the first and last names
- Reversed quotation mark (or backtick) (`)
- Tilde characters (~)
- Single quotes (')
- Period (.)
- Caret character (^)

Previously, letting users include other special characters affected the way training certificates were printed both from Oracle Clinical One Platform and Oracle Health Learn Manager, since the latter did not accept special characters.

Retracted workaround: None. (Issue **33216371**)

Help link for Japanese users points to the right page

All Japanese users: When you set your language preference to Japanese, now, the Help link takes you to the Japanese documentation published on the Oracle Clinical One Platform Help Center. Previously, the Help URL was pointing to the English product documentation which made it difficult for Japanese users to get the proper user assistance that they needed. (Issue **33020367**)

Several fields in study design and settings now translated to Japanese

All Japanese users: When you set your language preference to Japanese, you will notice that the following fields are now properly translated in Japanese:

- The cohort type and randomization type you select, on the Create Randomization dialog. For more information, see enhancements **32864396** and **32864678**.
- On the Source Data Verification tab, The options you select for which questions to be verified, on the Source Data Verification tab. For more information, see enhancement **32905561**.
- On the Forms tab, The Coding Question and Rollover Question options in the Add Property drop-down (from the Advanced pane), on the Forms tab. For more information, see enhancement **32910405**.

Forms, visits, and rules

Partial dates and date validation rules do not work as expected (former known issue)

Study designers: Now, when you define a Date/Time type of question to accept partial dates and define a Minimum Date Answer (either YYYY or MON-YYYY), as well as a validation rule (such as an On or After type of validation rule), site users can complete these date fields successfully without encountering validation error messages despite the data being correct.

Previously, site users could not complete these Date/Time fields whether they had completed all fields of the date or just met the minimum allowed requirement. Moreover, when consulting the Study Design report, you may have noticed that the validation rule for that Date/Time type of question indicated that the date entered must be On or After the last modified date of the indicated date field.

Retracted workaround: None. (Issue **32459681**)

Select Exactly validation rule does not work for drop-down question

Study designers and site users: Now, when you design a drop-down question that has an Select Exactly 1 validation rule applied to it, the validation rule will work, as expected. A site user will not be able to choose multiple options for an answer without a validation error message appearing. Previously, a site user was able to select multiple options for a drop-down question and no validation error messages were displayed. This issue was encountered when completing required questions and in repeating forms, as well. (Issue **33420928**)

Advanced study version updates do not work in a two-section form (former known issue)

Study designers: Now, in a two-section form that is already included in a live study version, you can add or update a question in the Questions Before the Table section of that form (in Draft), and apply that change to another study version (including the live one). Previously, you could not do that due to a limitation of the two-section form feature and the presence of label items in the second section of the form.

Retracted workaround: None. (Issue **33146232**)

Cannot insert a visit in the beginning of a branch (former known issue)

Study designers: Now, you can insert a scheduled visit as the first visit in a branch. Previously, you were only able to insert a visit as the second one in the branch and then schedule it starting from the already existing first visit in the branch.

Retracted workaround: None. (Issue **33150377**)

Details of an age question are not translated in Japanese

Study designers: Now, all details that you must specify for an age question are properly translated in Japanese (the Format and Unit fields). Previously, when using the application with Japanese set as the preferred language, these two fields were still displayed in English. (Issue **32877375**)

An inserted visit is not properly updated after its removal (former known issue)

Study designers: Now, when you insert a visit into the schedule of one live study version (impacting both future and past subjects enrolled in the study) and then you remove the same visit within the context of another study version, that inserted visit is updated, as expected, for all subjects in a state of New. Previously, this update was not completed as you'd expect. An inserted visit that is removed from the schedule, at one point, must be removed from the schedule of all subjects in a state of New which was not the case for this issue.

Retracted workaround: None. (Issue **3314544**)

Automated queries do not work when visit start date is updated automatically (former known issue)

Rule designers and testers: Now, in a visit, whether the visit start date is automatically entered by the system or filled in manually, any automated queries that use the visit start date field as a rule operand will work. Previously, an automated query would not have worked for this use case.

Retracted workaround: You no longer have to follow the two options (listed below) to work your way around this issue.

- If you have the possibility of manually entering the visit start date, then we suggest you do so. That way, you ensure that automated queries will run.
- If you cannot enter the visit start date manually, then we recommend you add a trigger variable in the rule definition of the automated query.

(Issue **33213738**)

Integrations

Browser becomes unresponsive while jobs are loading for SmartSupplies PMD integrations

Integration managers and viewers: Now, when you sign in Oracle Clinical One Digital Gateway, your browser works as expected when you attempt to load and view multiple jobs for an integration with SmartSupplies PMD. This includes integrations with over 1000 jobs. Previously, the more jobs your integration displayed, the more unresponsive your browser became. (Issue **32525526**)

Incorrect error message displayed for missing values for integration

Integration managers: Now, jobs for an integration with Fisher Clinical Services display a proper error message whenever a mandatory value is missing for a depot or a site in Oracle Clinical One Platform. Previously, if a mandatory field (such as Telephone or Site address) in Oracle Clinical One Platform was missing a value, jobs for that integration failed with a confusing error message that didn't explain to the user what the cause of the failure was. (Issue **29777152**)

Error message is not clear enough for failing jobs

Integration managers: Now, for an integration with Catalent Clinical Supply Services, a more detailed error message is displayed whenever a job fails for a shipment that was previously cancelled in Oracle Clinical One Platform. Previously, this error message didn't exactly explain what the cause of the error was, so you did not have enough information to troubleshoot the issue. (Issue **32655163**)

Randomization and kits

Certain labels are not translated for a minimization design

Study designers: Now, when you edit or design a minimization list, you'll see that the Ranges and Group Name labels are properly translated in the Japanese language. Previously, these two labels were displayed in English, even though your preferred language in the application was set to Japanese. (Issue **32911092**)

Treatment arm options not displayed when accessed from a non-randomization visit

Study designers: Now, when you attempt to add a kit to a non-randomization visit, treatment arm options are displayed as expected in the Add Kits to Visit Schedule dialog. Previously, the treatment options weren't displayed at all. (Issue **33279532**)

Numbers in randomization list are unordered (former known issue)

Clinical supply managers and statisticians: Now, in a randomization list, randomization numbers are displayed in their expected order. Also, every time the randomization list is refreshed, the numbers are still displayed as you would expect. Previously, randomization numbers in a list were unordered.

Retracted workaround: None. (Issue **33292140**)

Unblinded randomization design icon is not displayed in the Japanese UI

Study designers: As a Japanese user, now, when you create an unblinded randomization design, the unblinded randomization design icon is displayed on the randomization card, as expected. Previously, this icon was not displayed at all, making it confusing for the user to confirm whether the randomization was marked as unblinded or not. (Issue **32896588**)

Reports, archives, extracts, and notifications

Archival PDFs cannot be generated for subjects whose data is entered in a two-section form (former known issue)

Sponsor and site users: Now, when you attempt to generate the Archival PDF, you will notice that the archive can be generated for all subjects at a site, as expected. Fixing this issue consisted of supporting data collected in two-section forms to be displayed in Oracle CRF Submit archives. Previously, you could not generate an Archival PDF for certain subjects at a site. Data associated with those subjects could not be generated due to data having been collected in two-section forms during certain visits.

Retracted workaround: None. (Issue **33097857**)

ODM-XML Admin data API displayed internal server error

Sponsor users: Now, when you attempt to extract admin data in an ODM-XML extract, but your Oracle Clinical One Platform study only has one version located in Draft mode, you may notice that the API returns a 400 Bad Request type of response. This is the expected and correct behavior because you must have a study version in either Testing or Production mode. Previously, when attempting to call the ODM-XML

Admin Data API, the endpoint returned a 500 Internal Server Error response. (Issue **33046286**)

Values used in the studymode parameter were not considered for the API response

Sponsor users: Now, when you attempt to extract metadata in an ODM-XML format, you must specify a study's mode (using the studymode parameter) as part of the authorization process of that API endpoint. Previously, even though you specified a study's mode in the studymode parameter, the API extracted all metadata regardless of the study mode parameter that you provided. (Issue **33040430**)

Extra field in the Japanese Study Design report

Now, as a Japanese user, in the Study Design report, you see the exact same fields that are displayed in the English Study Design report. Previously, the Japanese version of the Study Design report displayed an extra field for the Study GUID. This wasn't information that would be relevant to the study's design, so that field is now removed. This issue was only observed with the HTML version of the report. (Issue **33083154**)

Study Design report is missing some translated labels in Japanese

Study designers: For the Study Design report translated in Japanese, in the Forms section, you will now see a new column that properly translates the Date fo Birth and Question Group labels. Previously, these labels were still displayed in the English language. (Issue **33210692**)

Archives are not displayed when using Internet Explorer (former known issue)

Sponsor users: Now, when you're using Internet Explorer to navigate to the Archives tab, you'll see the Oracle CRF Submit archives, as expected. Previously, you could not see the archives using Internet Explorer as your browser.

Retracted workaround: Although this issue is fixed, we still recommend using Google Chrome for a better user experience. (Issue **32946379**)

Site users and subject data

Cannot edit a tabular form in place if one of the rows is frozen (former known issue)

Site users: Now, in a tabular form (a repeating form with label items), you can enter data directly into the table cells if one of the completed rows is frozen. Previously, you could not perform this task.

Retracted workaround: You no longer have to double-click a cell in the row to open up the data entry dialog and complete the fields. You can just complete the cell by clicking it once and adding a value straight into the tabular form. (Issue **32106780**)

Randomize button might not appear in environment (former known issue)

Site users: Now, after completing forms that contain dynamic questions, you can successfully screen or randomize a subject. Previously, after completing a form that contained dynamic questions, you may have noticed that the Randomize or Screen button were not displayed properly. Additionally, you may have noticed that your environment was very slow.

Retracted workaround: None. (Issue **32624265**)

Answer history displays unexpected characters in time stamps (former known issue)

Site users: Now, when you complete forms for a subject and click Save, in the answer history of a question, the time of completion is displayed, as expected. Previously, the time component was displayed using incorrect characters.

Retracted workaround: You no longer need to extract the data in your study in a CSV or SAS format to view the correct time of a form's completion. (Issue **32586137**)

Freeze a previously unfrozen question

Data managers: Now, you can freeze a previously unfrozen question, as expected. Previously, you could not do that. Whenever you froze an entire visit, unfroze one question associated with that visit, and then decided to freeze that specific question again, the Freeze button was no longer displayed. (Issue **33369194**)

Sites, labs, depots, settings, and user management

The clinical supply manager cannot assign a study version to a site (former known issue)

Global user managers or user administrators: Now, when you create a custom study role for a clinical supply manager and you specifically include the permission to assign a study version to a site, the user assigned to the role is able to perform that specific task. Previously, even though you included the appropriate permission in the custom study role, the clinical supply manager could not assign a study version to a site. The issue was caused by a wrong combination of rights that is now fixed.

Retracted workaround: None. (Issue **31593740**)

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Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.2.1 (August 2021)

- [Patch Log](#)
- [What's new](#)
- [Fixed issues](#)

Patch Log

This topic briefly describes the history of small fixes we have applied to the 21.2.1 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.2.1.1	22-September-2021	For this release, we fixed an issue with how data is displayed in the Kit Inventory (Unblinded) report.
Release 21.2.1.2	02-October-2021	For this release, we fixed several performance issues related to queries and forms in the application.

What's new

- [Enhanced data refresh process in Oracle Clinical One Analytics](#)
As a sponsor user working with analytics, you must know that the data in the application is now refreshed every time that data saved in the context of a visit, even though that visit may not yet be completed.
- [ODM-XML data pagination parameters](#)
Sponsor users can now incrementally receive data from Oracle Clinical One Platform APIs with the new data pagination parameters.
- [Translated notifications for Japanese users](#)
For a user who sets their language preference to Japanese in the application, Oracle Clinical One Platform now supports the translation of notifications in the language you chose.

Enhanced data refresh process in Oracle Clinical One Analytics

As a sponsor user working with analytics, you must know that the data in the application is now refreshed every time that data saved in the context of a visit, even though that visit may not yet be completed.

Specifically data is now refreshed whenever one of the following events takes place in Oracle Clinical One Platform:

- A new visit is started.
- The date is updated in the Visit Date field of a visit.
- Data is entered in a form and the form is saved.
- A form is saved.
- A question is updated after the form it belongs to was already completed.
- A query is created, updated, or closed.

ODM-XML data pagination parameters

Sponsor users can now incrementally receive data from Oracle Clinical One Platform APIs with the new data pagination parameters.

What are the benefits?

Currently, Oracle Clinical One Platform returns all data matching the request criteria for the CDISC ODM-XML APIs. This makes the management of data increasingly difficult, when it is received in large volumes. With the new data pagination parameters, sponsor users can programatically control how they receive the response through a set of enhanced APIs.

Details for sponsor users

CDISC ODM-XML APIs for clinical data, metadata, and administration now accept the following optional input parameters which allow you to segment the data into pages or chunks within the overall dataset:

- `offset`: row number to start from. First page starts with 0.
- `limit`: number of rows to return.

When the parameters are not provided, the APIs return all data.

Already working in a live study?

As soon as the upgrade for this release is ready, you can begin using the data pagination parameters in Clinical Data, Metadata, and Administration CDISC ODM-XML APIs.

Translated notifications for Japanese users

For a user who sets their language preference to Japanese in the application, Oracle Clinical One Platform now supports the translation of notifications in the language you chose.

The following notifications are translated in Japanese:

- Code Break
- Randomization Failed
- Dispensation Failed
- Subject Randomization Complete
- Subject Dispensation Complete
- Unblinded Pharmacist dispensation
- New Shipment Request
- Cancel Shipment
- Insufficient Shipments, Shipment Failure notifications
- Cohorts Limits Reached
- New Shipment for Destruction created
- Kit Missing from Shipment for Destruction
- Disable Kit List

Fixed issues

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

All users

Manual steps to convert Japanese CSV files no longer required

All Japanese users: From now on, you no longer need to convert CSV files (generated in the system) to a different file type to properly view Japanese characters. Previously, for every CSV file you generated in Oracle Clinical One Platform, you had to follow a set of steps in order to convert the file to 65001: Unicode (UTF-8), so Japanese characters could be displayed. You no longer have to perform this workaround either. (Issue **33008294**)

Forms, visits, and rules

Unexpected updates to original question with a Show Visit rule applied (former known issue)

Study designers: Now, when you copy a question with a Show Visit rule applied to it, from one study to another, and then update the Show Visit rule in the context of the copied question, the change is applied, as expected. Specifically, only the copied question displays the update you made for the Show Visit rule. Previously, when you updated the Show Visit rule of a copied question, you may have noticed that the original question was updated, too.

Retracted workaround: None. (Issue **33150577**)

Oracle Clinical One Analytics

Unscreened subjects sometimes appear in certain datasets (former known issue)

Now, in Oracle Clinical One Analytics, when using the Subject Forms and Subject Form Items datasets (and other datasets as well), subjects appear even when they haven't completed their screening visit. This issue is fixed by the implementation of an improved data refresh process for the application. For more information, see [Enhanced data refresh process in Oracle Clinical One Analytics](#).

Retracted workaround: None. (Issue **32976031**)

Randomization and kits

Randomization design appears restricted when it is not (former known issue)

Study designers: Now, when you define a blinded and central randomization, and allow randomization to occur outside the visit windows, as well as let site users assign new randomization numbers to all subjects, all details of the randomization are displayed as expected in the system.

Specifically, the randomization card is displayed with the appropriate details that you configured, instead of showing information that you never specified, such as the randomization being of a restricted type or not being allowed to take place outside the visit window.

Retracted workaround: None. (Issue **33180430**)

Reports, archives, extracts, and notifications

Some values are not translated in the dispensation-related sections of the Study Design report

Study designers and other sponsor users: Now, when you run the Study Design report, you will notice that Yes/ No values are properly translated in Japanese for the following sections and columns:

- Kits
- Kit Dispensation
- Randomization
- Calculated Doses

Previously, when you generated the Study Design report (with Japanese set as your preferred language), you may have noticed that Yes/ No values were not translated in the report. (Issue **33092853**)

Some values are not translated in the settings and visits sections of the Study Design report

Study designers and other sponsor users: Now, when you run the Study Design report, you will notice that Yes/ No values are properly translated in Japanese for the following sections:

- Study Settings
- Visit Settings

Previously, when you generated the Study Design report (with Japanese as your preferred language), you may have noticed that Yes/ No values were not translated in the report. (Issue **33092918**)

Data classifications do not appear in the Study Design report for other types of forms (former known issue)

Study designers: Now, classified questions are displayed as expected in the Study Design report when they're part of a form that you copied from one study to another. Previously, when you generated the Study Design report, you may have noticed that data classifications were not properly displayed in the Study Design report for one-section forms, lab forms, and repeating forms.

Retracted workaround: None. (Issue **33155595**)

StudyEventOID attribute missing for certain records

Sponsor users extracting data in an ODM-XML format: Now, when you extract clinical data in an ODM-XML format, the mandatory StudyEventOID attribute is displayed for all data records in the XML files, including for visits that are in progress at that time. Previously, when extracting clinical data in an ODM-XML format, you may noticed that the mandatory StudyEventOID was missing for some data records in the XML file. (Issue **33081266**)

Subject Data Extract fails to generate (former known issue)

Data managers and Support users: Now, when running the Subject Data Extract, you will notice that the extract is generated, as expected. Previously, the extract could not be generated and downloaded because the system did not accept special characters (such as apostrophes). Now, the system is optimized to allow the use of these characters.

Retracted workaround: None. (Issue **33160065**)

Missing coding fields in the Subject Data Extract

Sponsor users: Now, when you run the Subject Data Extract in an XPORT file format, you'll notice that all coding fields are displayed, as expected. Previously, some of these fields were missing and you may have also encountered errors when generating the extract. This issue was observed when no data classifications were configured for the coding fields (as it is expected in the system). (Issue **33169133**)

Site users and subject data

Cannot re-open queries in forms with coding questions when included (former known issue)

Clinical Research Associates (CRAs) and data managers: Now, when working in an unscheduled visit, you can re-open a query in a form that contains coding questions, and the query behaves as expected. Previously, if you tried to re-open a query in a form with coding questions, the re-opened query didn't appear in the visit.

Retracted workaround: None. (Issue **31940674**)

Visit details are not displayed for a selected subject (former known issue)

Site users: Now, when you enter a visit for a given subject and then attempt to change the selected subject from the Subject drop-down, on the visit page, all details associated with that visit (such as forms) are now properly loaded in the application. Previously, when you attempted to change the selected subjects, you may have noticed that visits and details associated with that visit (such as forms) were not loaded in the application. Instead, visit details for the previously selected subject were still displayed.

Retracted workaround: You no longer have to view visits and details for a subject from the Subjects page, by selecting each subject. (Issue **33008196**)

Visit date is not properly updated in form (former known issue)

Site users: Now, in a form, when you enter a date in a visit date field, save it, and then proceed with collecting the rest of the data, the visit date is saved as expected. Moreover, the audit trail displays the date that you entered in the visit date field. Previously, when you performed this action, you may have noticed that the visit date field was briefly highlighted as a field that contained incorrect data. Afterwards, the date in that field was changed to the current date. The audit trail of the field showed no record of the initial date that you entered, as a user.

Retracted workaround: None. (Issue **33224470**)

Data may be removed during validation of other forms (former known issue)

Site users: Now, in a two-section form, when you start completing form instances in the repeating form table (Questions in the Table) and then proceed with adding data into the second form instance, data in the previous form instance is saved, as expected. Previously, when you began adding data into multiple rows in a repeating form table, you may have noticed that the user interface focused on the first instance, removing all of the data that you previously entered in the repeating form table. This issue was caused by the validation of those newly completed questions that took longer to complete.

Retracted workaround: None. (Issue: **33223861**)

Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.2 (August 2021)

- [Patch Log](#)
- [What's new](#)
- [Fixed issues](#)

Patch Log

This topic briefly describes the history of small fixes we have applied to the 21.2 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.2.0.1	08-August-2021	For this planned release, we fixed an issue related to date fields that were unexpectedly highlighted in a form.
Release 21.2.0.2	19-August-2021	For this planned release, we fixed several issues affecting date/time fields in forms, advanced settings in the Subject Events report, as well as other performance issues impacting the Health Sciences Learn Training report and sites.

What's new

- [Data collection](#)
- [Integrations](#)
- [Randomization and trial management system](#)
- [Reporting and analytics](#)
- [Other enhancements](#)
Sponsor and site users can now follow better workflows with these new enhancements.
- [Data collection](#)
- [Data extraction](#)
- [Integrations](#)
- [Randomization and trial supply](#)

- [Rules management](#)
- [Other enhancements](#)

Data collection

- [Create a dynamic visit](#)
Study designers can now design a dynamic visit, so site users can start that visit only when it is relevant or required for a subject in the study.
- [Create a form with two sections](#)
Study designers can now design forms with multiple and repeatable sections, so site users can collect data in a logical and relevant way for the subject.
- [Insert a visit into the visit schedule of a live study](#)
You can now modify the visit schedule for a subject at any point in time during a live study version.
- [Copy forms with dynamic rules and form associations](#)
Study designers can now copy forms along with their configured dynamic rules and associated forms.

Create a dynamic visit

Study designers can now design a dynamic visit, so site users can start that visit only when it is relevant or required for a subject in the study.

What are the benefits?

If your study does not have a fixed visit schedule and you often need to start visits to cater to specific data collection or dispensation goals, then dynamic visits will do the trick for you. This new functionality allows you to add a visit based on specific answers to a question, to ensure a more targeted and relevant collection of data or dispensation of the investigational product.

Dynamic visits can be used for a variety of studies, depending on what you want to achieve with your protocol. For example, dynamic visits can be particularly useful for oncology studies that contain a pharmacokinetic substudy.

You can also use dynamic visits if you want to dispense the investigational product within a specific series of visits and collect data from subjects in a separate set of visits.

Details for study designers

When it comes to this new feature, you must first know that dispensation and non-dispensation visits, optional and required visits, as well as the last visit in a branch can be dynamically scheduled. However, you cannot dynamically schedule any visit that is a screening, randomization, or anchor visit, as well as events or the first visit in a branch, and the first and last visit in a cycle branch.

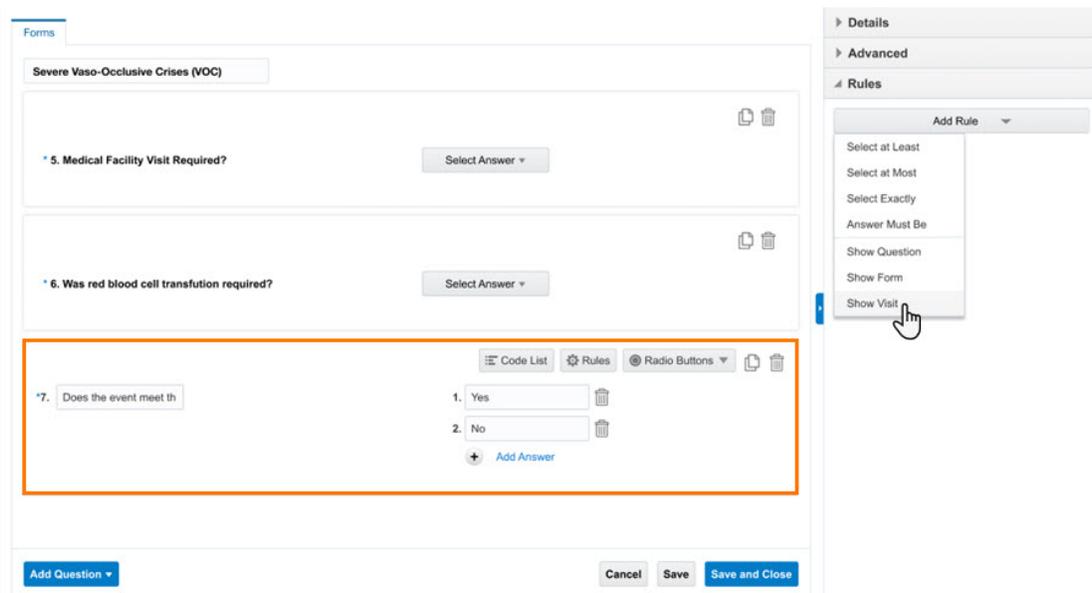
When it comes to changes in your workflow, here is what is new for you if you want to start including dynamic visits in your study schedule:

- On the Forms tab, upon selecting a question, you now see a new type of rule that you can configure for that question. This new rule is called **Show Visit**.

- To configure a Show Visit rule, you must specify the answer of the selected question that determines the display of a dynamic visit, as well as the visit that must be displayed.
- Typically, the question that is used to trigger the display of a dynamic visit must be a question with radio buttons, checkboxes, or a drop-down question, and two answer options: Yes or No. However, you can also use a code list containing one option for an answer or multiple answer options other than Yes or No.
- A dynamic visit can be scheduled just as you schedule any other visit in a study.
- Moreover, you can assign as many forms and kit types to a dynamic visit as you need.
- Lastly, you must know that you can also remove a dynamic visit from the study schedule, even though that visit is included in a live study version.

If you want to design more complex dynamic visits, you can also use a hidden or read-only question to trigger the display of a dynamic visit. A hidden or read-only field may be populated through an integration or with the help of custom JavaScript rules.

Figure 14-1 How a study designer sees the new option for configuring a dynamic visit



Details for site users

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

- After you answer a question, a dynamic visit can be displayed in the Next Visits pane, if it is coming up next. If the dynamic visit is scheduled at a later point in time, it will appear in the Next Visits pane when the subject is ready to complete that visit.
- If data hasn't been entered in fields associated with the dynamic visit, you can hide it by going back to the question that determines the display of the visit and changing the answer, so it does not display it in the schedule.
- If configured as an optional visit, you can also skip a dynamic visit, whether it is unscheduled or required.

Details for Clinical Research Associates (CRAs), data managers, and principal investigators

When it comes to your workflow, nothing has changed. What you do need to know is that questions and corresponding answer fields associated with dynamic visits can be either frozen, signed, or verified just like in any other type of visit.

Already working in a live study?

As soon as the upgrade is complete, you can begin configuring dynamic visits in your study. If you're working in an existing study and want to include one or more dynamic visits in your visit schedule, you must first configure the question that determines the display of a dynamic visit, whether you need to add or edit an existing question. Make sure you apply that change to the appropriate study version and that you follow the required steps for modifying the study schedule. For step-by-step instructions, see [Extend the treatment period for subjects during the study conduct period](#).

Create a form with two sections

Study designers can now design forms with multiple and repeatable sections, so site users can collect data in a logical and relevant way for the subject.

What are the benefits?

Until now, you were able to enter multiple records of data using the repeating form functionality. This repeating form type does not allow for a leading question.

Now, you can take data collection to the next level, with a much more granular and targeted approach when it comes to creating forms. With the new two-section form, you can create a single form that contains leading questions in the flat section of the form and a repeating section that allows for entry of multiple records of data. The combination makes a form instance. For example, you may first create a set of leading questions assessing a subject's tumor. In a table below, you can then include a different set of questions, multiple times, to collect more precise data on the subject's tumor characteristics.

Details for study designers

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

- On the Forms tab, upon clicking **Create Form**, you are now presented with two new options: **1 Section** (previously known as Standard Form), **2 Sections** (the new form with two sections), and **Lab Form**.
- A two-section form is marked as a repeating form that allows additional rows or form instances to be created, by default.
- Upon clicking **Add Question**, you now see two options for including the questions you are about to create: **Questions Before the Table** and **Questions in the Table**.
- Leading questions (Questions Before the Table) can be of any type, except for label items. Leading questions can also be hidden or made to appear as read-only.
- Questions included in the repeating section of the form (also known as Questions in the Table) can be of any type, except for question groups.
- You can reorder questions in this type of form by dragging and dropping each question within the same section.

Figure 14-2 How a study designer creates a form with two sections

The screenshot displays the Oracle Clinical study designer interface. The main workspace is divided into two sections: "Questions Before the Table" and "Questions in the Table".

- Questions Before the Table:** Contains a question labeled "A. Tumor Location" with an associated answer field.
- Questions in the Table:** Contains a question labeled "1. RECIST Diameter" with a unit of "cm".

The right-hand side of the interface features a "Details" panel with the following settings:

- Reference Code:** TEXT_06
- Question Hint:** Hint Text
- Apply Changes to Study Version:** Select a study version
- Required:**
- Hidden:**
- Data Classification:** Select data classification
- Read Only:**
- Source Data Verification (SDV for All Subjects):**
- Critical Variables (Target SDV):**
- Advanced:**
- Rules:**

At the bottom of the workspace, there are buttons for "Add Question", "Cancel", "Save", and "Save and Close". A green notification box at the top right states: "For calculated doses, only required numeric questions can be used. For stratum groups and demography cohorts, only (a) required numeric questions with one inclusive range check and (b) required Drop-down questions that require users to select only one option can be used."

Details for site users

When it comes to your workflow, not much has changed. However, you must be aware of how this new type form works for you.

First of all, you must know that anytime you encounter a form with two sections in a visit, you can repeat that entire form as many times as your study protocol allows you. For example, if you must collect data on multiple lesions, you can click **(+)** next to the form to add the required number form instances.

You can remove any of these forms.

Figure 14-3 How a site user sees a form with two sections

The screenshot shows a clinical trial form for subject 016-009. The form is titled "Tumor Measurement" and is divided into two sections: "Tumor Measurement: 1" and "Tumor Measurement: 2". The "Tumor Measurement: 2" section is currently active and contains fields for "Tumor Location", "Tumor ID", and a table for recording tumor measurements. The table has columns for "#", "RECIST Diameter", "Long Diameter", "Short Diameter", and "% of Change". Below the table are "Vital Signs" fields for Heart Rate, Height (cm), Weight (Kg), and BMI. The right sidebar shows the subject's history, including "Kit - Dispensed" events and a "Screened" event.

Already working in a live study?

As soon as the upgrade is complete, you can include a form with two sections in your study. If you want to include a form with two sections in a live study version, see [Add a new form to a live study version](#).

Insert a visit into the visit schedule of a live study

You can now modify the visit schedule for a subject at any point in time during a live study version.

What are the benefits?

Previously, the visit schedule up to the current visit could not be modified once a subject had started a visit. Now, you are able to update the visit schedule for a subject at any time during a live study version, as required by study amendments to your protocol.

This feature offers multiple benefits and enhancements, such as:

- The ability to control the impact of the inserted visit, whether it should appear for all subjects or subjects enrolled in the future.
- The ability to include almost any type of visit in the visit schedule, along with assigned forms or kit types. The inserted visit can be an anchor visit.
- Allowing users to add forms to an existing visit.

Details for study designers

If you would like to insert a visit into the schedule of a live study version, there are multiple changes to your workflow:

- You can insert a visit both as a regularly scheduled visit or as a cycle visit, including as the last visit in a branch or cycle branch. You cannot insert a new screening or randomization visit.

- On the Add Visit dialog, the **Shown in Timeline** field determines how the visit will behave during the study. For example, when you select **Future Only**, the inserted visit will only show for subjects that have the visit scheduled in the future. This is the default selection for new and existing visits. But when you choose **Future & Past**, the inserted visit will always show even if a subject has completed the visit.
- In a subject's schedule, an inserted visit appears as a visit that has not been started yet.
- An inserted visit appears for completed and withdrawn subjects just the same as a visit that has not been started yet.
- The visit property that prevents displaying visits for subjects who have completed a visit follows the newly inserted visit.
- If you assign a new form to a newly inserted visit, then you must make sure that the questions in those forms are applied to the correct study version. For step-by-step instructions, see [Add a new form to a live study version](#).
- Sites are required to be associated with the relevant study version in order for site users to see the visit.

Details for site users

Nothing has changed in your workflow. However, you must know that, depending on how an inserted visit is configured to impact a subject's schedule, this new visit may appear on the **Next Visits** column for you to complete.

Copy forms with dynamic rules and form associations

Study designers can now copy forms along with their configured dynamic rules and associated forms.

This feature is helpful in allowing you to choose whether you would like to include all or none of the forms connected to the forms you selected for copying, through various dynamic rules. When copying a form, study designers are able to copy the **Show Form**, **Show Question**, **Show Visit** and the **Link and Show Form** dynamic rules along with the form.

Want to learn more about the Show Visit dynamic rule? See [Create a dynamic visit](#).

Details for study designers

There are multiple changes to the user interface and your workflow:

- You can copy the **Show Form** and/or the **Link and Show Form** dynamic rules and copy all levels of a dynamic form. When you do this, a message will appear to inform you that the related form(s) can be copied, as well.
- You have the option to choose whether you would like to copy all connected forms or only copy the parent form.
- If a form with the same name already exists in the main study, the copied form with a **Show Form** and/or **Link and Show Form** dynamic rule is copied with a different name, using an underscore and incremental number. However, the associated link remains.
- On the Forms tab, when a form is duplicated within the main study, the duplicated form is copied with a different name, using an underscore and incremental number. The associated link is maintained.
- If the form being copied contains a question that was applied to a different study version, the newly copied form will not maintain that selected study version selected for that question in the **Apply to Study Version** field.

Data extraction

- [Extract clinical data in the CDISC ODM-XML format](#)
As a sponsor user, you can now programmatically extract clinical data in the ODM-XML format.

Extract clinical data in the CDISC ODM-XML format

As a sponsor user, you can now programmatically extract clinical data in the ODM-XML format.

What are the benefits?

A sponsor user can now leverage the new ODM-XML data extract feature for automating data feeds into downstream warehouse systems or on demand access to a standardized representation of their data. It provides comprehensive data coverage managed by RESTful API services for clinical data, metadata, and administration data.

The ODM-XML Extracts conform to the industry standard CDISC ODM-XML v1.3.2 format, encapsulating the data into Extensible Markup Language (XML) file, which can be easily parsed by most open-source software thus providing a near real-time data transfer between Oracle Clinical One Platform and the user's data repositories.

How does this new feature work?

Using a set of available Oracle Clinical One Platform REST API endpoints, you can make API calls to extract data as ODM-XML formatted text according to the CDISC ODM-XML version 1.3.2 standard format. Our solution offers you a programmatic and on-demand access to your study data for integration purposes, as well.

To provision a user with the required permissions, you must follow a set of steps in different applications. Step-by-step instructions are coming soon in the Oracle Clinical One Platform REST API Guide. If you need additional guidance with extracting data, contact your Oracle project manager.

What specific types of data can I extract in an ODM-XML format?

At a high level, you can extract all case report form data, as well as its associated metadata. You can also extract administrative, reference, and audit data from your study. Data can be extracted based on the existing study modes (Testing, Training, and Production). Here is a more extensive list of data that you can extract:

- Transactional data reflecting incremental data changes with audit information
- Snapshot data reflecting current data from the study.
- Blinded and unblinded data
- Other types of data such as: subjects, subject statuses, sites, countries, visits, visit sequences, visit statuses, form IDs, form sequences, form statuses
- Data elements such as item raw values, item decoded values, validation error attributes, and data statuses (such as Signed, Verified, or Frozen).
- Data flags

Already working in a live study?

As soon as the upgrade is complete and this feature is available, get in touch with your Oracle project manager to get started on extracting data in an ODM-XML format.

What other resources do I have to learn more about ODM-XML?

We have prepared a list of learning resources that can help you get started with this new feature. Some of them will be available as soon as the upgrade for this upcoming release is complete. Others are available for you to consult before you get started with your work.

Resource	Link
New REST API endpoints in the Oracle Clinical One Platform REST API Guide	Data Hub API v1.0
User provisioning workflow for users who extract data in an ODM-XML format Oracle Clinical One Platform REST API Guide	<ol style="list-style-type: none"> 1. Generate a client ID and secret. 2. Create a user account in Oracle Life Sciences IAMS. 3. Create a user account in Oracle Clinical One Platform.
Industry information on ODM-XML	ODM-XML description

Integrations

- [Send information on data flags to Oracle InForm](#)
With this newly introduced feature, integration managers can now send information related to data flags from Oracle Clinical One Platform to Oracle InForm.

Send information on data flags to Oracle InForm

With this newly introduced feature, integration managers can now send information related to data flags from Oracle Clinical One Platform to Oracle InForm.

How does this work?

With a properly configured integration template, whenever you update a data flag or a field that was flagged in Oracle Clinical One Platform, you can now send information on these data flag updates to Oracle InForm. Data flag information sent through this integration covers the following scenarios:

- When a data flag is applied to a field.
- When a data flag is updated.
- When a data flag is removed (either by removing the actual data flag from the field or by adding a value in the empty text field that was previously flagged).

In Oracle InForm, data flags correspond to the Reason Incomplete options available in the user interface for incomplete form answers. In Oracle InForm the Data Entry Flag is collected in the item comment section. Clicking the Comments icon in Oracle InForm displays the Reason Incomplete options, equivalent to those in Oracle Clinical One Platform. The Reason for Change from Oracle Clinical One Platform is featured on the Comment field above the Reason Incomplete options.

These are the default configurations in Oracle InForm. Make sure these settings are configured appropriately, so that data flag information can be sent from Oracle Clinical One Platform to Oracle InForm.

- The Require a comment setting (when entering N/A, Unknown, or Not Done) in Oracle InForm is set to No.
- The Display Comment Text Boxes setting is set to Yes.

To send information on data flags through your integration, reach out to your Oracle project manager.

Randomization and trial supply

- [Configure dose holds for kits](#)
Clinical supply managers can now configure settings for dose holds, so site users can pause dispensation for subjects, whenever that is needed during the study.
- [New option for dispensing kits](#)
Clinical supply managers can now define the dispensation logic in a study, by choosing whether kits should be dispensed by the closest expiration date and lowest kit number, or by the closest expiration date and lowest sequence number.

Configure dose holds for kits

Clinical supply managers can now configure settings for dose holds, so site users can pause dispensation for subjects, whenever that is needed during the study.

What are the benefits?

With this new functionality, investigators can temporarily stop dispensation for a subject by placing a dose hold. With dose holds, investigators can respond appropriately and in due time to subjects' experiences with the investigational product and take any safety reasons into consideration when dispensing kits to a subject.

Dose holds are particularly useful when more than one kit type is dispensed to a subject, as is the case in an oncology study, for example. The study protocol may allow one or all treatments to be paused by the investigator, and with dose holds, you can now do that in the study at any time.

Details for clinical supply managers

If your study requires you to configure dose holds, then keep reading the details below to learn about what's changing in your workflow:

- On the Supply Settings tab, there is now a new section called Dose Hold Settings. The new section features a toggle that you must click to activate the creation of dose holds. By default, the toggle is turned off.
- Clicking **Create Dose Holds** enables the Create Dose Hold dialog.
- On the Create Dose Hold dialog, you must specify all details required for successfully creating a dose hold: the kit type or titration group that can be put on hold for dispensation, the starting visit for the dose hold process, the maximum amount of pauses a subject may take from dispensation, as well as the frequency of these pauses.
- Upon completing all fields, you can either submit the dose hold and create another one right away, or simply click **Create** to configure one single dose hold at a time.

- All created dose holds are displayed in a table, in the Dose Holds Settings section.
- You can edit, remove, or deactivate an individual dose hold anytime during the study conduct period.
- You can create dose holds for any type of kit, as well as for any kind of dispensation visit, including visits that exist in visit branches.

Figure 14-4 How a clinical supply manager creates a dose hold

Create Dose Hold

Dose Hold Settings

* Kit Type or Titration Group: Ora 2

* Starting Visit: Branch 1 - Day 30

* Cycle: 2

Max per Subject: 5

Frequency per Subject:

- Unlimited
- Up to [] sequential dose holds
- Every 30 days

Buttons: Cancel, Submit & Create Another, Create

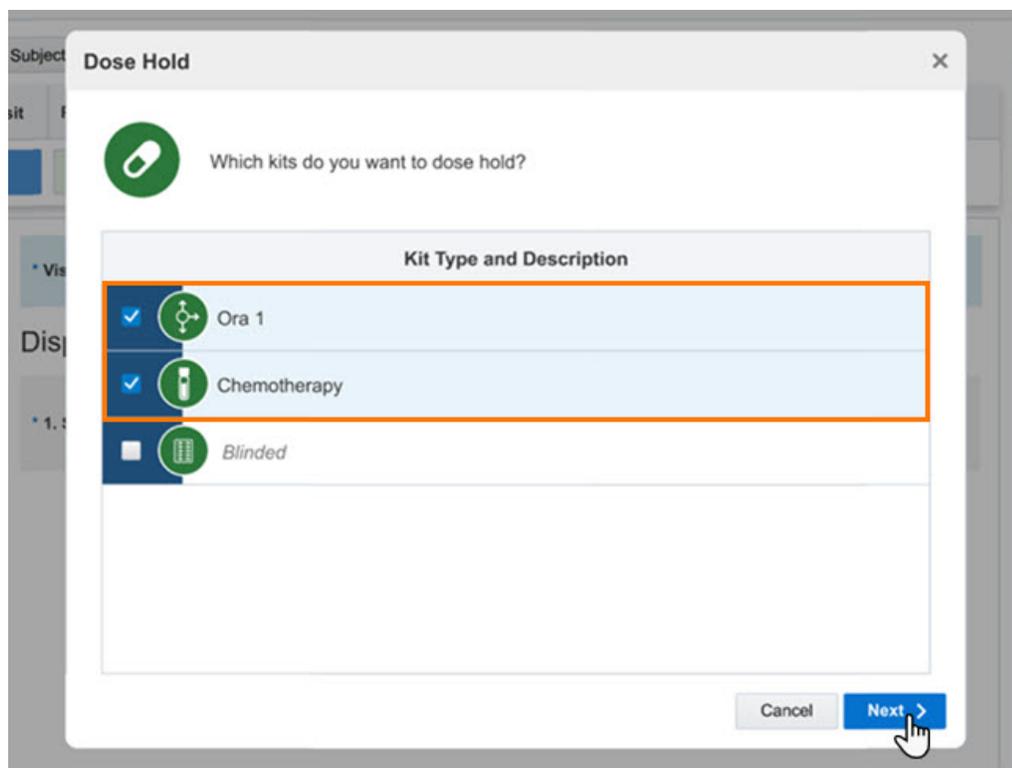
Details for site users

If you are required to pause dispensation for the safety of subjects, keep reading the details below to learn what's new for you:

- In a visit where dose holds are allowed, after completing all forms, a new button is displayed in the lower part of the page called **Dose Hold**.
- Clicking **Dose Hold** enables the Dose Hold dialog.
- On the Dose Hold dialog, all available kits for pausing dispensation are available. You must select at least one of the available kits to proceed to the Dispense Kits dialog.
- After clicking **Next**, on the Dispense Kits dialog, a list of kits that are dispensed to the subject is displayed, along with an associated message for the kit that was put on hold.

- All kits that were put on hold are displayed on the right side of the page and are marked as Dose Hold. If deemed safe and according to the protocol, you can always click the menu icon () next to a kit put on hold to dispense it to a subject.
- If you are a blinded site user and unblinded kits must be put on hold, on the Dose Hold dialog, you see a notice asking you to see your pharmacist or unblinded site user, so they can put the unblinded kits on hold.
- If you reach the maximum number of dose holds for a certain type of kit, then that kit type is no longer displayed on the Dose Hold dialog for you to pause dispensation on. If you reach the maximum number of dose holds for every type of kit available in a study, then the **Dose Hold** button is no longer displayed in a visit.

Figure 14-5 How a site user sees kits available for dose holds



Already working in a live study?

As soon as the upgrade for this release is ready, you can start configuring dose holds in your study in any of the three modes: Testing, Training, or Production.

New option for dispensing kits

Clinical supply managers can now define the dispensation logic in a study, by choosing whether kits should be dispensed by the closest expiration date and lowest kit number, or by the closest expiration date and lowest sequence number.

How does this new option work?

Today, the default dispensation method is to release kits by the closest expiration date and lowest sequence number. This method can result in partial unblinding if multiple kits are dispensed to a subject one at a time. For example, a site user could have a new patient who gets dispensed a kit from the same resupply order as another patient on the same treatment arm. In this situation, a site user may put together what treatment arm the patients are on. To maintain complete blindness in a study, clinical supply managers can change the dispensation protocol to dispense kits by the lowest expiration date and the lowest kit number.

This feature impacts the system differently when you have an open label drug (manufacturing lot) and a blinded drug (blinded lot). For example, a blinded lot expiration date is used as an expiration for all kits within the blinded lot regardless of their manufacturing lot expiration date. The system will pick the lowest kit number or lowest sequence number within the blinded lot regardless of the individual manufacturing lot expiration date.

Details for clinical supply managers

When it comes to your workflow, you must know that there is now a new supply setting called **Dispense Kits By**. This new setting allows you to choose between dispensing kits by the closest expiration date and the lowest kit number or the closest expiration date and the lowest sequence number.

You can configure this new setting for both new and existing studies.

Rules management

- [New rule expressions for fetching values](#)
As a rule designer, you now have new rule helper functions for creating queries programatically.

New rule expressions for fetching values

As a rule designer, you now have new rule helper functions for creating queries programatically.

What are the benefits?

With these new rule expressions, you can now read and filter data from forms, for a multitude of use cases, from creating a query if a value in a form increases by more than 10% to filtering values.

How does this new feature work?

Using a set of available Oracle Clinical One Platform helper functions, you can make use of functions tailored for users and maximizing productivity while creating custom rules. The new helper functions are:

- `GetValues()`

- FilterValues()

Already working in a live study?

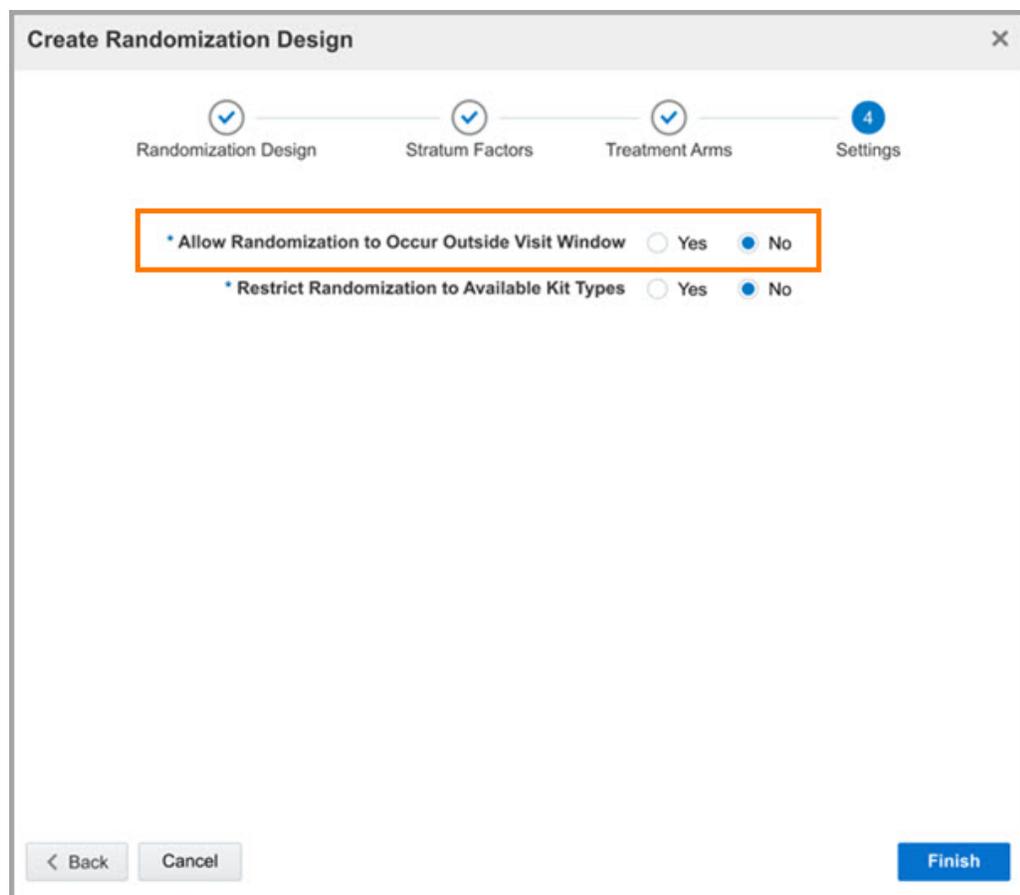
As soon as the upgrade is complete and this feature is available, get in touch with your Oracle project manager to get started on using the new helper functions. This feature is compatible with all existing and new studies.

Other enhancements

Create a non-dispensing randomization visit outside of its visit window

Study designers can now create a non-dispensing randomization visit and specify whether a subject's randomization can occur outside of the randomization visit window. To do that, a new setting is introduced on the Create Randomization Design dialog, called **Allow Randomization to Occur Outside Visit Window**. For that setting, a study designer can select either **Yes** or **No**, depending on what they want site users to do.

Figure 14-6 How a study designer configures the new randomization setting



The screenshot shows a dialog box titled "Create Randomization Design" with a close button (X) in the top right corner. At the top, there is a progress indicator with four steps: "Randomization Design", "Stratum Factors", "Treatment Arms", and "Settings". The "Settings" step is highlighted with a blue circle containing the number 4. Below the progress indicator, there are two settings, each with a radio button and a label:

- * Allow Randomization to Occur Outside Visit Window Yes No
- * Restrict Randomization to Available Kit Types Yes No

At the bottom of the dialog, there are three buttons: "< Back", "Cancel", and "Finish".

As for site users, if this setting is enabled in the study, they can start and complete a non-dispensation visit outside of its visit window. On the Subjects page, when they

begin the randomization visit of a subject outside of the visit window, a confirmation dialog is displayed, asking them whether they want to start the visit or not.

Update a treatment arm's name after study design approval

Whether you need to update your adaptive randomization design or the team made a typographical error, as a study designer, you can now update a treatment arm's name after the study version has already been moved to Approved.

In Draft, once you change a treatment arm's name and move that study version to Approved, the change is reflected in multiple product areas:

- In all study versions in Testing, Training, or Production.
- In the Randomization List, Kit Dispensation, the Titration Summary (Unblinded), and Subject Visits (Unblinded) reports.
- In an open label study or when a user performs a Code View or Code Break on a subject.

Blinded kit expiration dates now visible in the user interface

The blinded expiration date is now displayed for site users to see in the user interface. Using the blinded lot expiration date minimizes impact to existing studies and is helpful to have visibility when verifying kit expiration dates.

On the Site Inventory tab, the expiration date for a blinded kit is displayed to the right of the **Status** column.

The column for the expiration date will be hidden if the study does not have any blinded lots.

New reports in the application available in Japanese

Certain reports in the application are now available in the Japanese language. From now on, when you change your language preference to Japanese, the following reports will also be available in the same language:

- Subject Data Extract (in all formats: CSV, XPORT, and CPORT)
- Subject Visits (in all formats: CSV, HTML, and PDF)
- Kit Dispensation (in the HTML and PDF formats)
- Subject Queries (in all formats: CSV, HTML, PDF)
- Study Design (in the HTML and PDF formats)

Browse the rest of our Japanese documentation here: [Oracle Clinical One Platform and Oracle Clinical One Integration Hub in Japanese](#).

Dedicated user guide for study designers

With each release, the study design component of our application becomes more powerful and more complex, too. To further help study designers get the quality user assistance that they need, we have created a brand new and improved user guide for study designers. In there, they can find step-by-step instructions for every task, organized by category, whether it is related to visits, forms, questions, code lists, or dispensation.

Previously found in the *Information for CRO and Sponsor Users* publication, almost all of the study design tasks and conceptual information are now part of the Study Designer User Guide.



Note:

Step-by-step instructions for the advanced study versioning techniques remain in the *Information for CRO and Sponsor Users* publication.

Fixed issues

- Fixed issues affecting all users
- Integrations
- Forms, visits, and rules
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data
- Oracle Clinical One Analytics fixed issues
- Forms, visits, and rules
- Integrations
- Sites, labs, depots, settings, and user management
- Site users and subject data
- Randomization and kits
- Reports, archives, extracts, and notifications
- Forms, visits, and rules
- Integrations
- Randomization, shipments, and kits
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site user and subject data

Oracle Clinical One Analytics fixed issues

Some data elements are not properly displayed in all datasets (former known issue)

Now, in all datasets in the application, some data elements no longer display a null value when being used in a report for the first time. The data elements displaying proper data in reports are the corresponding elements for the site permissions in Oracle Clinical One Platform:

- Add Subjects
- Screen Subjects
- Randomize Subjects
- Dispense to Subjects

Previously, upon changing the corresponding settings in Oracle Clinical One Platform, the value was displayed as either True or False for each data element. Instead, the value for each data element should have been displayed as it was reflected in Oracle Clinical One Platform from the start, without requiring an in-app update by the user.

Retracted workaround: None. (Issue **32913138**)

Total_Form count not properly displayed in Subject dataset (former known issue)

Now, the value of Total_Form refreshes properly in the Subject dataset report and shows the correct value as soon as a new form is created in Oracle Clinical One Platform:

Previously, when a new form was created in Oracle Clinical One Platform in a live study through an in-place revision, Total_Form was not being updated properly until the visit was closed and re-opened.

Retracted workaround: None. (Issue **32939736**)

Forms, visits, and rules

Empty code list fields are not highlighted in the user interface (former known issue)

Study designers: Now, when you attempt to save a code list that contains empty mandatory fields, the user interface now highlights all of those fields, letting you know what is wrong with your code list. Previously, the UI did not highlight all empty mandatory fields. Instead, you simply could not save the code list. This created confusion, since you did not know what prevented you from saving the code list.

Retracted workaround: None. (Issue: **32893048**)

Some new forms are not displayed in the expected study versions (former known issue)

Study designers: Now, when you add new forms to a live study version and assign them to multiple visits, using advanced study versioning techniques, these new forms are displayed for all subjects at all sites. Previously, there were times when not all forms added into a live study version were displayed during all of the visits that they were assigned to, for subjects at certain sites.

For example, you created a new form and applied each question in the form to the desired study version. After that, you assigned the new form to Visit A and Visit B. On the Subjects page, you may have noticed that the newly added form was only displayed for Visit A, but not for Visit B.

Retracted workaround: You no longer have to sign out and then sign back in, to see if the newly added form is displayed, as expected. (Issue **32883082**)

Form cannot be saved upon removing Show Visit dynamic rule

Study designers: Now, when you dynamically schedule a visit in a study (not in a branch) and then you attempt to remove the Show Visit dynamic rule applied to the question that determines the display of the visit, you can save your changes in the form, as expected. Previously, upon clicking **Save**, a confusing error message was displayed stating "Update form failed" and none of your changes were saved. (Issue **33053839**)

Cannot update cycle visit settings for a Production study (former known issue)

Study designers: Now, when you attempt to change the settings of a cycle visit (specifically, the Starting Cycle Number and Restart Cycle Numbering settings), an error message is no longer displayed. Previously, whenever you attempted to update any of these two settings, an error message was displayed letting you know that you cannot update a branch after a study version has been approved.

Retracted workaround: None. (Issue **32656031**)

Integrations

Integration group status displayed only based on enabled integrations

Integration managers: Now, in the Oracle Clinical One Digital Gateway application, only the statuses of enabled integrations are taken into consideration when displaying an overall status of an integration group. If an integration group contains only disabled integrations, then no group status is displayed at all. Previously, the application took disabled integrations into account, as well, sometimes displaying statuses for integration groups that were not relevant to the user. (Issue **32525577**)

Cleared answers for a question with radio buttons not sent to Oracle InForm

Integration managers: Now, in Oracle Clinical One Platform, when you change the answer of a question with radio buttons, the update is properly sent to Oracle InForm. Previously, when you made this type of change, the data was not cleared in Oracle InForm, as expected. (Issue **32806345**)

This fix is part of an enhancement introduced in this release. For more information, see [Send information on data flags to Oracle InForm](#).

Data not sent to Oracle InForm after a manual screen failure

Integration managers: Now, in Oracle Clinical One Platform, when you manually screen fail a subject and then update the data in a form assigned to the screening visit, those data updates are sent to Oracle InForm, as expected. Previously, data updates were only sent to Oracle InForm after an automated screen fail, as the visit was considered completed in the system. (Issue **32859366**)

Sites, labs, depots, settings, and user management

Timezones not properly displayed in Japanese

Clinical supply managers: On the Supply Settings tab, timezones and their details are properly displayed when the selected language for the application is Japanese. Previously, these details weren't displayed as expected in the user interface. (Issue **32750540**)

Custom enrollment group using complex criteria may not work (former known issue)

Study managers: Now, when you create a custom enrollment group using criteria associated with multiple visits, the enrollment group works as expected. Previously, when you used such a type of a custom enrollment group, the limits were not properly enforced in the application.

Retracted workaround: None. (Issue **32911507**)

Japanese characters cannot be used in a region's title

Study managers: Now, when the application's language is set to Japanese, and you attempt to enter a title for a region, you notice that Japanese characters are saved as expected. Previously, upon using Japanese characters to name a region, an error message was displayed stating that only letters and numbers were allowed. (Issue **32707029**)

Consistency validation in custom enrollment groups not working as intended (former known issue)

Study managers: Now, when working with custom enrollment groups in your studies, you are prevented from using form questions that are different from the latest study version. Previously, you were allowed to save the custom enrollment limit that created deprecated questions.

Retracted workaround: None. (Issue: **32904639**)

Site users and subject data

Verify checkbox not displayed for all lab form instances (former known issue)

Clinical Research Associates (CRAs): Now, in a lab form, you can properly verify all completed instances in a form. Previously, checkboxes for data verification were displayed for all lab form instances except for the completed ones.

Retracted workaround: None. (Issue **31949885**)

Using the Tab key to navigate between answer options might not work (former known issue)

Site users: Now, when creating a new subject and attempting to select an answer for a question with checkboxes, you can use the Tab key to navigate between all answer options. Previously, pressing the Tab key only allowed you to move backwards to the first item automatically.

Retracted workaround: You no longer need to use only the Up and Down keys or mouse to navigate between the checkboxes. (Issue **32288019**)

Incorrect error message is displayed when editing a validation rule for the Fasting question (former known issue)

Study designers: Now, when you attempt to change the Select Exactly validation rule applied to a Fasting question, a proper user interface message is displayed letting you know of the condition. Previously, a confusing error message was displayed instead of stating that only that exact type of rule can be applied for a Fasting question.

Retracted workaround: None. (Issue **32465008**)

Site inventory filters do not work for an unblinded site user

Site users: Now, as an unblinded site user, when you want to view kits on the Site Inventory tab, you can do so without experiencing any issues. Previously, you could not view all kits on this tab and you could not use any of the search filters on the page. (Issue **32868418**)

Dates in the Japanese language follow the expected format

Site users and sponsor users: When setting your language preference to Japanese, you will now notice that the dates are properly displayed using the YYYY-MM-DD format in the following product areas:

- Subjects page
- Subject History
- Answer History
- Visit History
- Queries
- Subject Transfer confirmation dialog

Previously, dates in these product areas were displayed using the DD-MON-YYYY format where the MON element was sometimes translated to Japanese and other times it was displayed in English. (Issue **32936975**)

Optional visits inside a branch will now work different than outside a branch (former known issue)

Site users: Now, when part of a branch, an optional visit can be skipped. Previously, an optional visit included in a visit branch had to be completed in order to be able to get to the next visit.

Retracted workaround: You no longer have to avoid using optional visits in a branch. (Issue **32747495**)

Randomization and kits

Minimization design displays confusing error message (former known issue)

Study designers: Now, when you create a minimization design and attempt to save it, the right error message is displayed stating that you should use a multiple-choice question with a Select Exactly or Answer Must Be validation rule applied to it. Previously, a confusing error message was displayed when you used the incorrect type of question to define the minimization criteria.

Retracted workaround: None. (Issue **32641743**)

Updates to a predictive resupply strategy are not saved

Clinical supply managers: Now, when you attempt to change the Trigger Weeks and Resupply Weeks in a predictive resupply strategy, you can save these changes in the application, as expected. Previously, upon updating any of those two values, you may have noticed that the application did not let you save these changes. Instead, the application only let you save the updates when you made any changes to the other fields or columns, such as Minimum Buffer, Maximum Buffer, First Shipment, or Manual Shipment. (Issue **33160901**)

Confusing user experience noticed with system-generated randomization lists (former known issue)

Clinical supply managers: Now, you can successfully upload a system-generated randomization list in the application, even though the file contains commas within any

fields. Previously, when uploading a system-generated randomization list, an error message appeared stating that the file contains invalid characters, empty rows, or cells. However, the file itself was generated by the system, so it shouldn't have contained characters or formatting issues that would have prevented you from uploading it. Moreover, upon receiving the error message described above, you may have noticed that the list was actually uploaded and displayed in the user interface. The following issues were observed for a randomization list that contained commas within a field.

Retracted workaround: You no longer need to double-check your randomization list to make sure it does not contain any commas within any fields. (Issue 32267431)

Reports, archives, extracts, and notifications

Updated reference code not displayed as expected in Rules Report (former known issue)

Study designers and rule designers: For a published JavaScript rule, when a study designer updates a question's reference code, the updated reference code for that question is now displayed in the Rules Report, in the columns labelled "Question RefName" and "Variables". Previously, the previous reference code was displayed in these columns instead of the updated one.

This issue impacts the Rule Report only. The published JavaScript rule continues to run as specified by the rule designer.

Retracted workaround: None. (Issue 32064664)

Cannot download empty Site Confirmation report (former known issue)

Sponsor users: Now, on the Reports & Archives tab, when you attempt to generate a Site Confirmation report without a required confirmation of sites, you can complete the task. Previously, even though no confirmation was required for downloading an Archival PDF, you could not generate and download a Site Confirmation report.

Retracted workaround: None. (Issue 32705509)

Duplicate records displayed in Download Log (former known issue)

Sponsor users: Now, while your application is set to Japanese, when you attempt to generate and download a Download Log in a CSV format, no more duplicate records appear. Previously, in Testing mode, you may have seen duplicate records.

Retracted workaround: None. (Issue 32928254)

Bookmarks in the Blank Form PDF displayed in the wrong language

Sponsor users: Now, when you generate a Blank Form PDF and the application language is set to Japanese, the bookmarks of the Study Version PDF are displayed as expected, indicating that they are in the Japanese language. Previously, bookmarks were displayed as though the language was English for every study version. (Issue 32896315)

Old study name appears in Oracle CRF Submit Archive (former known issue)

Study team members: From now on, in an integration between Oracle Clinical One Platform and Oracle CRF Submit, if you need to update the name of the integrated study in Oracle CRF Submit, the updated study name will be displayed as expected in the Archival PDF. Previously, you may have noticed that, despite updating it, the old study name continued to appear in the Archival PDFs you generated in Oracle Clinical One Platform.

Retracted workaround: None. (Issue **32359641**)

Site Confirmation Report should return data as-of-date specified

Site users: Now, the as-of-date data is displayed when you attempt to run a Site Confirmation report. Previously, it was not specified in this report.

Retracted workaround: None. (Issue: **32418549**)

Date of Visit is not translated in Japanese in the Submission PDF

Sponsor users: Now, when generating a Submission PDF, you will notice that the Date of Visit field is translated to Japanese in the Subject and Blank Form PDFs. Previously, this field was not translated and the issue was observed when you had already changed the application's language to Japanese.

Retracted workaround: None. (Issue: **32901067**)

Reason for Change in Audit Trail field not translated to Japanese (former known issue)

Sponsor users: Now, when you generate the Submission Request PDF, you will notice that the Reason for Change field is translated to Japanese. Previously, this field was not translated. This issue was observed when you had already changed the application's language to Japanese.

Retracted workaround: None. (Issue: **32912245**)

Signature Affidavit text is not displayed in Japanese (former known issue)

Sponsor users: Now, when downloading an Archival PDF in Japanese, the Signature Affidavit text is translated. Previously, this piece of text was not translated to Japanese.

Retracted workaround: None. (Issue: **32927762**)

Subject Data report does not display question labels for newly added forms (former known issue)

Site users: Now, in the Subject Data report, when you run a report for a previous study version where a new form was added, all subjects have the question labels included in the new form displayed on the Question Label column. Previously, some subjects had "N/A" displayed on the Question Label column for the newly added questions.

Retracted workaround: none. (Issue **32850647**)

Download and Confirm links are not properly translated in Japanese

Site users: Now, when you attempt to download and confirm the download of an Oracle CRF Submit archive, you notice that both the Download and Confirm links are properly translated in Japanese. Previously, these two links were displayed in English, despite the user having selected their language preference as Japanese. (Issue **32873220**)

Apply Changes to Study Version column displays expected data in the Study Design report

Study designers: Now, when you run the Study Design report, the Apply Changes to Study Version column displays the expected data for questions and forms that were

updated for different study versions. Previously, when consulting the report you may have noticed that the Apply Changes to Study Version column displayed N/A even though the question or form was added or updated for another study version. (Issue **33103334**)

Queries-related data is not displayed in Japanese in an Archival PDF (former known issue)

Sponsor users: Now, when downloading an Archival PDF in Japanese, the query text in the Audit page is displayed in Japanese. Previously, the query information was not displayed in Japanese, even though that was the language preference set in the application. This happened for queries in a state of Answered, Closed, and Candidate.

Retracted workaround: None. (Issue **32927878**)

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 21.1.1 (May 2021)

- [Patch Log](#)
- [What's new](#)
- [Fixed issues](#)

Patch Log

This topic briefly describes the history of small fixes we have applied to the 21.1.1 release. None of these fixes affect the user workflow 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.**

Release number	Release date	Notes
Release 21.1.1.1	07-June-2021	For this release, we fixed some issues affecting subject queries.
Release 21.1.1.2	14-June-2021	This release is a patch to enable Oracle Clinical One Analytics for customers to Release 21.1.1.
Release 21.1.1.3	24-June-2021	This release is a patch to improve the user experience of Oracle Clinical One Analytics users.
Release 21.1.1.4	05-July-2021	This release is a patch to apply some fixes related to reports, coded terms, and Oracle Clinical One Analytics.
Release 21.1.1.5	16-July-2021	This release is a patch to turn on additional logging for an API related to the integration that sends data from Oracle Clinical One Platform to Oracle InForm.

What's new

- [Set custom enrollment limits](#)
Study managers can now control the enrollment of subjects in their study based on specific criteria. This allows them to customize their subject pool to meet the needs of their study or limit enrollment in a long-term study.

- [Add new forms to a live study](#)
Study designers can now add new forms to visits in live study versions.
- [Operate studies in the Japanese language](#)
Oracle Clinical One Platform now gives you the option of operating the application and studies in the Japanese language.

Set custom enrollment limits

Study managers can now control the enrollment of subjects in their study based on specific criteria. This allows them to customize their subject pool to meet the needs of their study or limit enrollment in a long-term study.

The limits study managers create can be used to determine the number of subjects that must be screened, enrolled, or moved to a new phase of the study. Study managers are able to restrict the enrollment of subjects based on multiple answer and number types of questions.

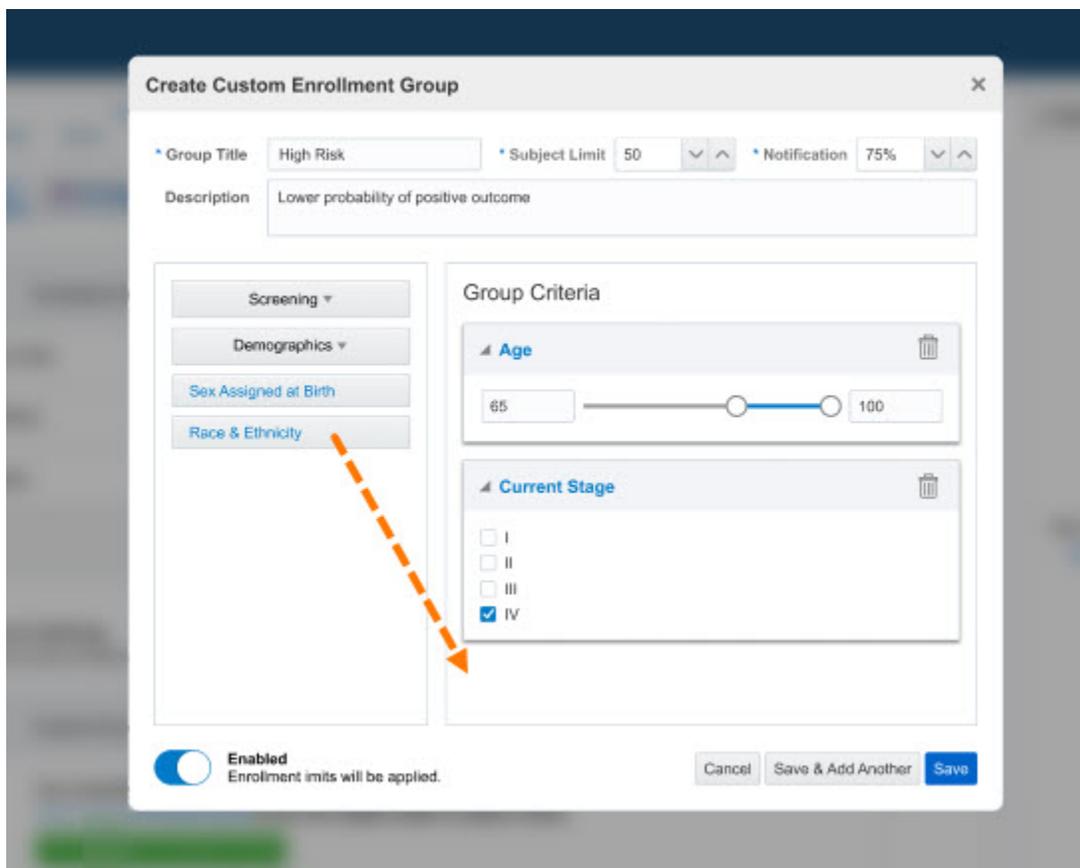
Details for study managers

If you plan on creating custom enrollment limits for your study, there are several changes in your workflow:

- On the Study Settings tab, a new Custom Enrollment Settings section is displayed where you can define your custom enrollment groups.
- Upon clicking the **Add Custom Enrollment Group** button, a new dialog appears where you can define the exact criteria and limits of enrollment.
- On the Create Custom Enrollment Group dialog, you must first specify different types of data for your limits, including the title of the custom enrollment group, the subject limit, the percentage of enrolled subjects that should generate a notification, and a description if there is additional information that does not fit in the title.
- In the Create Custom Enrollment Group dialog, you can click **Select a Visit** to view the Screening visit.
- Forms from multiple visits can be selected to use for enrollment limits.
- You can view a visit's form questions by clicking the **Select a Form** button in the Create Custom Enrollment Group dialog.
- On the Group Criteria section, you must drag and drop elements that will serve as criteria for your custom enrollment groups, such as number questions, or questions with radio buttons and multiple choices.
- Each category within the Enrollment Settings field can be toggled on or off. This allows you to separate or combine multiple answers in a multi-select question.
- Each category within the **Enrollment Settings** field can have its own screening and enrollment limits, as well as percentage indicators for notifications sent to authorized users.
- Typically, a study manager, clinical supply manager or CRA can be notified of this limit and when it is reached by assigning them with the *Receive the Study Limits Notification* permission.
- When overlapping limit groups are defined, the system will match against these groups in the order that they were added. Once the first group's limit is met, then

the system will fulfill the next group's limit, and so on, until all overlapping group limits are met.

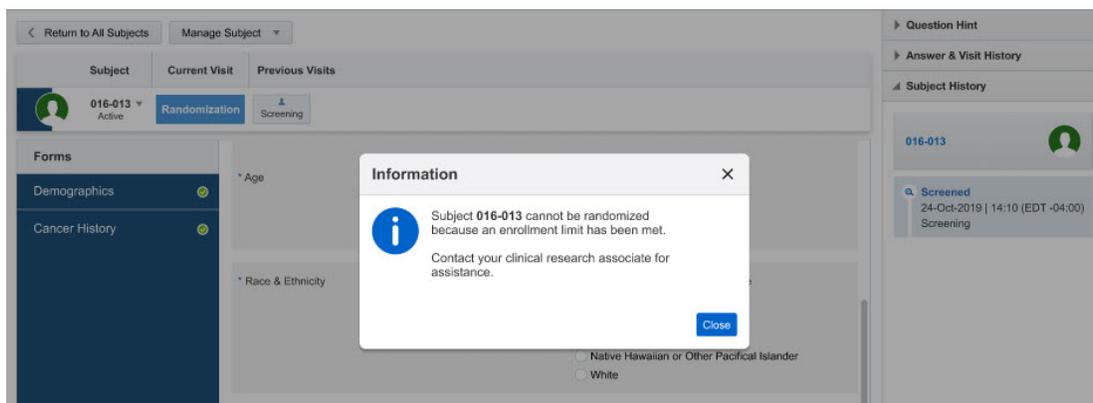
Figure 15-1 How a study manager defines criteria for a custom enrollment group



Details for site users

When it comes to this new feature, there are no changes in your workflow. However, you must know that an information message may appear whenever you attempt to screen or enroll a subject beyond the enrollment limit set in your study.

Figure 15-2 What a site user sees when they reach a custom enrollment limit at a site



Already working in a live study?

As soon as the upgrade is ready, you can begin creating custom enrollment groups in any mode (Testing, Training, and Production) for your study. Additionally, you must know that:

- The system always uses the latest study version in a given mode for the enrollment limits. When you edit a limit group, the system validates the settings and form questions against the latest study version, and flags any errors where there are inconsistencies. This makes the **Save** button inactive since you are only able to save your changes in an enrollment group, as long as they are correctly defined.
- When handling sites with older study versions, the system always uses the data on the subject to match against the enrollment limits groups, regardless of the study version assigned to a site. If the data matches the settings, the enrollment limit is enforced.
- Once the enrollment limit is implemented, subjects screened prior to implementation will not be counted towards enrollment limit.

Add new forms to a live study

Study designers can now add new forms to visits in live study versions.

With this new advanced study versioning enhancement, you not only gain more flexibility when it comes to planning the study design, but can also implement changes into multiple study versions with no downtime.

From now on, whenever you want to create a new form and add it to a live study version, you must:

- Use the **Apply Changes to Version** setting for each question in the newly designed form.
- From the drop-down list, make sure you select the earliest study version to which you want to add the new form. The drop-down contains a list of all study versions in Testing, Approved, and Archived mode.
- Assign the form to a visit and move the Draft study version to to the Testing mode.

Newly added forms are displayed in the selected study version and subsequent versions.

Operate studies in the Japanese language

Oracle Clinical One Platform now gives you the option of operating the application and studies in the Japanese language.

As an end user, you now have a simple and user-friendly way of switching to the Japanese language in the Oracle Clinical One Platform application.

The first time you sign into the application, you will notice that the default language of the application is English. On the Home page, click your user name, and choose **Japanese** from the **Choose Language** drop-down to switch to Japanese at any time. After you select the Japanese language, the user interface refreshes, allowing you to see it translated into Japanese. Your language preference is preserved for the next login session.

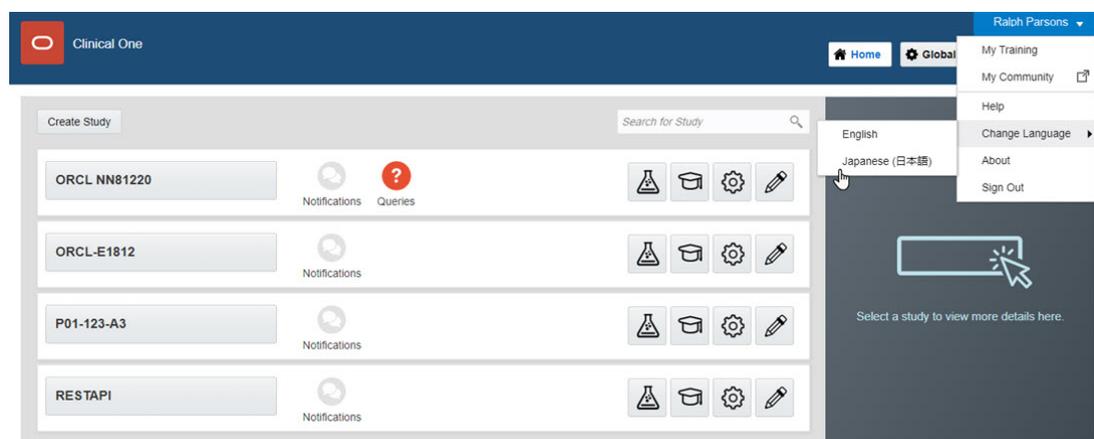
Localizing the Oracle Clinical One Platform application to accommodate the needs of users who speak different languages is part of a broader project that our team is currently working on. For this release, we focused only on translating all product areas that impact the site user's experience, as well as core labels, titles, system messages, and site-facing code lists. Standard reports and notifications will also be translated as part of an upcoming feature.

User documentation in Japanese

To make sure your user experience is complete, we have translated our entire Oracle Clinical One Platform documentation set to Japanese. From now on, not only can you operate your study in Japanese, but if you ever need user assistance, you can browse the documentation in the same language.

To learn more, see [the Japanese documentation on the Oracle Help Center](#).

Figure 15-3 How a user sees the Change Language drop-down



Fixed issues

- [Forms, visits, and rules](#)
- [Reports, archives, extracts, and notifications](#)
- [Site users and subject data](#)
- [Sites, labs, depots, settings, and user management](#)

Forms, visits, and rules

Oracle Central Coding Japanese dictionaries are currently unavailable (former known issue)

Study designers and site users: Now, in Oracle Clinical One Platform, when you design a coding question and select either one of the Japanese versions of a dictionary (JDRUG or MedDRA-J), the terms then collected by a site user are properly coded in the Japanese language. Previously, even though the Japanese dictionaries were displayed in the user interface, they could not be used for coding terms in a study.

Retracted workaround: None. You can now use Japanese dictionaries to code terms. (Issue **32581325**).

APIs display incorrect count of copied rules

Study designers and API developers: Now, when you duplicate or copy a form from one study to another, and that form contains an age type of question, the ruleCopyCount parameter displays 0 in the API Request. Previously, upon copying or duplicating this type of form, the ruleCopyCount parameter displayed 1. This count should only take custom rules into account and not any predefined or validation rules created in study design. (Issue **32619655**)

Study Supplies tab is not properly translated in the Japanese language

Study designers and clinical supply managers: Now, when you switch from English to Japanese in the application, you will notice that the Study Supplies tab name is properly translated in the Japanese language, in all modes (Testing, Training, and Production). Previously, the translation of this word in Japanese was considered incorrect. (Issue **32820317**)

Don't move randomization after subjects are randomized (former known issue)

Study designers: Now, when you move the randomization design to a different visit (after subjects have been already randomized in the study), the Randomize option is no longer displayed for subjects who have already been randomized. Previously, the Randomize option was still displayed on the Manage Subjects drop-down, possibly confusing a site user and determining them to attempt to randomize a subject again.

Retracted workaround: You no longer have to create additional visits with new randomization designs assigned to them. (Issue **27469976**)

Reports, archives, extracts, and notifications

Japanese characters not allowed in the title of an archive (former known issue)

Sponsor users: Now, on the Reports & Archives page, the Archives tab, you can generate an Oracle CRF Submit Archive with a title containing Japanese characters. Previously, an error message was displayed, stating that you must only use a name that contains letters or numbers. This issue is now fixed with the implementation of our localization feature.

Retracted workaround: You no longer have to avoid using Japanese characters when naming your Oracle CRF Submit archives. (Issue **32585904**)

Scheduled visits are out of order in the Study Design report (former known issue)

Study designers: Now, in the Study Design report, the Study Design Summary section displays the scheduled visits as they were ordered in the study design. Previously, scheduled visits displayed in this section were out of order.

Retracted workaround: None. (Issue **32420850**)

Site users encounter issues with Blank Form PDFs (former known issue)

Site and sponsor users: Now, when you are assigned the Site User predefined study role, you can generate a Blank Form PDF without any issues.

Previously, when you were assigned certain predefined study roles, you may have noticed that you could not generate a Blank Form PDF. This issue was especially

encountered when the user attempting to generate the archive was assigned the predefined study role template for a site user and when the selected study version contained a form with all of its questions marked as **Hidden**, in study design.

This issue is now fixed by excluding forms that contain hidden questions from the archive.

Retracted workaround: None. (Issue **32430001**)

Updated lab name is displayed in Archival PDF with wrong date (former known issue)

Study team members: Now, when a site user completes a lab form and then changes the laboratory's name, you'll notice the previous name of the lab appears in the Archival PDF (the Subject PDF) in the As-of-Date field, as expected. Previously, upon updating a lab's name and then generating the Archival PDF you noticed that the newly updated lab name was displayed for the As-of-Date field.

Retracted workaround: None. (Issue **32057781**)

Blank Form PDF cannot be downloaded when Japanese characters are included

Site and sponsor users: Now, when you generate a Blank Form PDF in a study whose title contains Japanese characters, the Blank Form PDF is generated and can be downloaded successfully. Previously, when Japanese characters were included in a study's title, and you attempted to generate a Blank Form PDF, the archive request was submitted, but you could not download the archive. (Issue **32586565**)

Site users and subject data

No validation message displayed for multi-byte characters (former known issues)

Site users: Now, in a form, when you attempt to answer a number type of question and enter multi-byte characters (such as roman numerals or Japanese characters), and then save the form, a proper validation error message is displayed. That error message clearly states that you must only type numbers, no letters, no spaces, and no special characters, except for commas and periods. Previously, upon entering multi-byte characters in an answer field for a number type of question, the application did not save your changes and it did not notify you of the data not being entered in an expected format.

Retracted workaround: None. (Issue **32614394**)

Sites, labs, depots, settings, and user management

First site and depot address does not recognize Japanese characters

Site managers and clinical supply managers: Now, on both the Create Site and Create Depot dialogs, in the Address 1 field, when you enter a site's or depot's address written in Japanese characters, a validation error is no longer displayed and you can proceed with creating your site or depot in the application. Previously, when you entered an address written in Japanese characters, a validation error message was displayed. The error message stated that the address must contain at least one text character. (Issue **32582279**)

Permission to edit classified sponsor data not working for a data manager (former known issue)

Data managers: Now, when you are assigned the permission to both view and edit certain types of data, classified fields in a form are displayed as editable. Previously, with the permission to both view and edit sponsor data, when you accessed a form that contained

classified sponsor data, you may noticed that every field in the form was read-only, including fields that you should have been able to edit. This issue is now fixed with the introduction of two new permissions for viewing and editing classified data.

Retracted workaround: None. (Issue **32063773**)

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Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.1 (April 2021)

- [What's new](#)
- [Fixed issues](#)
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What's new

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Integrations

- [Send data on unscheduled visits to Oracle InForm](#)
With this newly introduced feature, integration managers can now send data on unscheduled visits from Oracle Clinical One Platform to Oracle InForm.

Send data on unscheduled visits to Oracle InForm

With this newly introduced feature, integration managers can now send data on unscheduled visits from Oracle Clinical One Platform to Oracle InForm.

How does this work?

In short, if unscheduled visits are included in a study in Oracle Clinical One Platform, with a properly configured integration template, you can now send data on unscheduled visits to Oracle InForm. Data sent through an integration can include dispensation of kits, kit replacement, and re-allocation of kits that took place during an unscheduled visit.

To send unscheduled visit data through your integration, reach out to your Oracle Project Manager.

Randomization and trial supply management

- [Minimize imbalances between treatment arms](#)
Study designers can now choose to use the minimization technique for a study randomization. This method reduces imbalances between subjects in treatment arms.

This new feature includes impact on the workflow of clinical supply managers and study managers, as well.

- [Define more relevant details for visit cycles](#)
Study designers can now define more details for visit cycles in a branch.
- [Update the order form after the shipment request has been changed](#)
Clinical supply managers and depot users can now update the Shipment Order Form after the initial order has been modified.

Minimize imbalances between treatment arms

Study designers can now choose to use the minimization technique for a study randomization. This method reduces imbalances between subjects in treatment arms. This new feature includes impact on the workflow of clinical supply managers and study managers, as well.

What are the benefits?

Minimization aims to balance treatment arms within a study while eliminating treatment selection bias. Oracle Clinical One Platform provides a configurable, validated system that accommodates any number of prognostic (stratum) factors, treatment allocation proportions, and the weight of each stratum factor.

Details for study designers

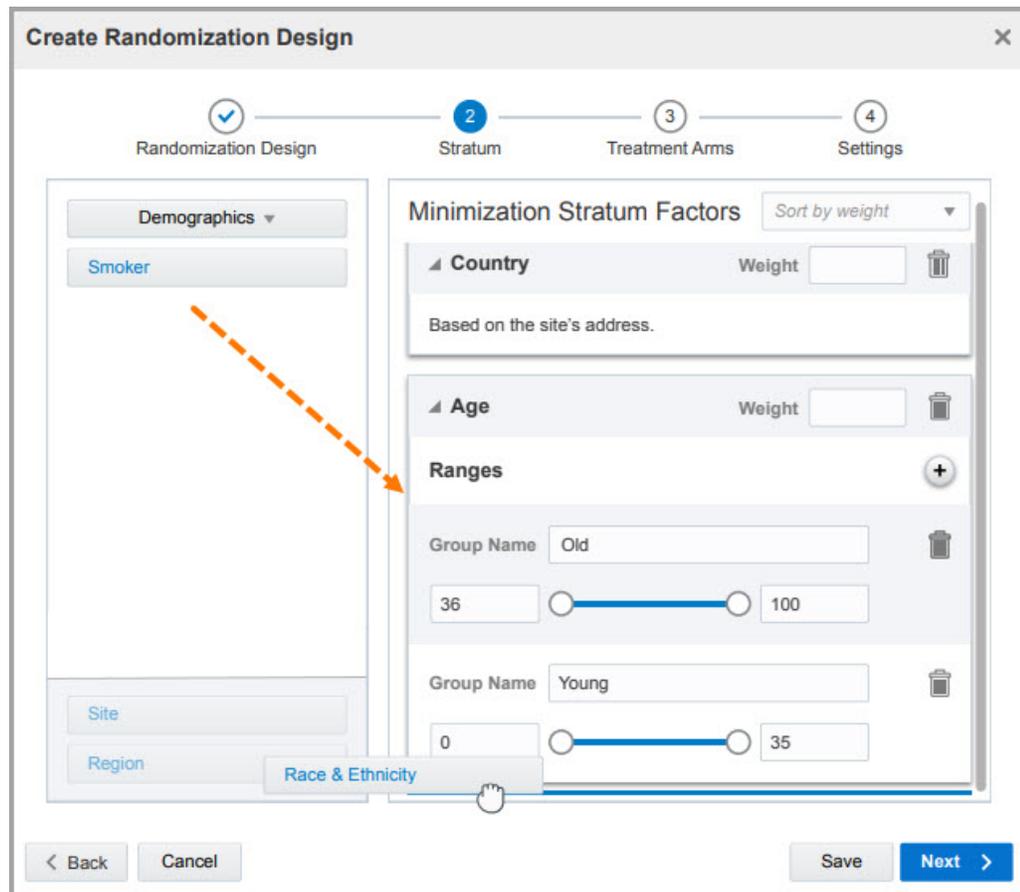
While the defining steps for creating a randomization design are more or less the same, there are some user interface changes that you must be aware of:

- On the Study Supplies tab, the Create Randomization Design dialog, you can now choose to create a **Minimization** type of randomization design.
- On the same Create Randomization Design dialog, you can also define this design's minimization stratum factors using location elements such as country, site, or region, and questions typically included in the Demographics form, such as questions on age, race and ethnicity, or questions on a subject's health patterns.
- You must define the weight of each minimization stratum factor by entering an even number (from 0 to 99) in the **Weight** field displayed for each factor. This way, the system knows how to balance the number of subjects between stratum factors throughout the course of the study. Multiple minimization stratum factors can have the same weight.
- By default, the system maintains a balance between all options of a multiple-choice type of question used in a stratum factor. However, you can also maintain balance across fewer of these groups (based on the selected choice) by combining all of the question's options into your own custom groups. For example, for a stratum group built based on the Age question, you can define two custom groups for old and young patients, each with its own age range.
- Additionally, for an age type of question, you must specify a range validation rule, to make sure you can create the appropriate custom groups for the Age stratum factor. For more details, see [Create a validation rule for a question](#).
- Questions used in minimization designs are marked appropriately in the user interface with a specific icon. Attempting to remove or modify these questions enables a confirmation from the system to ensure that you really want to make updates that will affect your minimization design.

Figure 16-1 How a study designer sets a minimization

The screenshot shows a 'Create Randomization Design' dialog box with a progress indicator at the top showing four steps: 1. Randomization Design (active), 2. Stratum Factors, 3. Treatment Arms, and 4. Settings. The 'Randomization Design' section includes a 'Title' field, a 'Description' text area, a 'Type' dropdown menu set to 'Blinded', a 'Randomization' dropdown menu set to 'Minimization', and 'Re-Randomization' radio buttons for 'Yes' and 'No' (with 'No' selected). A preview window on the right displays a green circular icon with a white double-headed arrow and the text 'Type: Blinded' and 'Randomization: Minimization'. At the bottom, there are 'Cancel', 'Save', and 'Next >' buttons.

Figure 16-2 How a study designer sets stratum factors



Details for study managers

On the Study Settings tab, under Enrollment Settings, you can now configure limits and settings for the existing minimization cohorts.

First off, for each minimization cohort, you can turn on a toggle to open the enrollment of subjects.

In the **Enrollment and Randomization Limits** column, you can define the limits for enrolling and randomizing subjects in the minimization cohorts designed in a study. And in the **Notifications** column, you can indicate the percentage of subjects who can be randomized or enrolled before a notification occurs.

Figure 16-3 Where a study manager configures limits for minimization cohorts

The screenshot displays the 'Enrollment Settings' interface. It features a table with three columns: 'Enrollment Open/Closed', 'Enrollment/Randomization Limits', and 'Notification'. The rows include 'Study Total', 'Site Total', and 'Country', each with a toggle switch and numerical input fields. Below these, the 'Minimization Cohorts' section is highlighted with an orange border and contains a sub-section for 'Minimization 2.0 Cohorts'.

Enrollment Open/Closed	Enrollment/Randomization Limits	Notification
<input type="checkbox"/> Study Total	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>
<input type="checkbox"/> Site Total	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>
<input type="checkbox"/> Country	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>	<input type="text"/> <input type="button" value="v"/> <input type="button" value="^"/>
Minimization Cohorts		
▶ Minimization 2.0 Cohorts		

Details for clinical supply managers

When it comes to your workflow, a few things have changed. For a minimization design, you must keep in mind the following details:

- You can only upload a randomization list, you cannot generate a randomization list in the system.
- Typically, minimization does not use a randomization list and the assignment of treatment arms is done dynamically based on the balance of subjects across the defined parameters. Still, you can upload a randomization list that must contain two columns: a column for the **Randomization Number** and another column for the **Probability Factor**, that defines a probability score for each randomization number. The probability number must be a decimal value between 0 and 1, exclusive.
- Randomization numbers are assigned in a sequential order.
- In any study mode (Training, Testing, or Production), on the Randomizations tab, you can select the list used for minimization and then proceed to update randomization numbers in the context of the selected minimization design.

Figure 16-4 How a clinical supply manager maps columns in a randomization list

Upload Randomization List

Select Randomization List Settings **3** Map Headers Finish

Tip: Choose a new column label for each column in the file.

Imported File Headers	Mapped To
Randomization Number	Don't import
Probability Factor	Don't import

< Back Cancel Upload >

Already working in a live study?

If your study is currently live, but you wish to integrate minimization into your study, you can absolutely do that. But before you dive into this advanced study versioning task, here are some things that you must know:

- As a study designer, you cannot update the site, country, or region selection of a minimization design for a study version that's currently running live. You also cannot update, add or remove stratum factors and custom groups within a stratum factor for a live study version.
- As a clinical supply manager, you can associate a new minimization design to a new randomization list or even remove their association in the system. Updates to an existing minimization design do not affect a randomization list used in the system.
- When a minimization design is updated, the balance between stratum groups and treatment arms may be off in the beginning because subjects previously randomized will be characterized based on the defined stratum groups at the time of the randomization.
- When uploading a new randomization list for a minimization, keep in mind that the balance of subjects is based on that list, not across multiple lists. With that in mind,

you should upload a randomization list that contains extra randomization numbers to reduce the risk of running out of randomization numbers if the protocol changes to include more subjects in a study.

Define more relevant details for visit cycles

Study designers can now define more details for visit cycles in a branch.

What are the benefits?

This feature is particularly useful for an oncology study, for example, where visits are often run for an infinite number of cycles, with the starting cycle collecting much more detailed data.

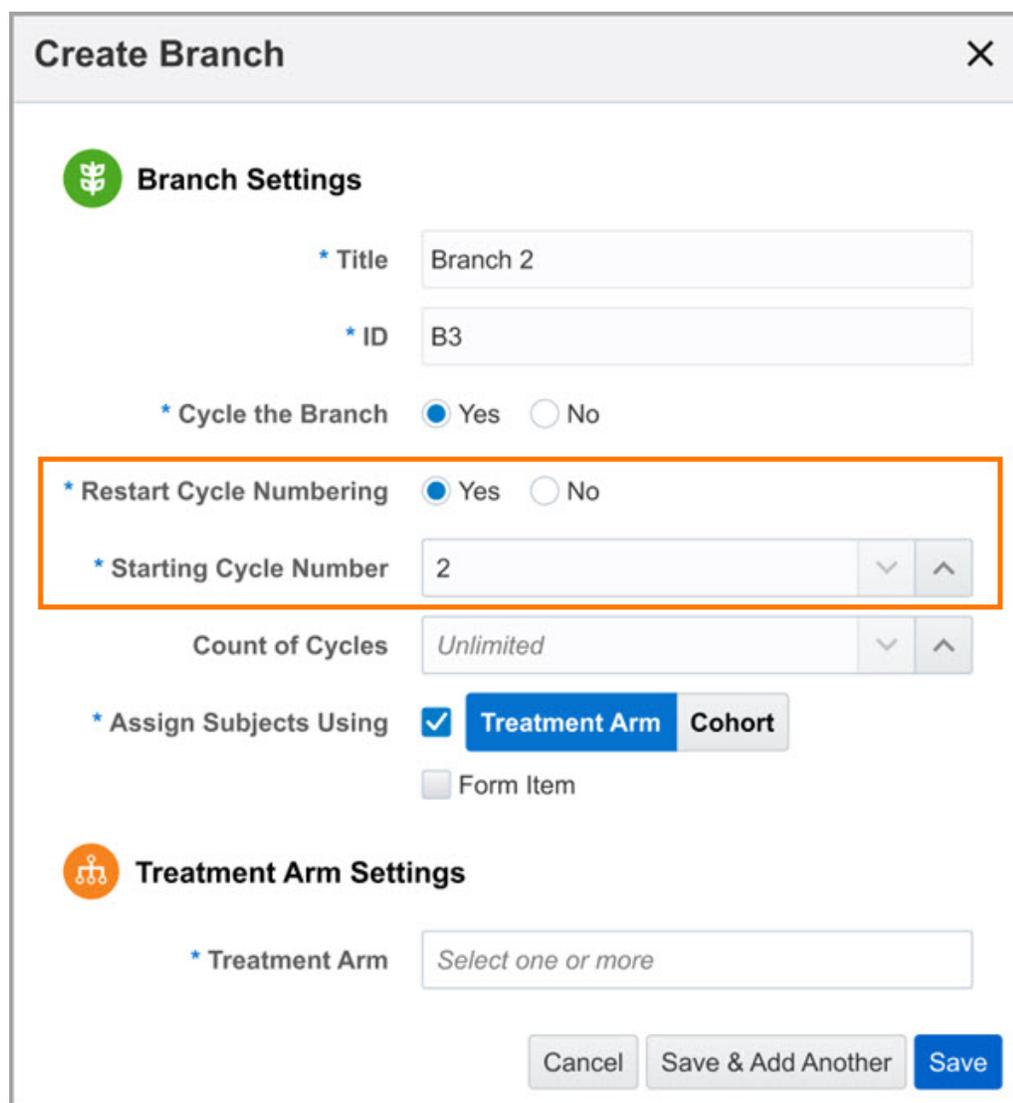
Details for study designers

On the Create Branch dialog, you can now configure two new settings for visit cycles. The Restart Cycle Numbering option is only available when creating a second or later branch.

- **Starting Cycle Number:** This number indicates when the cycling of visits should start, if defined. Assigning a number to the starting cycle also helps a site user better understand when a visit cycle starts and which cycle a subject is placed on.
- **Restart Cycle Numbering:** You can choose whether the cycling of visits should restart during the study or not. For example, if a subject completes all of their visits in Branch A, in cycle 6 and they are about to start visits in Branch B, then they can restart their visit cycle or continue with visit cycle 7, in Branch B.

Subjects who are transferred between sites continue their existing cycle numbering pattern in a branch based on their starting number at the initial site.

Figure 16-5 How a study designer sees the new settings for cycles in a branch



The screenshot shows a 'Create Branch' dialog box with the following settings:

- Branch Settings**
 - * Title: Branch 2
 - * ID: B3
 - * Cycle the Branch: Yes No
 - * Restart Cycle Numbering: Yes No
 - * Starting Cycle Number: 2 (with up/down arrows)
 - Count of Cycles: Unlimited (with up/down arrows)
 - * Assign Subjects Using: Treatment Arm Cohort Form Item
- Treatment Arm Settings**
 - * Treatment Arm: Select one or more

Buttons at the bottom: Cancel, Save & Add Another, Save.

Already working in a live study?

If an existing subject is already cycling, the subject's cycle continues to increment based on how the setting was configured when the subject entered the branch. If a subject skips a branch or tier of cycling visits, and the branch they entered indicates to continue the numbering of the cycles, a subject begins cycling at Cycle 1 again.

Update the order form after the shipment request has been changed

Clinical supply managers and depot users can now update the Shipment Order Form after the initial order has been modified.

What are the benefits?

With this new feature, clinical supply managers and depot users can quickly update the Shipment Order Form after they modify a shipment request. For instance, if a kit

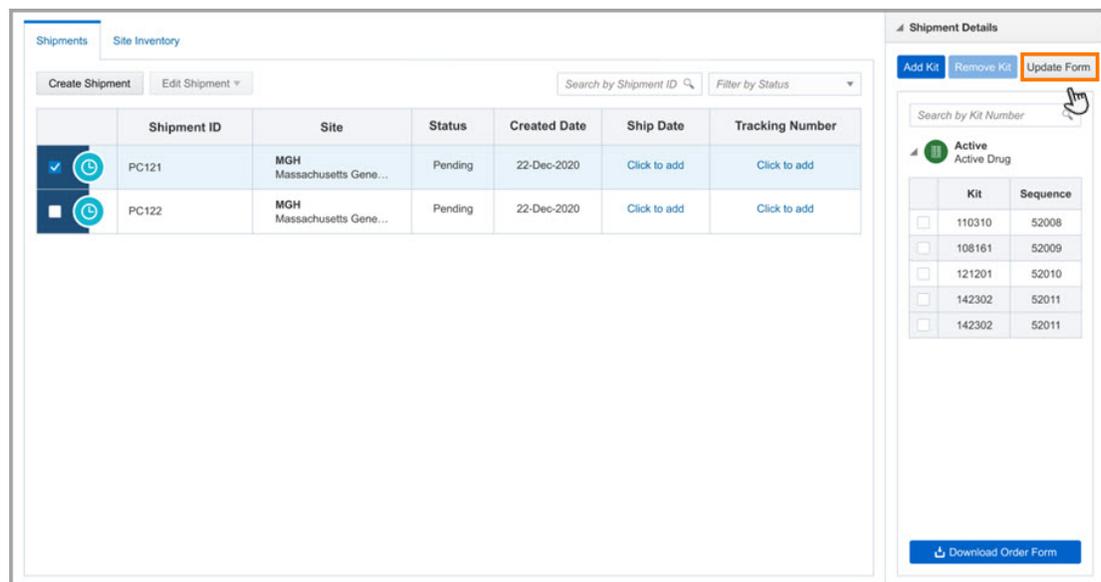
has been damaged and they need to replace it with a new kit before the order gets shipped out, they can modify the order and easily update the Shipment Order Form just by clicking a button. Previously, they could update the order but not the order form and the only way to update the form was to delete the initial request and create a new order with a new form.

Details for clinical supply managers and depot users

Your workflow for updating a shipment order has slightly changed. After you either remove or add a new kit to the order, a new **Update Form** button appears next to the **Remove Kit** button. When you click the **Update Form** button the shipment order form is instantly updated with the latest order details.

Upon removing or adding kits to a shipment order, the system displays a Confirmation dialog asking you whether you want to update the form or not. If you choose to update the form, the system automatically generates the updated form, as well.

Figure 16-6 The new button for updating the Shipment Order Form



Already working in a live study?

After the system upgrade, clinical supply managers and depot users can start updating the Shipment Order Forms when modifying a shipment request.

Reports and analytics

- [Create custom reports and dashboards using Oracle Life Sciences Clinical One Analytics](#)
Sponsor users can now create custom reports and dashboards to better visualize and analyze data from Oracle Clinical One Platform using Oracle Clinical One Analytics.
- [New Site Confirmation report for the Archival PDF](#)
Sponsor users can now enable site confirmation for site users to confirm that they have downloaded and reviewed the archives generated in the system.

Create custom reports and dashboards using Oracle Life Sciences Clinical One Analytics

Sponsor users can now create custom reports and dashboards to better visualize and analyze data from Oracle Clinical One Platform using Oracle Clinical One Analytics.

What are the benefits?

Thanks to Oracle Clinical One Analytics, you can now create more robust and customized reports using your operational and clinical study data. Moreover, you can also create your own data dashboards that let you visualize study data in a smart and easy way. This new feature lets you:

- Create custom tabular reports where you can view the data that is relevant to your task
- Visualize study analytics through customized dashboards to make data-driven decisions
- Perform cross-study reporting and data analysis
- Export data in a CSV or PDF format

Details for user administrators

There are six new permissions that a user administrator can assign to a user who should access Oracle Clinical One Analytics. A sponsor user cannot work in the Oracle Clinical One Analytics environment without at least one of the required permissions. Each type of dataset has a corresponding permission.

- *Run the Blinded Subject Events Dataset*
- *Run the Subject Dataset*
- *Run the Subject Form Items Dataset*
- *Run the Subject Forms Dataset*
- *Run the Unblinded Subject Events Dataset*
- *Run the Queries Dataset*

Details for study team members

When it comes to custom reports and dashboards, you can create them by clicking the new **Analytics** tab. This will take you to the Oracle Clinical One Analytics environment where you can access your datasets and use them to export data, and create visualizations or dashboards. The Analytics tab is available for studies in Testing, Training, and Production mode in Oracle Clinical One Platform.

Datasets represent a consolidated view of study information that allows a non-technical user to combine many different levels of data in a useful and visual way.

For more details on how you can visualize data in Oracle Clinical One Analytics, see [Get Started with Visualizing Data](#).

Here is a list of all the predefined datasets that you can use to generate custom reports and dashboards:

Type of custom report	Examples of data that can be viewed
Subject Dataset	<p>This dataset will make subject-related data easier to view and analyze, allowing you to make better data-driven decisions. For example, you can:</p> <ul style="list-style-type: none"> • Create a dashboard that displays the number of active subjects per site in your study. • View trends in enrollment and dropout in your study over time.
Unblinded Subject Events Dataset	<p>This dataset offers you all data available in the Blinded Subject Events Dataset plus additional unblinded information about kits and treatment arms. For example, you can:</p> <ul style="list-style-type: none"> • Create a visit status report for all subjects within a certain treatment arm. • View trends in dosage for subjects over the course of their visits.
Blinded Subject Events Dataset	<p>This dataset allows you to view the events and visits data collected throughout your study. For example, you can:</p> <ul style="list-style-type: none"> • View subjects who have completed a screening visit in a certain country. • Create a report of all events that occurred at a site during a certain month. • Create a dashboard that displays visit status per subject to quickly pinpoint missing visits.
Subject Forms Dataset	<p>This dataset complements the Subject Items Dataset well. If you are only interested in looking at data at the form level, without the need to see individual questions, this report meets your needs. For example, you can:</p> <ul style="list-style-type: none"> • View what forms are available for source data verification at a certain site. • View when should you schedule an onsite visit based on the amount of completed forms since their last onsite visit.
Subject Form Items Dataset	<p>This dataset allows you to create reports and dashboards on all subject form items collected in your study. For example, with this dataset you can:</p> <ul style="list-style-type: none"> • View missing items for each form across all subjects in your study. • View all form items that have been signed and verified for a subject. • Generate reports for subject age, gender, height, weight, and more for a study.
Queries Dataset	<p>This dataset offers you an overview of all queries that have been raised in your study, so you can quickly resolve those queries and ensure you have accurate and clean data from your sites. For example, you can:</p> <ul style="list-style-type: none"> • View all open and answered queries for quick resolution • Identify questions with the most queries across your study

Already working in a live study?

As a sponsor user, whether you are working in a brand new or existing study, you can go ahead and start using Oracle Clinical One Analytics after the deployment of this feature is complete and you are assigned the appropriate permissions.

Keep in mind that the deployment of this feature is gradual. Depending on the organization that you work in, you may not see the new **Analytics** tab right away and you may have to wait some time until you can use the feature. For more questions and detailed guidance on how to use this new feature, contact your Oracle Project Manager.

New Site Confirmation report for the Archival PDF

Sponsor users can now enable site confirmation for site users to confirm that they have downloaded and reviewed the archives generated in the system.

What are the benefits?

The Site Confirmation report lets sponsor users understand how many of the archives are downloaded and reviewed by site users in a study. By getting an overview and exact count of site confirmations, they can also notify site users, outside of Oracle Clinical One Platform, in case they discover that some archives have not been downloaded and reviewed.

Details for user administrators

Nothing has changed in your workflow. However, you do need to know that only a sponsor user who is assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate the Site Confirmation report.

Details for study team members

On the Reports & Archives tab, under Archives, you now see the new Site Confirmation report. You can generate that report in either a CSV or PDF format, as well as give it a different name.

Additionally, for an Archival PDF, you can now configure the **Confirm Site Downloads** setting to either **Yes** or **No**.

Details for site users

From now on, upon downloading an Oracle CRF Submit archive, you may have to confirm that you have downloaded and reviewed the archives.

Already working in a live study?

As soon as the upgrade for this release is done, with the appropriate permission, you can start configuring the **Confirm Site Downloads** setting for the Archival PDF and generating the Site Confirmation report.

Rules management

- [Create new custom rules for multiple visits schedules and cycle visits](#)
Rules designers can now use new custom rules for collecting data on multiple visit schedules and cycles visits.
- [Send an e-mail notification with a rule](#)
Rule designers can now send e-mail notifications when running a rule.

Create new custom rules for multiple visits schedules and cycle visits

Rules designers can now use new custom rules for collecting data on multiple visit schedules and cycles visits.

What are the benefits?

Rules turn the complexity of multiple visit schedules and cycle visits into a simple and accurate data collection process. For instance, in a study with 4 week cycles over a period of 24 months, you might need to complete a certain form every 8 weeks until 12 months of treatment and every 12 weeks thereafter. With these new custom rules, you can trigger the form to appear according to this specific schedule just by writing a few lines of JavaScript code.

Details for rule designers

You can now use new custom rules to better control data collection on multiple visit schedules and cycles visits. These new rules will include JavaScript functions that let you:

- Retrieve the current branch a subject is on
- Retrieve the current cycle number for a given branch that a subject is on
- Retrieve the treatment arm a subject is assigned to
- Retrieve a value for a question from a given cycle, visit, or form

For more information on the syntax for each JavaScript expression, see [Multiple visit schedules and cycle visits](#).

Already working in a live study?

Once the upgrade is complete, rule designers can start creating these new type of rules in their studies.

Send an e-mail notification with a rule

Rule designers can now send e-mail notifications when running a rule.

What are the benefits?

Rules now support a new type of Rule Action for testing and sending system notifications to users in a study.

A notification will have the following user-defined properties:

- **Who the notification is sent to:** this is a list of one or more e-mail addresses. The Rule Action allows you to define separate e-mail addresses for Production and Testing.
- **Notification Subject Line:** the e-mail subject line

- **Notification Body:** text that you can set on the user interface

A notification will have some properties automatically defined by the system, such as the standard notification properties: Study Name, Study Mode, Site Name, Subject Number, Visit Branch, Visit, Form, Form Sequence Number, Question, and Date & Time of Notification.

A notification must be tied to a rule expression that you define in the Expression field. The rule expression can determine whether or not a notification should be sent. To see how to send e-mail notifications, see [Create a rule to send an e-mail notification](#).

Already working in a live study

Once the upgrade is complete, rule designers can start creating these new type of rules in their studies.

User experience

- [Updated sign in experience](#)
Users working with the Oracle Clinical One Platform, Oracle Clinical One Digital Gateway, and Oracle Health Learn Manager applications now have an updated sign in and sign out experience.

Updated sign in experience

Users working with the Oracle Clinical One Platform, Oracle Clinical One Digital Gateway, and Oracle Health Learn Manager applications now have an updated sign in and sign out experience.

First, you can now sign into your application while having the third-party cookies disabled by default. That means you no longer have to enable third-party cookies in your web browser to be able to access the application you work with. If you enabled third-party cookies in the past in order to access Oracle Clinical One Platform, you can now disable them in your browser.

Second, in addition to an updated look and feel of the sign in page, for security reasons, you will now be sent to a specific sign out page when you sign out of the application.

For more information on the sign in process, see [Provision users: Clinical One and Digital Gateway](#).

Other enhancements

This release brings you multiple enhancements that significantly improve your work in the study, whether you work in study design or manage kits and subject data.

No delays in moving subjects to visit branches when using form data

When a subject gives the answer selected by the study designer to launch a new visit branch, the visit schedule is instantly updated so the next scheduled visit for that subject is in the new branch. However, when the initial visit schedule includes intermediary visits between the visit in which the form is answered and the branch, a site user must skip these intermediary visits prior to moving the subject onto the visit branch. For instance, if a visit schedule includes Screening visit, Week 1 visit, Week 2 visit and two new branches (Branch 1 and Branch 2) and the form question that

launches Branch 1 is in Week 1, when a subject gives the expected answer to this question, a site user must skip the Week 2 visit, so the subject can begin their visits in Branch 1.

To assign subjects to a branch based on form data, you can only use a drop-down type of question or question with checkboxes (that has a Select Exactly One validation rule applied to it), as well as a question with radio buttons in a non-repeating form. The question that launches a visit branch or cycle can be assigned to any type of visit or unscheduled event.

A new study role and permissions in the system

User administrators and global user managers now have a new predefined study role template that they can assign to users.

The Adjudicator predefined study role template contains permissions to view classified subject data and edit classified subject data, as well as to view sites. The Adjudicator predefined study role template should be copied and customized with permissions for data classifications, as well. After that, it should be assigned to a user whose tasks include viewing and editing classified subject data in certain forms included in a study, so they can validate the accuracy of the collected data.

Additionally, the new permissions (*View Classified Subject Data Only* and *Edit Classified Subject Data Only*) can also be assigned to a data manager who can typically edit form data classified as Sponsor Data. The predefined study role template for a data manager now also contains the *Edit Classified Subject Data Only* permission by default.

Form association audit history

All users can now see the audit history for forms associations. The **Answer History** section displays form association changes as part of the audit history.

Sign, verify, freeze, and data extracts on form associations

Principal investigators can now sign, Clinical Research Associates (CRAs) can now verify, and data managers can now freeze form associations. If any change occurs to the form association, for instance a new form association is added or an existing one is removed, the leading question becomes unsigned or unverified. If the leading question, that is the question that launches the form association, is frozen then users are not allowed to add a new association or remove an existing one.

Additionally, data managers and statisticians can now generate a data extract that includes form associations. The report is available in both CSV and SAS formats.

Better manage expired kits

Kits that have exceeded their expiration dates now appear with a status of **Expired** in the user interface, so sponsor users can quickly determine the status of kits and help site users easily assess the state of their inventory. Previously the **Expired** status was displayed only in the reports.

There are two ways a kit is marked as **Expired**, depending on the type of lot it is associated with:

- Kits associated with a blinded lot will be marked as expired when the blinded lot expiry date is reached even if this date is earlier than the manufacturing lot expiration date
- Kits associated with a manufacturing lot will be marked as expired when the manufacturing lot expiration date is reached.

Site or sponsor users cannot update a kit's status to **Expired**. The update is automatically done by the system. However, if a user wants a batch of kits to be immediately updated in the system as **Expired**, a sponsor user can trigger a resupply run in the Supply Settings tab.

As a site user, you can process an expired kit for reconciliation or mark it as **Misallocated** in the Site Inventory tab. As a clinical supply manager, you can also mark an expired kit for destruction.

Deleted repeating forms now appear in Subject Data Extract

Data Managers and Statisticians can now run the subject data extract and view deleted rows from a repeating form.

For each data element or form association, a new row labeled **DELETED** indicates **Y** if this row has been deleted or **N** if the row contains current data or it is a row belonging to a non-repeating form.

Fixed issues

- [All users](#)
- [Integrations](#)
- [Forms, visits, and rules](#)
- [Site users and subject data](#)
- [Sites, labs, depots, settings, and user management](#)
- [Randomization and kits](#)
- [Reports, archives, extracts, and notifications](#)

All users

The Subjects tab does not load

All users: The Subject tab is now loading and working as expected. Any user working on the Subject tab can now access that product area without any performance issues. Previously, upon attempting to access the Subjects tab, you may have noticed that the tab was not loading at all. (Issue **32702852**)

Integrations

Integration status now displayed correctly (enhancement)

Integration managers: In the Oracle Clinical One Digital Gateway user interface, an integration whose jobs have a **Successful** status after a previous job had a **Superseded** status, is now displayed with a status of **Successful**, as expected. Previously, if a job associated with an integration had a **Superseded** status and subsequent jobs were successful, the overall integration was displayed with a status of **Superseded**. (Issue **31776031**)

Cycle visit data can now be sent through an integration with a third-party electronic data capture system (enhancement)

Integration managers: If cycle visits are set up in your Oracle Clinical One Platform study, you can now send data associated with those visits to a third-party electronic data capture system, including dispensation, kit replacement, and kit reallocation data. Keep in mind that the scope of this enhancement does not include visit branching, but only a single repeating schedule.

For information on how to set up this integration, please reach out to your Oracle Project Manager. (Issue **32378195**)

Unexpected login experience for a user with no appropriate global role

Integration managers and integration viewers: From now on, upon logging into the Oracle Clinical One Digital Gateway application, if you lack any of the appropriate global roles (Integration Manager or Integration Viewer), a message is displayed advising you to reach out to your global user manager to get provisioned with the required role. Previously, upon logging into the application without the required global role, you were immediately signed out without any guidance on how to troubleshoot your issue. (Issue **31924116**)

Forms, visits, and rules

Updated tags for coding questions are not properly displayed (former known issue)

Study designers: Now, when you update a coding question's tags, the respective values are properly updated and displayed in Oracle Central Coding. Previously, when you updated a coding question's tags, the same tags were displayed with a status of **REMOVED** in Oracle Central Coding. This issue occurred due to the system considering the old tag as being deleted, instead of updating it.

Retracted workaround: None. (Issue **32590362**)

Data not displayed in repeating form table for newly added questions (former known issue)

Study designers and site users: Now, when a study designer adds a new question with radio buttons into a form for a live study version, a site user can view the data that they have collected in the table view. Previously, when a question with radio buttons was added into a repeating form table, a site user had to open each repeating form instance separately to view the collected data.

Retracted workaround: None. (Issue **32460735**)

Site users and subject data

Subject actions are frozen in the system

Site users: Now, when you attempt to screen, randomize, or dispense kits to a subject, and click **Return to All Subjects** while the system loads the results, the user interface behaves as expected. Moreover, you will notice your actions being processed and reflected in the user interface. Previously, when attempting to perform any sort of action for a subject and then clicking **Return to All Subjects**, the system froze. (Issue **32586988**)

Oops error no longer encountered when attempting to verify a subject (former known issue)

Clinical Research Associates (CRAs): When a site user completes a subject's visit in a study and you attempt to verify data for for that visit, you no longer notice an Oops error message upon clicking the **Verify** button. You can perform this task without any issues.

Previously, this issue was only encountered when the same form was used as a dynamic form in one visit and as a scheduled, expected form in another visit. For example, if the Concomitant Medications form was assigned as a dynamic form to Visit 1 and as an expected form to Visit 2, you were not able to verify data at a question level for Visit 2.

Retracted workaround: You no longer have to exclusively verify data at a form level to avoid any Oops type of errors. (Issues **31558038** and **31245075**)

Hidden questions also frozen when an entire visit is frozen (former known issue)

Site users: When opening a frozen visit, you can view and edit hidden and classified questions, as expected. Previously, when opening a frozen visit, you noticed that hidden and classified question were also frozen and not editable. This issue occurred when a user, who was assigned the predefined Data Manager study role, froze a visit with hidden and visible questions.

Retracted workaround: None. (Issue **32052559**)

Saving the Visit Start Date field might take longer when numerous visits exist in a study (former known issue)

Site users: When saving the date you entered in the Visit Date field, the saving process is instantaneous. Previously, the saving process took longer than expected and the issue may have been caused by a large number of visits included in the study's design.

Retracted workaround: None. (Issue **32342403**)

Missing user ID for a question with multiple audit entries (former known issue)

Site users: When a question has multiple audit entries by different users, all audit entries now have the proper user ID displayed in the Answer and Visit History pane. Previously, some of these audit entries may have missed a user ID.

Retracted workaround: You no longer have to click between different questions until the system successfully loads the complete history of a question. (Issue **32400050**)

Unable to update a query's status in Oracle Central Coding

Sponsor users: Now, in Oracle Clinical One Platform, when you attempt to re-open a query that was already answered , you can also update its status in Oracle Central Coding. Previously, you could not update a query's status in Oracle Central Coding. (Issue **32384217**)

Some answer fields might not appear in previously skipped visits (former known issue)

Site users: Now, when you enter into a visit you previously skipped, all answer fields are displayed and you can enter data in them. Previously, when accessing a skipped visit, you may have noticed that some answer fields were not displayed.

Retracted workaround: You no longer have to refresh your browser's page to make the answer fields display. (Issue: **32427512**)

Visit branch scheduled affected by skipped visit (former known issue)

Site users: Now, when you skip the last visit prior to a visit branch, the system calculates the expected visit date for the first visit within the branch as expected. Previously, if you skipped the last visit prior to a visit branch, you may have noticed that the system miscalculated the expected visit date for the first visit in the following branch.

For example, if you skipped visit D (on 08-February-2021) in the original schedule, and then proceeded to visit A in a branch, and entered the current date in the Visit Date field, you may have received an error stating that the visit date must be on or after 10-March-2021.

Retracted workaround: None. (Issue **32483995**)

Coding target fields are not cleared as expected

Site users: Now, when you submit a form without one or more of the coding answer fields, and you complete the respective fields later, the coding target fields are cleared, as expected, based on your newly added data. Previously, when you submitted a form without one or more of the coding answer fields completed, and you entered data in those fields after previously having coded the terms, you may have noticed that the coding target fields were not cleared in Oracle Clinical One Platform. (Issue **32583043**)

Lab names are cleared without entering a reason for the update (former known issue)

Site users: Now, when you attempt to clear a lab you previously selected for a lab form, you are prompted to enter a reason for this change. This fix also applies to situations when you change the current lab selection. Previously, you were not prompted to enter a reason for change and that could have created gaps of audit trail data in your study.

Retracted workaround: Now, when you generate the Subject Data report, you can see the exact reason of change specified by a user, instead of viewing an audit of system-generated reasons. (Issue **32402331**)

Error message displayed while verifying unanswered question in a form (former known issue)

Clinical Research Associates (CRAs): Now, when a question is unanswered or classified, you no longer see a check box for Source Data Verification (SDV). Previously, when an SDV strategy was used at a site and you attempted to verify an unanswered question, you got an Oops error message when clicking **Verify**.

Retracted workaround: None. (Issue **32002835**)

Sites, labs, depots, settings, and user management

Download Order form button and PDF exhibit inconsistent behavior

Unblinded depot users: From now on, the **Download Order Form** button is displayed and active for all shipments that you can download an order form for. Furthermore, the data displayed in the downloaded order form is also consistent with the details associated with the shipments. Previously, not only did the Download Order Form button appear inactive for certain types of shipments, the data displayed in the order form was not consistent between shipment status, resupply type, number of kits in shipment, and much more.

Both of these issues are now fixed. (Issue **32188978**)

Shipment Order Form now properly updated

Clinical supply managers and unblinded depot users: Upon updating the contents of a shipment, you are now prompted to update the associated order form right away, as well. This ensures that the Shipment Order Form is always updated with the latest changes you performed to any requested shipments.

For more details on this new enhancement, see [Update the order form after the shipment request has been changed](#). (Issue **29903057**)

Cannot view full names of certain lab tests (former known issue)

Site users or data managers: When defining lab normals for certain lab tests that have similar and very long names, you can now properly view full names of those lab tests in order to differentiate between the two. Previously, you could not view and differentiate the two names, so you did not know which test to select to define lab normals for its.

For example, there were two lab tests with the following names: *Mean Corpuscular Hemoglobin Concentration* and *Mean Corpuscular Hemoglobin*. On the Sites & Labs tab, on the Lab Tests column, you may have noticed that you cannot expand or hover over the two lab test names to determine which one was *Mean Corpuscular Hemoglobin Concentration* and which one was *Mean Corpuscular Hemoglobin*. Instead, both lab tests appeared as *Mean Corpuscular Hemoglobin*.

Retracted workaround: None. (Issue **32267363**)

Creator of assigned query can answer the query (former known issue)

Sponsor users: Now, when you create a query and assign it to a specific user role in a study, only users with that specific role and the appropriate permissions can answer that assigned query. Previously, you were able to answer that assigned query yourself and that was not the expected product behavior.

Retracted workaround: None. (Issue **32415778**)

Any user with the right permission can close an assigned query (former known issue)

Sponsor users: Now, as the creator of an assigned query (assigned with the appropriate *Close Queries* permission), you are the only one who can close an assigned query. Previously, any user in a study who was assigned the *Close Queries* permission could have closed an assigned query that you created.

Retracted workaround: None. (Issue **32415792**)

Randomization and kits

Unable to add titration kits from visit dialog (former known issue)

Study designers: Now, in the Add Titration to Visit dialog, when you attempt to add kit type titrations to a visit, visits are displayed in the dialog, as expected. Previously, when you attempted to assign a kit type titration to a visit, no visits were displayed in the Add Titration to Visit dialog.

This behavior was encountered when you were assigned the study designer predefined study role.

Retracted workaround: None. (Issue **31984737**)

Reports, archives, extracts, and notifications

Subject Data Extract cannot be generated for certain sites (former known issue)

Data managers and statisticians: Now, you can generate a Subject Data Extract in an XPORT or CPORT format for all sites in a study, as expected. Previously, you may have noticed that you were unable to extract data in a SAS format for certain sites. The issue was caused by leading 0 values encountered in the data collected at a site.

Now, if the data collected in a certain field is "001.450", the SAS format does not display leading zeros, displaying the value "1.450" instead.

Retracted workaround: None. (Issue **32499723**)

Unblinded Subject Events data set does not display randomization details (former known issue)

Unblinded sponsor users: Now, when managing an Unblinded Subject Events data set through the Oracle Clinical One Platform APIs, the randomization and treatment arm details are displayed for the dispensation visit following the randomization visit, as expected. Previously, upon opening this data set, you may have noticed that some randomization details were not properly displayed.

Retracted workaround: None. (Issue **32523297**)

Multiplied data displayed in Archival PDF (former known issue)

Site users: Now, when you generate an Archival PDF, any data for label items included in tabular forms is displayed as expected in the Subject PDF. Previously, you may have noticed that some of that data was displayed multiple times. For example, a Physical Exam repeating form that contained a label item and a code list for various body systems may have resulted in multiplied data being displayed in the Subject PDF.

Retracted workaround: None. (Issue **32454353**)

Columns in SAS Subject Data Extract not displayed as expected (former known issue)

Data managers and statisticians: Now, when you generate and open a Subject Data Extract in either a XPORT or CPORT format, the SAS Variable and Label are properly displayed for columns that are hidden. A column represents a question in a form and the proper SAS data is now displayed for those hidden questions.

Previously, when you performed this task, you may have noticed that the Sas Variable or Label were not displayed as expected for hidden columns.

Retracted workaround: None. (Issue **32503694**)

Fixed issues in 21.1.0.1

Initial shipment not triggered for reactivated site with assigned resupply strategy and study version

Site managers and clinical supply managers: Now, when you retire, re-activate, and assign a resupply strategy and study version to a site, the initial shipment is triggered as expected. Previously, if you activated a site without a resupply strategy and study version and then proceeded to retire and re-activate it with the appropriate strategy assigned to it, the initial shipment was still not triggered in the system. (Issue **32804368**)

Saving a form in Testing mode does not work properly

Site users: Now, when you complete all forms in a visit and save everything, you will notice that all forms are marked with a green icon, as expected. Previously, upon going back to a visit with all forms previously completed, you may have noticed that some forms within the visit were still marked as incomplete and you could not complete them. (Issues **32767985** and **32606012**)

Save and Close button is not working properly (former known issue)

Site users: Now, when you collect data in a visit, the **Save and Close** button works as expected, both saving the data you just added and taking you to the Subjects page. Previously, upon clicking the **Save and Close** button, the system only saved the data you entered without navigating to the Subjects page.

Retracted workaround: You no longer have to click **Save and Close** twice, to save the data and navigate back to the Subjects page. (Issue **32766956**)

No error prompt when entering wrong numeric values in fields

Site users: Now, when you enter a number with more than two decimal places in a numeric field, the application rounds the number to use two decimal places. Previously, upon entering a value with more than two decimal places, no error message was displayed, and screening the subject failed. (Issue **32686996**)

Subject Visits report not working for medium and large studies

Sponsor and site users: Now, for a medium or large study, you can run the Subject Visits report as expected. Previously, the Subject Visits report had certain limits (such as failing to generate when more than 1000 subjects were enrolled in a study). (Issue **31521402**)

Fixed issues in 21.1.0.2

Subject Data Extract seemed incomplete upon download

Data managers and statisticians: Now, when you extract subject data in a CSV format (with **All Sites** selected), the data you see in the extract is complete and correct.

Previously, upon downloading data extracts in a CSV format for all sites in a study, you may have noticed that the extract data was incomplete.

This issue was previously caused by how lab data was displayed in the extract, along with leading lab-related questions on the sample collection date and fasting status. From now on, the Subject Data Extract will contain an upper row that displays data entered for the sample collection date and fasting status of a subject. The rows underneath are populated with lab values collected by a site user. If no lab values are collected, and the site user has only collected data for the lab-related questions, you will only see one row for the laboratory, without any lab values.

Each row in a lab form (where data was collected) is marked by a sequence number in the table. This indicator is not displayed on the rows dedicated to the sample collection date and fasting questions. (Issue **32816247**)

Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 21.0 (February 2021)

- [What's new](#)
- [Fixed issues](#)
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What's new

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Data collection

- [Link forms and connect data across visits](#)
Study designers can now link two or more forms in a study and site users can connect data in these forms to easily track and report data.

Link forms and connect data across visits

Study designers can now link two or more forms in a study and site users can connect data in these forms to easily track and report data.

What are the benefits?

This new feature allows study designers and site users to connect forms across various visits and easily link together related data. For instance, study designers can link the Adverse Events form to the Concomitant Medications form and site users can then link data in these forms to record which medications were taken because of a particular adverse event or to indicate if an adverse event is related to a medication. This allows sponsor and site users to view subject data in a larger context, easily track and report related data, and achieve accurate results.

Details for study designers

When you create or edit a form you can now add a **Link & Show Form** rule to a question with radio buttons to associate it with one or more forms in the study. For instance, in the Concomitant Medications form you can add a **Link & Show Form** rule to the question "Is this medication related to an adverse event?" to connect this form to the Adverse Events form. When the subject answers "Yes", the Adverse Event form is displayed and the site user is able to link the data entered in the Concomitant Medications form to a specific adverse event in the Adverse Events form.

You can add multiple **Link & Show Form** rules to the same question with radio buttons in the form. Moreover, a form can contain multiple **Link & Show Form** rules on various questions. And you can also link forms that are included in different visits.

Figure 17-1 How a study designer can associate data on forms

The screenshot displays the Oracle Clinical form editor interface. The main area shows a form titled "Con Med" with five columns. Column 5 contains a question: "5. Did any adverse event occur due to this medication?" with radio buttons for "Yes" and "No". A hand cursor is pointing at the "Yes" radio button. To the right of the question are "Rules" and "Radio Buttons" dropdown menus. At the bottom left is an "Add Question" button, and at the bottom right are "Cancel" and "Save" buttons. On the right side, a "Details" sidebar is open, showing "Advanced" settings. Under "Rules", there is an "Add Rule" button and a list of rules. The first rule, "1. Action", is expanded to show a "Link & Show Form" dropdown menu. This menu is highlighted with an orange border and contains the following options: "Link & Show Form", "When Selection is" (with a hand cursor), "Yes", "Link & Show Form", and "Adverse Event" (with an 'X' icon).

Details for site users

You can now link the information collected from subjects on different forms and visits. If the association was set in study design, you will now notice that when you answer a certain question in a form a new form appears in the same window. In the new form, you can then select the record or records that relate to the data you entered in the original form. For instance, when you add data about a new adverse event in the Adverse Event Form and you enter "Yes" to the question assessing if the subject is taking any concomitant medication, the Concomitant Medications form appears in the same window. In that form, you can select the medication that relates to the adverse event you just added in the Adverse Event form.

A form can be linked to one or more forms, so multiple forms can be displayed in the same window for you to link related data.

Figure 17-2 How a site user can associate data on forms

Add Adverse Event

4. Severity Low Mild Severe Extreme

5. Serious Intervention Required Medically Significant Hospitalized Life Threatening Disability Death

*6. Con-meds Yes No

Con Med
You can select one or many forms below to link to this form.

#	Visits & Events	Product Trade Name	* Start Date	* Stop Date	* Dose
1	Adverse Event	Advil	16-Mar-2020	17-Mar-2020	250 mg OD
2	Adverse Event	Ofloxacin	21-Mar-2020	29-Mar-2020	100 mg BID
3	Adverse Event	Visine	21-Mar-2020	29-Mar-2020	3 drops BID

Question Information
Question Hint
No question hint provided.

Answer & Visit History
Subject History
Queries

Cancel Save

Already working in a live study?

Once the upgrade is complete, a study designer can start linking new forms in the study. After the updated study version is moved to the Approved container, site users can start linking these new forms when collecting data.

Data review

- [Assign queries to specific user roles](#)
Sponsor users can now create a new type of query and assign it to specific user roles.

Assign queries to specific user roles

Sponsor users can now create a new type of query and assign it to specific user roles.

What are the benefits?

With this new feature, sponsor users can ensure that each query is directed to the user that is most suited to answer and solve that specific issue. For instance, a data manager can create a query and assign it to a pharmacist to resolve a discrepancy in the subject data. In this case, the pharmacist is notified about the request and can address the issue in a timely manner.

Details for user administrators

When it comes to this new feature, there is one new permission that you can assign to both site and sponsor users, so they can answer queries of an **Assigned Query** type. That permissions is called *Answer Assigned Queries*.

Additionally, keep in mind that a site user who is already assigned the *Answer Queries* permission can also answer non-assigned queries, as well as queries assigned to a specific role.

For step-by-step instructions on how to edit an existing study role, see *Edit a study role that is already assigned to users*. For step-by-step instructions on how to create a brand new study role, see *Create a study-level study role* or *Create an organization-level study role*.

Details for sponsor users

When you create a query on a question, you can now:

- Select a new type of query: **Assigned Query**
- Choose the user roles that should get notified about the query
- Re-assign a query to other user roles

Figure 17-3 How a sponsor user can assign queries to specific user roles

The screenshot shows the Oracle Clinical interface for editing a query. On the left, a sidebar lists 'Forms' with 'Date of Dosing', 'Vital Signs', and 'Cornea Image'. The main area shows the 'Date of Dosing' form. The 'Vital Signs' section is active, showing a question '2. Blood Pressure' with a value of '135/96' and unit 'mmHg'. Below the question, the 'Query Text' field contains the text: 'The blood pressure over the last 32 visits has always been below 135/96 and the blood pressure after this visit is also below 135/96. Please confirm the blood pressure collected is accurate or correct the value.' The 'Type' dropdown is set to 'Assigned Query' (radio button selected). The 'Roles' dropdown is open, showing a list of roles to select. The 'Submit' button is highlighted in blue. At the bottom right, there are 'Save' and 'Save & Close' buttons.

The **Roles** drop-down list contains only the study roles that have been created in the study. The template study roles are not included in the list.

Once you assign the query to a specific role, it will be sent to all users with that given role. The query will be visible to all users that have the permission to view this new type of query, but only the users with the permission to answer a query will be able to also update the query.

Details for rule designers

Your workflow for creating a rule that generates an automated query has changed. In the Rule Editor, you now have a new option for creating an **Assigned Query**. Moreover, from a new drop-down list, you can select one or more roles that should receive and address the query.

Details for site users

Your workflow for answering queries hasn't changed. If a query is assigned to you, you can answer it following the usual process. For more details, see [Answer a query](#).

Already working in a live study?

Once the upgrade is complete, a sponsor user can start creating this new type of queries and assign them to specific user roles.

Lab data management

- [Integrate more relevant data in lab forms](#)

Study designers can now define a sample collection date field in lab forms, as well as create a question on a subject's fasting status. Site users must answer these questions before collecting data in a lab form.

Integrate more relevant data in lab forms

Study designers can now define a sample collection date field in lab forms, as well as create a question on a subject's fasting status. Site users must answer these questions before collecting data in a lab form.

What are the benefits?

With these new questions, study designers can create more robust lab forms that allow site users to collect better, more detailed lab data. The sample collection date allows the system to accurately calculate the subject's age at the time of collection and allows for proper integration of normal ranges based on a subject's age and the effective date of the lab normal range. Including a question on a subject's fasting status further improves the collection of specific lab normal ranges.

Details for study designers

On the Forms tab, when creating a lab form, you will notice the form contains two new predefined questions placed first, before the Label item defined in the lab form. These questions are:

- **Sample Collection Date:** A Date/Time required question that is tagged with a new **Sample Collection Date** lab normals tag.
- **Fasting:** A required drop-down type of question that is tagged with a new **Fasting** lab normals tag. The question also has an **Exactly 1** validation rule applied to it. Additionally, this question also includes a new code list that is already tagged with the **Fasting** code list tag. Values in the code list are predefined as **Yes** and **No**. This question can also be changed to a question with radio buttons with no validation rules.

If needed, these two questions can be hidden from the lab form. If you choose to hide any of the two new questions, you can also classify them for other users to view or edit, if they have the appropriate permissions.

Figure 17-4 How a study designer sees the two new introductory questions

The screenshot shows the 'Lab Form' configuration page. Under the 'Questions Before the Table' section, there are two questions:

- *A. Sample Collection Date: A date input field with a placeholder 'DD-MON-YYYY' and a 'Date/Time' dropdown menu.
- *B. Fasting: A text input field with a 'Select Answer' dropdown menu.

On the right side, there is a 'Details' panel with an 'Advanced' section containing an 'Add Property' dropdown and a list of properties: SAS Variable (DTC), SAS Label (Lab Sample Collection Date), and Lab Normals Tag (Sample Collection Date).

Details for data managers and site users

Whether you're a data manager or a site user who needs to define lab normal values and ranges for a local lab, you should know that, on the Sites & Labs tab, there's a new Fasting column that uses the **All** option, by default. For each lab test, you can change that value to indicate whether the range applies to a fasting or non-fasting subject.

Additionally, there are more updates for a site user's workflow. When starting a visit that contains a lab form with the two new introductory questions, you must first answer the **Sample Collection Date** and **Fasting** questions. Afterwards, you must select a lab for which the lab data will be collected. Only after you perform these three tasks you will be able to see and complete the lab form itself.

Figure 17-5 How a site user or data manager sees the new questions in a form

The screenshot shows the 'Lab Form' user interface. The top section contains two questions:

- * Sample Collection Date: A date input field with dropdown menus for 'DD', 'MON', and 'YYYY'.
- * Fasting: A text input field.

Below the questions, there is a message: 'This is a lab form. Add an existing lab or create a new one below.' with a link 'See how it works!'. At the bottom, there is a 'Select Lab' dropdown menu with the text 'Select existing lab' and a hand icon pointing to it.

Already working in a live study?

As soon as the upgrade for this release is done, you can start using the new types of questions.

For an existing lab form, if you want to include the two new questions, access the study in Draft mode and edit the existing lab form. The two new questions appear as hidden. Turn off the **Hidden** toggle for the two new questions. After that, move the study version from Draft to Testing and test out the two new questions. If everything looks and works as expected, move the study version to Production. The two new questions will now appear in the new and live study version. For step-by-step instructions, see Create a new Draft version of a study to update the Approved version.

If the Sample Collection Date question is left unanswered, the system uses the visit start date to calculate the sample collection date of lab results. If the Fasting question is left unanswered, lab normals for Fasting will not be displayed in forms or reports.

For a new lab form, you will notice that the lab form already contains the two new questions. Finish defining all of the details of your new lab form and assign it to a visit. Once your study is tested in Testing mode and moved to Production mode, the lab form updates will be live.

Rules management

- [Design new types of JavaScript rules](#)
Rule designers can now create two different types of custom rules. Additionally, they can also allow site users to edit a form while the rule associated with that form runs.

Design new types of JavaScript rules

Rule designers can now create two different types of custom rules. Additionally, they can also allow site users to edit a form while the rule associated with that form runs.

Select a value in a drop-down question

A rule designer can now create a custom rule to set values for drop-down questions and decide whether certain dynamic questions for forms should be displayed, based on the previously selected answer. For example, this type of rule can be configured in a way that will only show a specific form or question based on the calculated and selected value for a drop-down question.

Execute a rule in different visits

A rule designer can now create better and smarter rules for questions associated with multiple visits. When a rule is created against a question in a form, and that form is associated with multiple visits, the rule can be executed in a certain way for some visits. For example, this type of rule can be configured in a way that will only raise an automated query against the question associated with certain visits in a study, not all visits.

Allow site users to edit a form while a rule runs

When creating a rule, rule designers can now specify that the running of a custom rule should not block a site user from editing or saving the form with which the rule is associated.

On the Rule Editor dialog, you will notice the new **Unblock Form** toggle. Turning it on allows a site user to edit or save a form while a rule is running. The time it takes for the rule to run depends on the complexity of the rule. And while site users can still enter values and save the form, some form updates generated by more complex rules might be delayed and only appear after a page refresh.

User experience

- [Introducing the new Clinical One 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!

Introducing the new Clinical One 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 Clinical One 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 Clinical One 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**.

Key points that you should know about the community

- 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.
- You can customize your profile in multiple ways, including your notification preferences. This will empower your experience within the community and help you connect with other users.
- You can subscribe to groups within the community.
- Since we are just getting started, the Clinical One community now contains four major groups of discussion. In time, the community will expand more, based primarily on your feedback.

-  **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.

Other enhancements

For this release, study designers, data managers, and statisticians can perform certain tasks in an improved and more efficient manner thanks to new product enhancements.

Run better data extracts in your study

Data managers and statisticians can now extract data in a study in true SAS formats, such as Transport XPORT or CPORT. When you generate a data extract in one of

these two new formats, you will be able to see each question's defined SAS properties (the SAS variable and SAS label). A data extract can still be generated in a CSV format, if required.

Please note that you must have a SAS client installed on your computer to be able to view data extracts in an XPORT or CPORT format. In Oracle Clinical One Platform, SAS Transport File Formats are currently running on Version 8, so make sure you use a SAS client that's on version 9.3 or later. For more details, see the [SAS documentation platform](#).¹

Safely update your data after the study version is approved

When updating an approved study version, study designers are no longer allowed to perform the following actions:

- Update or delete answer options included in multiple choice type of questions (Drop-down, Check boxes, Radio Buttons, and Labels)
- Update or delete in the Code lists page any field of a code list used in multiple choice type of questions. Study designers can only edit the code list if they use it in a new question or a new form
- Change the **Format**, **Accept Partial Date**, and **Minimum Date Answer** fields of **Date/Time** questions. Study designers are no longer allowed to change a partial date into a full date or a full date into a partial date.

In case study designers need to correct an error in a multiple choice question included in a live form, a solution would be to hide the incorrect question and add a new question with the appropriate code list or values.

A minimum of no kits with calculated doses can now be dispensed to a subject

What this means for you, as a study designer, is that you can now allow for calculated doses to result in no kits of a specific type to be dispensed to a subject, when it is appropriate for your study protocol. For example, a subject registers a change in lab values and perhaps is situated below the limit to be dispensed a particular kit type (Kit A).

As a site user, in this example, you must know that the subject can continue to receive Kit B, as part of the protocol because the system allows the dispensation to continue without dispensing Kit A, thus allowing the subject to continue with their next visit in the system.

Fixed issues

- [Fixed issues affecting all users](#)
- [Integrations](#)
- [Forms, visits, and rules](#)
- [Reports, archives, extracts, and notifications](#)
- [Sites, labs, depots, settings, and user management](#)
- [Site users and subject data](#)
- [Oracle Clinical One Analytics fixed issues](#)
- [Forms, visits, and rules](#)
- [Integrations](#)

¹ SAS is a registered trademark or trademark of SAS Institute, Inc. in the USA and other countries. Other brand and product names are registered trademarks of their respective companies.

- Sites, labs, depots, settings, and user management
- Site users and subject data
- Randomization and kits
- Reports, archives, extracts, and notifications
- Forms, visits, and rules
- Integrations
- Randomization, shipments, and kits
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site user and subject data

Forms, visits, and rules

You can now reorder questions in a lab or repeating form (former known issue)

Study designers: From now on, when working with lab or repeating forms, you can reorder questions after they are created. Previously, this feature was not supported.

Retracted workaround: In a repeating form, you no longer have to delete the questions and add them again in the required order. In a lab form, you no longer have to delete the questions placed after the predefined ones. (Issue **31890469**)

Blinded user cannot view queries for hidden questions (former known issue)

Study designers: While a study is in Testing mode, a blinded user (such as a blinded site user) without any permissions to view or edit hidden questions, cannot view all queries assigned to those hidden questions on the Queries side bar. This is the expected behavior.

Retracted workaround: None. (Issue **32062888**)

You can copy more forms (former known issue)

Study designers: From now on, you no longer have to limit your number of copied forms to a maximum of 9 copied or duplicated forms per study.

Retracted workaround: None. (Issue **31893935**)

You cannot update certain question types for multiple study versions (former known issue)

Study designers: For a question with checkboxes, radio buttons, or a drop-down question, whether its answer options are generated based on a code list or directly created into the form, you can only update it if the form containing that question isn't currently used in a live study version. Previously, multiple-choice questions (particularly questions with check boxes) that contained code lists were automatically and randomly updated for all subjects in the study. This happened whenever you removed a code list or answer option from the multiple-choice question, triggering the selection of another existing option in the study for all subjects.

Retracted workaround: You no longer have to refrain from making any updates to multiple-choice questions and applying those updates to a live study version because

you are no longer allowed to update code lists or multiple-choice types of questions that are used in live forms. For more details, see [Other enhancements](#). (Issue **31876300**)

Can now use the same visit title across branches (former known issue)

Study designers: You can now use the same visit title across multiple branches in a study without running into errors when attempting to dispense kits during those visits. The system will now validate different visits with identical visit titles based on their visit ID.

Retracted workaround: You no longer have to use unique visit titles across branches, if your study design includes identical visit titles. (Issue **32259937**)

Re-running a calculation rule no longer interferes with signed and verified visits (former known issue)

Rule designers and rule testers: From now on, when you re-run a rule for calculating a value, the subjects and visits associated with that re-calculated value will no longer become unsigned or unverified after the re-calculation.

Retracted workaround: Principal investigators and CRAs don't have to re-sign or re-verify re-calculated values and the associated subjects. (Issue **32106063**)

Coding targets are now properly cleared in repeating forms (former known issue)

Study designers: From now on, when clearing the answer to a coding question (typically a verbatim term mapped to either the WHODrug or MedDRA dictionary) the coding target field will also get cleared. Previously, upon clearing the answer to a coding question, coded terms in the coding targets fields would still appear. This behavior was only encountered in copied repeating forms.

Retracted workaround: You no longer have to create a new form from scratch and include your coding question and coding targets in that form. (Issue **31922081**)

Can now create a custom rule for a repeating form instance

Rule designers: From now on, you can double-click the first repeating form instance in a table and then define a custom rule for any of the included fields, as expected. Previously, upon double-clicking the first repeating form instance in a table, you may have noticed that you could not define a custom rule for any fields in the form, including adding variables or modifying the form and action of the rule. (Issue **32199214**)

Automated queries no longer displayed for hidden questions in a question group (former known issue)

Rule designers and site users: From now on, when you create a custom rule that should generate an automated query against a hidden question in a question group, the query is no longer displayed next to the respective target field, so site users can see it, even though they shouldn't. Instead, the query is displayed only on the visit card and in the Queries sidebar. Previously, in a question group, when a hidden question was used as a target field for a calculated value, and the variable fields used in that rule were populated with values that generated an incorrect calculated value, you noticed a query being raised on one of those fields.

Retracted workaround: You no longer have to avoid including hidden questions or items in a question group. (Issue **31870133**)

Projected visit dates are now correctly displayed in reports

Study team members: From now on, when generating the Subject Visits report, you will notice that the projected visit dates are correctly calculated and displayed in the report. Previously, upon generating the Subject Visits report, you may have noticed that projected visit dates were incorrectly calculated. For example, if visit B was scheduled 5 days before and 3 days after visit A, the next projected visit date was displayed as happening after 2 days, which was the minimum number of days between visits. Instead, the projected visit date should have been set 5 days after visit A.

This reporting issue did not affect the trial supply management and is now fixed. (Issue **32138874**)

Proper UI message is displayed when assigning a kit type titration to a branch visit

Study designers: From now on, when you attempt to assign a kit type titration to a visit in a branch, even though visits in that branch are not scheduled based on the original visit schedule, a proper error message appears letting you know that you must first properly schedule visits in the initial schedule, and then assign a kit type titration to visits in a branch. Previously, you could perform this task without receiving any kind of error message, even though in the Add Titration to Visit Schedule dialog, you could not see the visits included in the branch. (Issue **32101745**)

Updating code list used for lab tests impacts normal ranges (former known issue)

Study designers: Now, when you update a value in a code list that has a lab tag, the code list is updated in all forms in which the code list was applied. Previously, whenever you performed this change, you may have noticed that the value was updated for all lab normal ranges across all studies at your organization. Moreover, the original lab normal range values associated with the updated code list value were removed from the lab forms for all subjects.

Retracted workaround: Previously, we recommended you do not update or remove values from code lists used in live studies for lab normal ranges and lab forms. Right now, you cannot update values in code lists used in live study version, so the workaround is no longer required. (Issue **31962038**)

Integrations

Jobs are now correctly sorted in the user interface

Integration managers: In the Oracle Clinical One Digital Gateway user interface, job statuses now appear properly ordered on the right pane, from the latest job status to the oldest job status. Previously, the sort order only considered the job timestamp up to the minute, meaning if the job had more than one execution/status in the same minute the order in which the corresponding information appeared was not necessarily correct. Now the right pane considers the timestamp seconds, therefore job statuses appear in the exact order they were executed. (Issue **31017849**)

User interface now behaves as expected when no Integration Builder integrations are present

Integration managers: When there are no Integration Builder integrations registered in the system, the **Other** button, which would otherwise lead you to define the integration configuration, is no longer displayed. Previously, upon clicking the **Other** button, the UI displayed an empty list of Categories and Integration Types to select from, making it seem as though there was a problem with the application. (Issue **31466284**)

Cycle visit data can now be sent through integrations

Integration managers: If cycle visits are set up in your Oracle Clinical One Platform study, you can now send data associated with those visits to Oracle InForm, including dispensation, kit replacement, and kit reallocation data. Keep in mind that the scope of this enhancement does not include visit branching, but only a single repeating schedule.

For information on how to set up this integration, please reach out to your Oracle Project Manager. (Issue **32248125**)

Randomization, shipments, and kits

Transition from an Invalid to a Confirmed status now allowed for shipments

Clinical supply managers, depot users, and integration managers: For an integration between Oracle Clinical One Platform and Almac Global Depot Network, a shipment's status can now transition from **Invalid** to **Confirmed**, and ultimately **In Transit**. Previously, this transition was not possible, resulting in errors during the integration. (Issue **32073383**)

Discrepancy in calculations for DNS and DNC no longer causing shipments to be raised in error (former known issue)

Clinical supply managers: There is no longer a discrepancy in how the system does calculations for Do not count (DNC) days and Do not ship (DNS) days when these values are set to the same day. Shipments are no longer at risk of being raised in error throughout the course of a study.

Retracted workaround: None. (Issue **31765437**)

Mismatch between dates for created shipments no longer happening

Clinical supply managers and site users: From now on, on the Shipments tab, when you filter by shipment ID and the **In Transit** status, mismatches between the Created Date and Shipped Date of shipments are no longer encountered in the user interface. Previously, on the Shipments tab, you may have noticed that there was a mismatch between the Created Date and Shipped Date of certain shipments. (Issue **32346164**)

Reports, archives, extracts, and notifications

Data flags for age questions are now displayed correctly in archive (former known issue)

Blinded study team members: When a data flag is applied to an age type of question, and the subject is then transferred to another site, the data flag no longer appears underlined in the Submission and Archival PDFs for the transferred subject associated with that flagged question.

Retracted workaround: None. (Issue **31697694**)

Audit history in Subject PDF now displays all actions performed for a query

Study team members: In an Archival PDF, the Subject PDF now displays the entire audit history of actions performed on a query, including the latest modification performed by a user. Previously, only the latest actions performed on a query were displayed in the Subject PDF. (Issue **31921018**)

Label for total number of kits displayed correctly in Kit Reconciliation report

Sponsor users and site users: Now, when you run the Kit Reconciliation report, you will notice that the **Total Kits Reconciled** section in the report is renamed to **Total Kits**. Previously, the **Total Kits Reconciled** title was still used despite the report now retrieving data on kits of all statuses, not just reconciled kits. (Issue **31451625**)

Transaction dates still display after clearing settings for Kit Chain of Custody (Unblinded) report (former known issue)

Clinical supply managers and unblinded depot users: Now, when you select **Yes** for the **Include Audit Trail** setting of this report, and then clear the settings, date fields for transaction dates are no longer displayed in the user interface, as expected. Previously, for the Kit Chain of Custody (Unblinded) report, when you selected **Yes** for the **Include Audit Trail** setting, date fields for transaction dates appeared. Upon clicking **Clear Settings**, those fields were still displayed.

Retracted workaround: None. (Issue **31363842**)

Sites, labs, depots, settings, and user management

Oops error no longer shown in various tabs and modes of a study

Site users and study team members: From now on, whenever you navigate to either the Subjects or the Supplies tab, you no longer see an Oops error or witness the page loading indefinitely. Previously, whenever a site user, for example, would navigate to any of those tabs, they either received an Oops error in the system or other pages kept refreshing in a loop without the user interface being properly loaded. This behavior was caused by a backend issue related to the modes of a study that is now fixed. (Issue **32332186**)

Site user and subject data

Visit display no longer focuses on lab form (former known issue)

Site users: From now on, when opening a visit that contains multiple standard forms and a lab form, the visit display no longer focuses on the lab form only, obscuring the standard forms assigned to the visit.

Retracted workaround: None. This is a minor visual issue. (Issue **32054010**)

Queries now properly displayed in Answer History (former known issue)

Site users: When a study is in Testing mode and you answer an opened query, that update is now properly reflected in the Answer History of the respective question. This error was only visual, the edit was applied correctly in the system.

Moreover, when you now create a query on a question, its details are properly displayed in the Answer History sidebar. Previously, you had to navigate between questions to make the system display the query's details.

Retracted workaround: You no longer have to refresh the page so the Answer History properly displays the updated query status or the details of a newly created query. (Issue **32058092** and **32164478**)

Inconsistent behavior no longer encountered in saving repeating forms (former known issue)

Site users: On the Forms pane, when you click the plus sign icon (+) to add a new repeating form instance, you will notice that the data you entered and saved is now displayed in the repeating form table as expected. Previously, upon performing this task, you may have encountered an error message stating "Your changes on this page won't be saved". Or you may have noticed that your changes were not displayed in the repeating form table, despite not receiving an error message.

Retracted workaround: None. (Issue **30792327**)

Select Lab drop-down no longer present in skipped visits (former known issue)

Site users: From now on, you will no longer see the Select Lab drop-down in a previously skipped visit. Previously, when you attempted to select a lab to collect lab data during a skipped visit, an Oops error message appeared.

Retracted workaround: None. (Issue **32170259**)

Hidden questions no longer frozen when an entire visit is frozen (former known issue)

Data managers: When opening a frozen visit, hidden and classified questions (that only you can view and edit) are no longer frozen and not editable. Previously, this issue occurred when a user assigned the predefined Data Manager study role froze a visit with hidden and non-hidden questions.

Retracted workaround: None. (Issue **32052559**)

Error icon no longer displayed in a previously skipped visit (former known issue)

Site users: From now on, when you undo a skipped visit, empty fields will no longer display random error icons.

Retracted workaround: None. (Issue **31178183**)

Queries in unscheduled visits can now be re-opened (former known issue)

Clinical Research Associates (CRAs) and data managers: When working in an unscheduled visit, you can now re-open a query in a form with coding questions, and the re-opened query will appear in the visit.

Retracted workaround: None. (Issue **31940674**)

Form data is not saved as expected when navigating visits (former known issue)

Site users: From now on, when you enter data into a form and switch visits without either navigating to a different form within the same visit, or clicking **Save** or **Save & Close**, data entered in those fields will be saved. Previously, data was not saved unless you specifically saved the forms associated with that visit. This behavior applies to all forms.

Retracted workaround: You no longer have to actively perform any of these steps to make sure the entered data is saved:

- Navigate to another form within the visit
- Click **Save** or **Save & Close** to save the data that you just entered. (Issue **32360414**)

Fixed issues in 21.0.0.3

Verify Visit Data button now displayed in Adverse Event (former known issue)

Clinical Research Associates (CRAs): From now on, on the Subjects tab, when clicking an Adverse Event to verify all forms in that event, the **Verify Visit Data** button is displayed as expected. Previously, when accessing an Adverse Event, you may have noticed that the Verify Visit Data button was not displayed.

Retracted workaround: You no longer have to click the visit card for another visit located in the Next Visits column and then go back to the Adverse Event. (Issue **32474377**)

Adverse event is now saved automatically when opening another repeating form instance (former known issue)

Site users: From now on, when you enter an instance of a record in a repeating form straight from the table view, and then click the link for another record on a repeating form (for example, a Concomitant Medications form), the record you add is saved as expected. Previously, when performing these steps, you may have noticed that your newly added record was not saved. The unsaved record was also not displayed in the list of linked forms for the second repeating form (the Concomitant Medications form).

Retracted workaround: When adding a new record in a repeating form, you no longer need to make sure you click the **Save** button to save the newly added record before opening a form linked to it. (Issue **32464798**)

Fixed issues in 21.0.0.4

For this release, we fixed one performance issue that was affecting the dispensation of kits in Testing mode. The behavior described below was not observed in any other study modes.

Kits are now properly dispensed to subjects

Now, when a kit is modified in Draft mode for the same study version used in Testing mode, a subject is dispensed the correct amount of the modified kit. Previously, after updating a kit in Draft mode and dispensing that kit in Testing mode, the subject was at risk of receiving duplicate kits. (Issue **32549131**)

Fixed issues in 21.0.0.5

For this release, we fixed two issues that were affecting site users' experience in Testing and Production modes.

Could not link or unlink forms within the same visit

Now, form association works properly when you attempt to link or unlink two forms, and one of the forms is already linked to a third form within the same visit. Previously, when you linked two or more forms during the same visit, and then tried to unlink the forms, an error was displayed. (Issue **32507337**)

Randomization button is grayed out

Now, when attempting to randomize a subject, the **Randomize** button works properly. Previously, after completing all forms for a randomization visit, the button was still not active. (Issue **32606407**)

Fixed issues in 21.0.0.6

For this release, we fixed an issue regarding the Oracle CRF Submit Archival PDF.

Time component incorrectly shown as being part of the visit date (former known issue)

Sponsor users: Now, when generating an Archival PDF, a time component no longer shows as being part of the Visit Date field on the Blank Casebook generated for an Oracle Clinical One Platform study. Previously, the time was being displayed even though there was no field to collect it in the user interface. (Issue **32449295**)

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Oracle Clinical One Platform 20.3.2.1 (January 2021)

- [Fixed issues](#)

Fixed issues

For this 20.3.2.1 release, we fixed several performance issues that were affecting the user experience of site users when adding data into repeating forms. For reference, see issues **32299215**, **32299235** , and **32285473**.

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Releases in 2020

Browse the content of all Oracle Clinical One Platform and Oracle Clinical One Digital Gateway releases in 2020.

- [Oracle Clinical One Platform 20.3.2 \(December 2020\)](#)
- [Oracle Clinical One Platform 20.3.1.3](#)
- [Oracle Clinical One Platform 20.3.1.2](#)
- [Oracle Clinical One Platform 20.3.1.1](#)
- [Oracle Clinical One Platform 20.3.1](#)
- [Oracle Clinical One Platform 20.3.0.1](#)
- [Oracle Clinical One Platform 20.3 \(October 2020\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.2.3 \(September 2020\)](#)
- [Oracle Clinical One Platform 20.2.2 \(August 2020\)](#)
- [Oracle Clinical One Platform 20.2.1.2 \(August 2020\)](#)
- [Oracle Clinical One Platform 20.2.1.1 \(August 2020\)](#)
- [Oracle Clinical One Platform 20.2.1 \(July 2020\)](#)
- [Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 20.2 \(July 2020\)](#)
- [Oracle Clinical One Platform 20.1.1.1](#)
- [Oracle Clinical One Platform and Oracle Clinical One Integration Hub 20.1.1 \(May 2020\)](#)
- [Oracle Clinical One Platform 20.1.0.1 \(April 2020\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.1 \(March 2020\)](#)
- [Oracle Clinical One Platform 20.0.2 \(February 2020\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.0.1 \(January 2020\)](#)

Oracle Clinical One Platform 20.3.2 (December 2020)

- [What's new](#)
- [Fixed issues](#)

What's new

- [Data collection enhancements](#)
Site users now benefit from two new enhancements that make the data collection process easier and the overall user experience much better.
- [Rule design enhancements](#)
Rule designers can now set query messages dynamically within rules.

- [Data collection](#)
- [Data review](#)
- [Lab data management](#)
- [Randomization and supplies](#)
- [Reports and archives](#)
- [Rules Management](#)

Data collection enhancements

Site users now benefit from two new enhancements that make the data collection process easier and the overall user experience much better.

These new usability enhancements are related to the following types of questions and forms:

Questions with radio buttons

You can now deselect a radio button, if you don't want to choose any of the answer options defined for a question with radio buttons. Keep in mind that a question with radio buttons that is required must still be answered in order to complete the form.

Tabular forms

Tabular forms are now much more streamlined to improve the way you collect data, from the way you can save data to how you navigate between editable table cells. More details about the exact usability improvements will be coming soon.

- You can now enter the data into the table by doing a single click within a table cell instead of a double-click.
- You can now add values directly into the table cells for all instances of data. Previously, this was possible only for the first table row.
- Tabular forms are now automatically saved when you click outside of the table.
- If you need to enter a partial date for a Date/Time type of question, now all the fields are displayed within the cell.
- Lastly, the **Add** button for adding new rows to the tabular form is now placed to the left of the form, making it more accessible.

All Forms

A "Saving & Validating..." message is now displayed every time you save a form. The status message appears on the screen until saving is complete.

Figure 19-1 The new status message is displayed when a form is saved



Rule design enhancements

Rule designers can now set query messages dynamically within rules.

Details for rule designers

When designing a new rule you can now define a custom query message within the JavaScript expression:

```
setQueryMessage(<Insert your query message here>)
```

Details for site users

There are no changes in your workflow. All you need to know is that messages associated with automated queries can now be customized, making it easier for you to know how to correct certain values.

Already working in a live study?

This enhancement does not affect existing live studies. Rules can be updated and re-published to make use of the new enhancements.

Fixed issues

For this 20.3.2 release, we fixed several performance issues that were affecting the user experience of study designers, rule designers, clinical supply managers, and site users. For reference, see a detailed description of issue **32204955** below:

Clinical supply managers and study designers: You can now design multiple cohorts with similar criteria, as well as assign randomization numbers from that larger selection of cohorts. Previously, you were limited to only using one cohort with similar characteristics when assigning a randomization number.

Oracle Clinical One Platform 20.3.1.3

- [Performance issues in 20.3.1.3](#)

Performance issues in 20.3.1.3

For this release, we fixed two performance issues, one related to proper triggering of dynamic forms and a second related to rules execution. (Issues **32177070** and **32171361**, respectively)

Oracle Clinical One Platform 20.3.1.2

- [Performance issues in 20.3.1.2](#)

Performance issues in 20.3.1.2

For this release, we fixed several performance issues that were affecting the user experience of study team members and sites working in complex study designs. For reference, see issue **32097828**.

Oracle Clinical One Platform 20.3.1.1

- [Fixed issues](#)

Fixed issues

- [Site users and subject data](#)

Site users and subject data

For this release, we fixed one performance issues that was preventing users at a site from properly navigating the Subjects tab, in the application (Issue **32117429**).

Oracle Clinical One Platform 20.3.1

- [What's new](#)
- [Fixed issues](#)

What's new

- [Classify data in a form](#)
Study designers can now classify data in a form to allow users access to hidden questions and user managers can assign users view and edit permissions based on data classifications.
- [Create multiple visit branches](#)
Study designers can now design multiple visit schedules and cycle visits in the same study. You can design multiple visit schedules based on either a randomization or business logic rule.
- [Enter data directly into a repeating form table](#)
Site users can now enter values directly into the table cells of a repeating form when adding the first instance of data.
- [Run the Subject Data Extract \(Blinded\)](#)
Data managers and statisticians can now extract cumulative subject data for data analysis or regulatory reporting for the study that they're working in based on their specific permissions

Classify data in a form

Study designers can now classify data in a form to allow users access to hidden questions and user managers can assign users view and edit permissions based on data classifications.

What are the benefits?

This new feature allows users to collect complex data in a simple and efficient way. Study designers can use data classification to hide or show questions in a form based on the users' study roles. It works just like a backstage pass that allows some users to see what's behind the curtain.

After study designers switch the **Hidden** toggle for a question or item, they can classify that data. Data classifications are predefined and are connected to study roles. For each data classification, the user administrator assigns permissions to view or edit that data category to a study role. This means that when a study designer selects a data classification for a hidden question, that question remains hidden to all users except the ones that are assigned the specific permission to view or edit that type of data.

For instance, when a study designer hides a subject's Social Security Number in a form and then classifies the data as Personal Identifiable Information (PII) data, that field will be hidden to all users except those the user administrator assigned the permissions to view or edit PII data. In this case, the user administrator assigned the permission to edit PII data to a site user and the permission to view data to an unblinded Data Manager.

Details for user administrators

From now on, your workflow for creating or editing a study role includes a few more steps. On the **Study Role** tab, on the right pane, there is a new **Data Classifications** section where you can assign users permissions to view or edit specific types of data that are otherwise hidden to other users. For example, you can assign the permission to view sponsor data to a data manager for the permission to edit Personal Identifiable Information (PII) data to a site user

Details for study designers

When it comes to your workflow, you can now classify data when hiding questions in a form. This allows you to create exceptions on hidden questions.

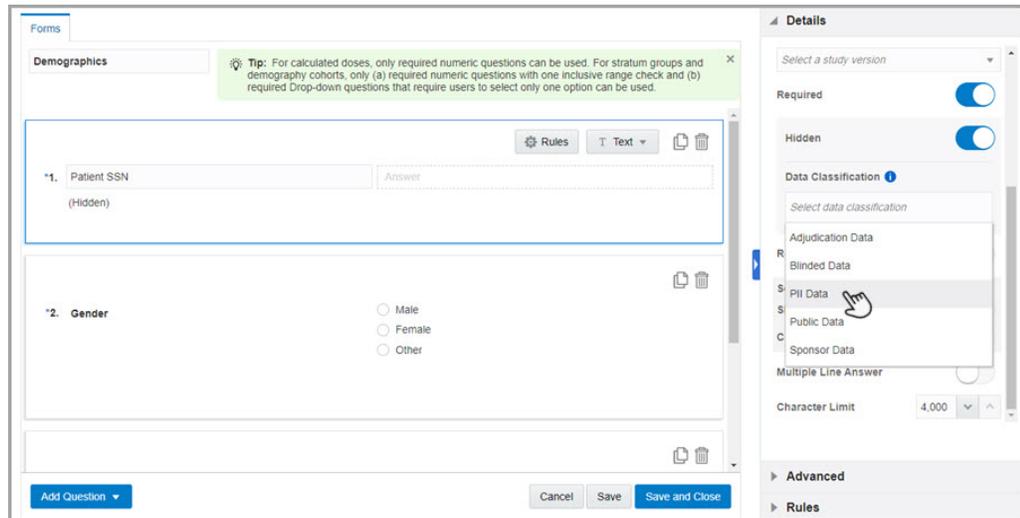
In a standard form, below the **Hidden** toggle there is a new **Data Classification** drop-down that allows you to further define the type of data the question belongs to. Data classifications are defined in the context of a study role. So when you choose a data classification from the drop-down, all users that are assigned the permissions to view or edit that type of data gain the appropriate access to that hidden question.



Note:

The **Data Classification** drop-down is enabled only after you switch the **Hidden** toggle.

Figure 19-2 How study designers classify data in forms



Reporting changes

In the following reports, hidden questions appear only if the users generating the reports have the permissions to view or edit the data classifications that were assigned to those questions:

- CRF Submit
- Subject Data
- Subject Data Extract. For more details on the changes in this report, see [Run the Subject Data Extract \(Blinded\)](#)
- Subject Events
- Subject Queries

Already working in a live study?

As soon as the release upgrade is done, study designers can start classifying data when hiding questions and user administrators can assign new permissions in the **Data Classifications** section to give users access to those hidden questions. For these changes in the study to become effective in Production, the updated study version must be moved to the Approved container.

Create multiple visit branches

Study designers can now design multiple visit schedules and cycle visits in the same study. You can design multiple visit schedules based on either a randomization or business logic rule.

What are the benefits?

Having multiple visit schedules can serve a multitude of use cases in a clinical study. Here's a quick list of different types of studies and how multiple visit schedules may help in these scenarios:

- **Washout periods:** designing another visit schedule for a washout period during a study allows you to only display the specific visit schedule for subjects who meet the requirements for entering this study period.
- **Studies with multiple cohorts or treatment arms:** multiple cohorts or treatment arms might require multiple visit schedules for subjects, based on a determining event during the study. For example, subjects who underwent surgery during a study might require a longer follow-up visit period as opposed to those who have had no surgeries. An oncology study is another example that might require different visit schedules, since the subjects' dispensation might vary based on the treatment arm assignment.
- **Global studies:** these studies have different visit structures based on specific local requirements in each country. For example, if a global study is also running in Japan, an extra visit schedule might be needed to accommodate the country's dispensation rule. If a global study is running in a country such as Germany, a different visit schedule with different form variants might be required to accommodate the country's rule forbidding the collection of full dates of birth.

Details for study designers

When it comes to your workflow, there are new updates that you should be aware of:

- On the Forms tab, there's a new option when adding a visit, called **Add Branch to Bottom**. Selecting that option displays the **Create Branch** dialog where you can define the new branch's settings, as well as the treatment arm settings, if required.
- You can create multiple visit branches in a study and include as many scheduled visits in a visit branch as necessary. You cannot include unscheduled visits or events in a visit branch.
- A visit branch can be edited, or deleted. Additionally, you can also cycle the visits in a branch for as many times as your protocol indicates.
- You can use treatment arms, cohorts, or form questions in the study to start the transition of a subject on a different branch. For example, if your study requires a long term extension you must include a question on the informed consent of a subject for the long term extension. If a subject answers Yes, they can be moved to the Long Term Follow Up visit branch. Or, if a subject is currently placed on the Standard of Care treatment arm, then they may be transitioned to the next visit branch using a different treatment arm, in the study.

Figure 19-3 How a study designer might create a branch

Create Branch [X]

Branch Settings

* Title

* ID

* Cycle the Branch Yes No

Count of Cycles [v] [^]

* Assign Subjects Using **Treatment Arm** Cohort Form Item

Treatment Arm Settings

* Treatment Arm

A - Standard of Care

B - Standard of Care Plus Active Drug

Save

Details for site users

When it comes to your workflow, the updates are minimal. All you need to know is that, from now on, on the Subjects tab, when you select a subject, you can see the visits included in branches.

Figure 19-4 How site users see the Subjects tab and branches

Subject	Adverse Event	Next Visits	Previous Visits
SG-LBSNAA22 Enrolled	0 Total	B2V2 (27-Oct - 31-Oct)	B2 (1) B2V1 Branch1 (2) B1V3 B1V2 B1V1 UnScVisit Branch1 (1) B1V3 B1V2 B1V1 Visit
SG-LBSNAA21 Enrolled	0 Total	B1V1 (26-Oct - 30-Oct)	Branch1 (1) B1V3 B1V2 B1V1 Visit Screening
SG-LBSNAA20 Enrolled	0 Total	B1V2 (26-Oct - 30-Oct)	Branch1 (2) B1V1 Branch1 (1) B1V3 UnSchV1 B1V2 B1V1 Visit Screening
SG-LBSNAA19 Screen Failed	0 Total	---	Screening
SG-LBSNAA18 Enrolled	0 Total	B1V3 (07-Oct - 13-Oct)	Branch1 (1) B1V2 B1V1 Visit Screening
SG-LBSNAA17 Enrolled	0 Total	---	B2 (2) B2V1 B2V2 B2V1 B1V3 Branch1 (2) B1V2 B1V1 Branch1 (1) B1V3 B1V2 B1

Already working in a live study?

Once the upgrade is complete, a study designer can start designing multiple visit schedules in an existing live study. After the visit schedule updates are done in Draft mode, the changes should be tested in Testing mode before being made live in Production.

Enter data directly into a repeating form table

Site users can now enter values directly into the table cells of a repeating form when adding the first instance of data.

Details for site users

When you enter the first instance of data in a repeating form, you can now add the values directly into the table by double-clicking the first row and then each table cell that you need to complete. Previously, when you double-clicked the first row in a repeating form table, a new data entry dialog appeared where you had to answer all questions. The data entry dialog now appears starting with the second row of the table, as well as when you edit data in the repeating form.

Already working in a live study?

As soon as the upgrade for this release is complete, site users can start entering data directly into the table cells of a repeating form when adding the first instance of data.

Run the Subject Data Extract (Blinded)

Data managers and statisticians can now extract cumulative subject data for data analysis or regulatory reporting for the study that they're working in based on their specific permissions

What are the benefits?

Until now, only unblinded subject data could be extracted in a study. For this release, data managers and statisticians will now see data based only on their permissions and what types of classified data they can view or edit. For more information on the data classification feature, see [Classify data in a form](#).

Details for data managers and statisticians

There are no changes in your workflow. What you need to know is that the Subject Data Extract (Blinded) consists of a ZIP file containing a CSV file for each form designed in your study. These CSV files now contain only data that you're allowed to view in a study. For example, if you can view PII data in a form, that type of data will also appear in the Subject Data Extract (Blinded).

Already working in a live study?

As soon as the upgrade for this release is complete, any user that's assigned the *Run the Blinded Subject Data Extract* permission can generate this report.

Fixed issues

- [Forms, visits, and rules](#)
- [Randomization and kits](#)
- [Site users and subject data](#)
- [Site, depot, settings, and user management](#)
- [Site users and subject data](#)

Forms, visits, and rules

Rollover icon now appears on lab form file (former known issue)

Study designers: From now on, on the Forms tab, when including a rollover type of question in a lab form, the icon appears on the lab form tile, as well.

Retracted workaround: None. (Issue 31907134)

You can now reorder default questions in a lab form (former known issue)

Study designers: When working with lab forms, you can now reorder the default questions.

Retracted workaround: None. (Issue 31896011)

Randomization and kits

Randomization design now applied to the correct study versions (former known issue)

Study designers: From now on, when you create a new question and a new randomization design for demography cohorts, and apply this change to previous live study versions, the new randomization design isn't applied along with the new question, as expected.

Retracted workaround: None. (Issue 31870075)

Site users and subject data

No error when screening a subject selected for SDV (former known issue)

Site users: From now on, you can successfully screen a subject selected for source data verification (SDV). The error message stating "Your change on this page won't be saved" no longer appears. Previously, you could not screen a subject selected for source data verification (SDV) because the system thought another user was working on the same subject.

Retracted workaround: You no longer have to refresh the page in your browser. (Issue **31937630**)

Answers to a question with checkboxes now displayed in the Answer History pane (former known issue)

Site users and lead site users: From now on, for an already answered question with checkboxes, when you select an answer option, the answer appears in the Answer History pane, as expected.

Retracted workaround: You no longer have to select a different answer and then click Save to see the answer history for a question with checkboxes. (Issue **31543586**)

Error seen when a data flag is applied in a Repeating form that contains a rule (former known issue)

Site users: From now on, in a repeating form, when applying a data flag to a default row where a rule is applied, you no longer observe an Oops error upon saving.

Retracted workaround: None. (Issue **31935069**)

Site, depot, settings, and user management

In-product video link now points to the right video (former known issue)

Data managers and site users: On the Sites & Labs tab, when creating a tab, you'll notice the "See how it works" hyperlink now points to the right video explaining how to create a lab. Previously, when clicking the in the Create Lab dialog, you were redirected to the Create/Activate/Retire Sites video.

Retracted workaround: See [Create Labs and Enter Normal Reference Ranges](#). (Issue **31884446**)

Oracle Clinical One Platform 20.3.0.1

- [Fixed issues](#)

Fixed issues

- [Forms, visits, and rules](#)
- [Randomization and kits](#)
- [Site users and subject data](#)
- [Site, depot, settings, and user management](#)

- [Site users and subject data](#)

Site users and subject data

For this release, we fixed several performance issues that were affecting the user experience of sites in the application. For more information on these issues, see the bug numbers listed below:

- 32014751
- 31960754
- 32009670
- 32008951
- 32010009

Oracle Clinical One Platform 20.3 (October 2020)

- [What's new](#)
- [Fixed issues](#)

What's new

- [Data collection enhancements](#)
Site users now benefit from two new enhancements that make the data collection process easier and the overall user experience much better.
- [Rule design enhancements](#)
Rule designers can now set query messages dynamically within rules.
- [Data collection](#)
- [Data review](#)
- [Lab data management](#)
- [Randomization and supplies](#)
- [Reports and archives](#)
- [Rules Management](#)

Data collection

- [Copy and reuse rules](#)
Study designers can now copy forms, along with their associated rules, from other studies.
- [Enroll subjects who were screened or randomized in another system](#)
Site users can now enroll subjects who were screened or randomized in a different system to an Oracle Clinical One Platform study. As a result, study designers can now create studies without screening or randomization visits.
- [Include predefined labels to create tabular forms](#)
Study designers can now add Label items to repeating forms and display data in a tabular format. This helps site users easily enter and compare data.

- [Hide questions and read-only items in a form](#)
Study designers can now hide questions and read-only items in a form and have more control over the questions that are displayed.
- [Update and manage changes in a live study](#)
Study designers can now update a form in a live study retrospectively. This allows you to make changes to forms within your study without changing the study version.

Copy and reuse rules

Study designers can now copy forms, along with their associated rules, from other studies.

What are the benefits?

As a study designer, you can now easily copy and reuse rules along with the forms the rules are associated with. By copying rules from other studies, you not only save time and build studies more efficiently, but you also ensure consistency with your designed rules.

Details for study designers

When it comes to your workflow, there are no major changes. What you need to know is that, from now on, when you copy forms from other studies, the rules that are associated with those forms are also copied. The rule is copied with the same status it had in the study you copied from. You can reuse a copied rule as-is, or you can modify and publish or re-publish it for the new study.

Already working in a live study?

As soon as the upgrade for this release is complete, you can start copying forms together with their associated rules.

Enroll subjects who were screened or randomized in another system

Site users can now enroll subjects who were screened or randomized in a different system to an Oracle Clinical One Platform study. As a result, study designers can now create studies without screening or randomization visits.

What are the benefits?

As a site user, you can now enroll subjects who were screened or randomized in another system. This new feature helps you provide consistency across subjects and gives you the flexibility to manage data and dispense kits to a subject, even if they are screened in a different system or you choose not to randomize in Oracle Clinical One Platform.

Details for study designers

You can now design a study without a screening or randomization visit. If a screening visit is not present in your study design, subjects that are screened or randomized outside of Oracle Clinical One Platform can be added to a study and are placed directly in the **Enrolled** state. If your study design includes a screening visit, subjects can still be added from an outside system. However, the subject status will not be set to Enrolled until after their screening visit is successfully completed.

Details for site users

When you add subjects that were screened or randomized outside of Oracle Clinical One Platform, their state is automatically set to **Enrolled** (this state is similar to the Active state for subjects screened and randomized in Oracle Clinical One Platform today). If the study design

contains a screening visit, the subject's state will change to **Enrolled** only after the screening is successfully completed.

Already working in a live study?

This new feature doesn't affect your live study as it applies only to new studies.

Include predefined labels to create tabular forms

Study designers can now add Label items to repeating forms and display data in a tabular format. This helps site users easily enter and compare data.

What are the benefits?

With predefined labels you can design tabular forms. A tabular form allows a site user to better review subject data during a study and offers them a holistic view of subjects' evolution.

As a study designer, Label items let you add predefined, read-only values to a repeating form and better control the data that is collected. By adding predefined labels to your repeating form, you can restrict or expand the number of rows that a site user can use to collect subject information. For example, when you create a Physical Exam form, you can now add a **Label** item as the first question on the form and title it **Body System**. You can then specify predefined, read-only values for each body system that is examined (such as, **Ears, Nose, Throat**). This allows you to define the exact number of rows to be displayed in the form and the items for which you want to collect data. Depending on your needs, you can let site users add additional rows for other body systems or you can limit the data they collect to a fixed number of rows. This gives you more control over the data collection process, reduces the potential for error, and allows for easier data entry.

Details for study designers

On the Data Collection tab, when you create a repeating form you can now:

- Add a **Label** item in the form, which serves as the column header for any predefined values
- Allow site users to add additional rows to a form

Figure 19-5 Study designers can now add a Label type item to a repeating form

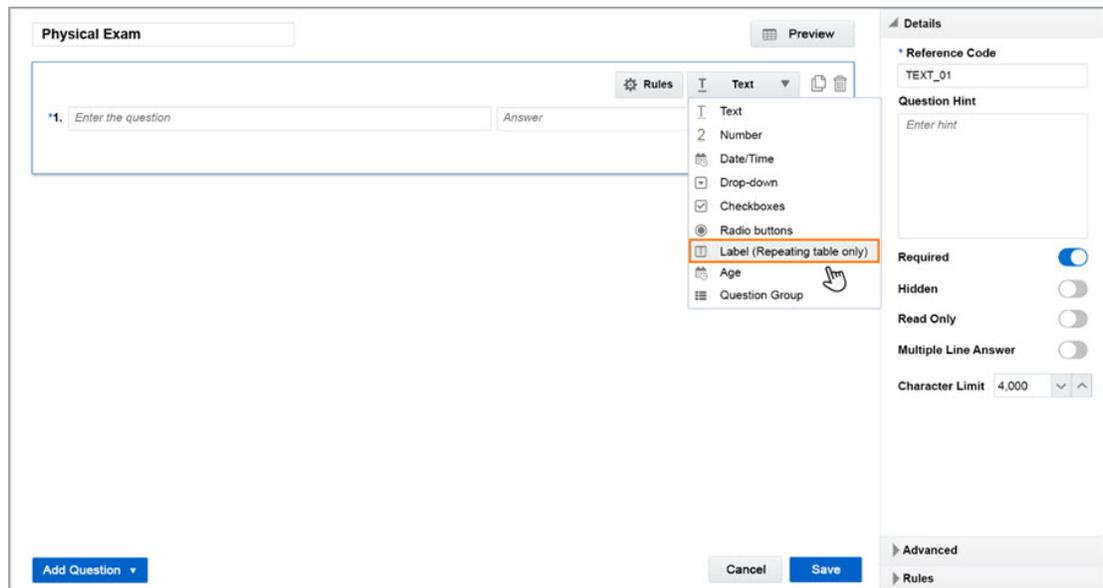


Figure 19-6 Study designers can allow site users to add new rows to a repeating form



Details for site users

Your workflow for collecting data hasn't changed, but you will notice some design updates if you are completing a tabular form with predefined labels. Here's what's new:

- Label values are read-only and you can't edit or delete them
- Depending on the study design, you may be allowed to add extra rows of data in a tabular form. The **Add** button is only present for forms that allow you to collect extra data rows

Figure 19-7 How site users see Label items in a repeating form

#	Body System	Normal	If Abnormal provide details
1	Ear	Double click to enter	Double click to enter
2	Nose	Double click to enter	Double click to enter
3	Throat	Double click to enter	Double click to enter

Vital Signs

* 1. Date of Data Collection

2. Blood Pressure mmHg

* 3. Temperature F

* 4. Pupil size mm

Already working in a live study?

As soon as the upgrade is complete, study designers can create tabular forms with predefined labels. After the study version is moved to the **Approved** container, site users may encounter tabular forms in new or updated live studies.

Hide questions and read-only items in a form

Study designers can now hide questions and read-only items in a form and have more control over the questions that are displayed.

What are the benefits?

From now on, study designers can choose which questions are displayed on forms and hide the items that shouldn't appear when collecting data. For example, when you create forms for collecting data on concomitant medications and you add coding questions to the form, now you can hide the read-only items that you create to get populated automatically with the coded term for Trade name or Drug name.

Details for study designers

On the **Data Collection** tab, when you create or edit a form, you now have a new toggle button that allows you to hide a question from site users.

Figure 19-8 How study designers see the new Hidden toggle button

Already working in a live study?

As soon as the upgrade for this release is complete, you can start hiding certain questions in a form so they don't appear to users who shouldn't have access to that data. You perform the update in Draft mode and it is now so much easier to apply the change to a live study version with the new study versioning feature. For more details, see [Update and manage changes in a live study](#)

Update and manage changes in a live study

Study designers can now update a form in a live study retrospectively. This allows you to make changes to forms within your study without changing the study version.

What are the benefits?

As a study designer, you can now modify a form in a live study version without changing the study version. This new feature gives you the ability to make changes to currently live study versions while data is being actively collected in the system. These changes can even be applied to completed forms. This ability gives you more flexibility when it comes to planning your study design and allows you to quickly integrate minor or unplanned study changes into multiple study versions without going through the entire study versioning process.

As an example, let's say you need to add a new question to a form that is included in a live study version (1.0.0.1). Data is already being collected on that form so you need to apply the change for all subjects, including those that already started or completed the form. You first create a new study version (1.0.0.2) and make the necessary changes to your form in Draft mode. When you edit the form you now have the option to apply the change directly to an existing live version (in our example, version 1.0.0.1). Once the new study version (1.0.0.2) is moved to the **Approved** container, the update automatically becomes available in the previous study version (1.0.0.1). You don't need to update the study version (1.0.0.1) for sites already on that version. Your updates appear for all subjects, including where data has already been collected. If the form you just updated was already completed by any of the

subjects during the study, site users must go back to that form and enter answers for any questions you added or modified.

Details for study designers

Your workflow for updating a live study includes a couple of changes.

Whenever you want to edit a form used in a live study version, you must use the new setting that allows you to apply the change to an existing live study version. When you click the **Apply Change to Version** drop-down, a list of all study versions in Testing, Approved, and Archived appears.

Once the new version is moved to the **Approved** container, the update also becomes available in the study version you selected when editing the form and to all sites to which that study version is assigned. Additionally, the change will apply to all study versions created after the study version you selected in the **Apply Change to Version** drop-down. That is, your change applies to the version you select as well as any version created more recently.

Details for site users

From now on, form design can be updated retrospectively. This means that forms you already completed, can become incomplete if a required item is later added to the form. The change becomes available only after you enter the visit and access the form. You can edit the form and click **Save**.

Already working in a live study?

As soon as the upgrade for this release is complete, you can start to retroactively modifying forms in live studies for existing and newly created forms.

Data review

- [Create a targeted source data verification strategy](#)
Study managers can now create a source data verification (SDV) strategy for their studies to customize, by site, which visits, forms, and questions in a study require source data verification by a Clinical Research Associate (CRA).
- [Protect your data with the freeze feature](#)
Data managers or Clinical Research Associates (CRAs) can now freeze data in a study. This prevents site users from modifying case report form data.

Create a targeted source data verification strategy

Study managers can now create a source data verification (SDV) strategy for their studies to customize, by site, which visits, forms, and questions in a study require source data verification by a Clinical Research Associate (CRA).

What are the benefits?

A targeted source-data verification strategy enables your study team to perform source data verification (SDV) in an effective manner. You can configure your study so that it only requires source data verification (SDV) for a certain number of subjects and only for critical questions in the study. This improves the efficiency of the source data verification (SDV) process, and helps the study team spend less time verifying data that is not critical to the study's efficacy or a patients' safety. Targeted source data verification (SDV) strategies are also less costly for your organization.

Details for user administrators and global user managers

Your workflow hasn't changed. However, there are some new permissions that you need to be aware of. Study designers and study managers must have the correct permissions included in their study roles in order to mark questions or items for source data verification (SDV) and to create a targeted source data verification (SDV) strategy.

You can assign these permissions to study roles created at either the study level or at the organization level.

Table 19-1 Required permissions

Study role	Permission
Study designer	Design SDV Properties on Forms
Study manager	Create and Manage SDV Strategies
CRA	Perform Source Data Verification and Reconcile Inventory

Details for study managers

When it comes to your workflow, you can now define a source data verification (SDV) strategy either at a study or site level. If you create a source data verification (SDV) strategy for the entire study, you can make specific changes to the strategy at a site level at any time. The site-level updates override the study-level strategy.

You can define a source data verification (SDV) strategy for each of the three modes: Testing, Training, and Production.

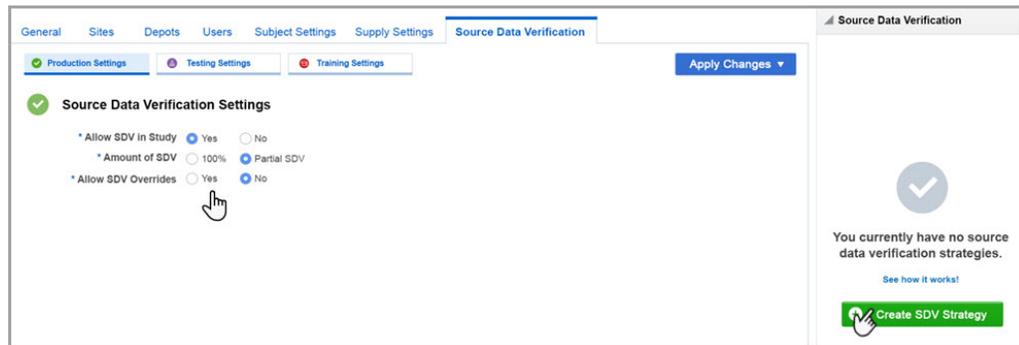
Most settings on the Source Data Verification tab are set to **No**, by default. The settings include:

- **Allow SDV in Study:** Leave **No** selected if you do not require source data verification in the study. If you want to allow source data verification (SDV) in your study, select **Yes**.
- **Amount of SDV:** If you select **100%**, Clinical Research Associates (CRAs) must verify all visits, forms, and questions for subjects at a site. If you select **Targeted SDV**, only certain data elements will need to be verified during a study.
- **Allow SDV Overrides:** Select **No** if you want to prevent CRAs from verifying any questions that aren't marked as **SDV for All Subjects** or **Critical Variables (Targeted SDV)** for source-data verification. If you select **Yes** for this setting, CRAs will be allowed to verify questions or items that aren't specifically marked for source data verification.

On the same Source Data Verification tab, you can also create multiple source data verification (SDV) strategies and define the number of subjects whose data should be verified in a study and you can select the type of verification CRAs can perform, for all questions or for critical questions only.

You can assign a source data verification (SDV) strategy to a site using the new SDV Strategy column on the Sites & Labs tab.

Figure 19-9 How a data manager configures a targeted source data verification (SDV) strategy



Details for study designers

When it comes to your workflow, you can now mark questions or items in a form so that CRAs know when to perform source data verification on the marked questions.

When you select a question, on the Details pane, you'll notice the **Source Data Verification** setting. Under that setting, select one of the following:

- **SDV for All Subjects:** this setting indicates that a CRA must always verify this question when specified in the Source Data Verification strategy
- **Critical Variables (Targeted SDV):** this setting indicates that a CRA must verify this question when the Source Data Verification strategy indicates that critical questions must be verified

If there is no targeted source data verification (SDV) strategy configured by the study manager or any other sponsor user, you can leave both options in the default state (unselected). Leaving both options unselected means no questions are required to be verified in the study.

Details for Clinical Research Associates (CRAs)

Depending on how your source data verification (SDV) strategy is designed, here's what's new for you:

- If an item or question in a form must be verified, you'll see an outlined checkbox next to the item.
- If an item or question in a form isn't required to be verified, but you can still verify it, you'll see a standard checkbox next to it. This is the same as in the existing system for items that can be verified.

Already working in a live study?

If you're currently working in a live study and want to create a targeted source data verification strategy for that live study version, you'll typically need to do the following:

- **Study manager or clinical operations manager:** On the Source Data Verification tab, for any of the three modes, configure the SDV settings, and create your targeted SDV groups.
- **Study manager, site administrator, or clinical operations manager:** On the Sites & Labs tab, assign the targeted SDV strategy to a site.

- **Study designer:** Depending on how the targeted SDV strategy is set up, mark questions or items in a form as either **Always** or **Critical** for SDV.

Protect your data with the freeze feature

Data managers or Clinical Research Associates (CRAs) can now freeze data in a study. This prevents site users from modifying case report form data.

What are the benefits?

With this feature, data managers can freeze visits, forms, or questions either temporarily during a study, or permanently at the end of a study. This secures data and helps ensure quality by preventing further changes to the data. This is typically done prior to data extraction for statistical analysis or data formatting for submission to regulatory agencies.

Details for user administrators

Your workflow hasn't changed. However, there is a new permission that you need to be aware of. Any user responsible for freezing and unfreezing data must have the *Freeze and unfreeze data* permission. This task is typically performed by a data manager or CRA.

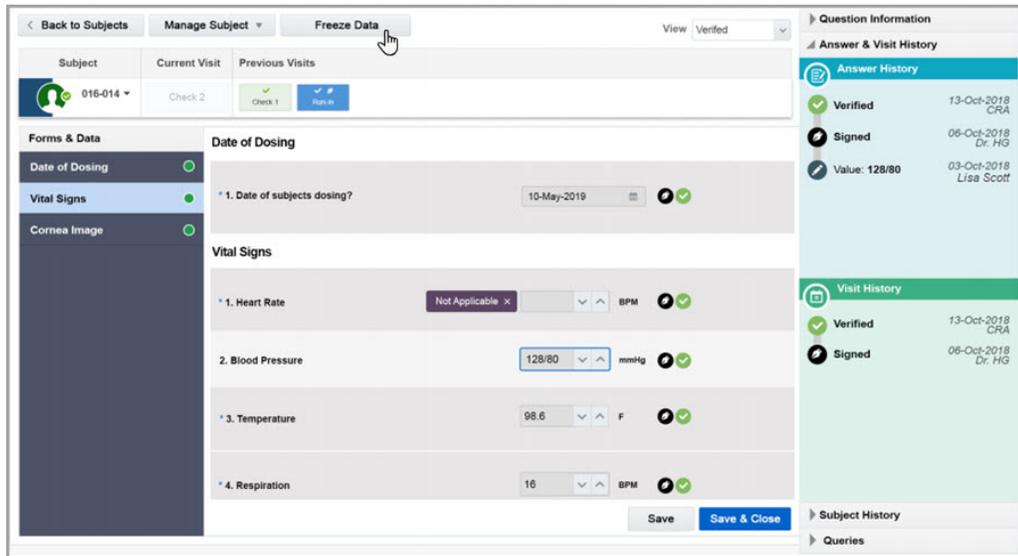
Details for data managers and CRAs

If you are responsible for this task, you can freeze data at a visit, form, or question level. Any type of object can be frozen. This includes items such as incomplete visits, forms, and unanswered questions as well as repeating form instances, dynamic forms, and read-only items.

You will also notice the following:

- You can freeze data that has been signed and verified. To do this, on the Subjects tab, select the **Signed & Verified** option. You can also freeze data before it has been signed or verified. It's up to you
- In a visit, there's a new **Freeze Data** button that you can click to freeze the data for an entire visit, or you can freeze certain forms and questions. After selecting the data that needs to be frozen, click **Freeze** or **Freeze & Close**
- Data can only be unfrozen at a question level
- When data is frozen or unfrozen, the updates appear in the Visit History
- Because read-only items are typically populated automatically using calculated values or coded terms, these items may still update, even when frozen

Figure 19-10 How data managers freeze data in a visit



Details for site users

Your workflow hasn't changed. However, keep in mind that you can no longer update any data for a frozen visit, form, or question.

Already working in a live study?

As soon as the upgrade for this release is complete, make sure the data manager on your study team has the correct permissions to start working with this feature. This feature can be used in any mode: Testing, Training, or Production.

Lab data management

- [Create and manage labs](#)
With Oracle Clinical One Platform, you can now create lab forms, manage labs, and collect lab results during a visit in a study.

Create and manage labs

With Oracle Clinical One Platform, you can now create lab forms, manage labs, and collect lab results during a visit in a study.

What are the benefits?

By creating and managing labs, as well as lab-specific forms, users at a sponsor organization and site users can now collect and compare crucial data during visits in a study. Lab data collection through lab forms can be used in a variety of ways during a clinical study. For example:

- **Screening labs** are used to establish inclusion and exclusion criteria. Collecting lab results allows site users to accurately determine whether a subject can be enrolled in a study
- **Safety labs** can be used to establish the safety of subjects during a study and to provide more data on how subjects respond to an investigational product

Details for user administrators and global user managers

Your workflow hasn't changed, but there are some new permissions that you need to be aware of. To add labs, define lab normals, and associate labs with sites, users must have the required permissions. These permissions are typically given to a data manager or other sponsor use. In some cases, depending on your study's protocol, you may assign some of these permissions to site users.

You can assign these permissions to study roles created at either a study level, or at an organization level.

Table 19-2 Required permissions

Study role	Permission
<ul style="list-style-type: none"> Data manager Site user Any other study role designed for sponsor users 	<ul style="list-style-type: none"> Create and Add Labs to a Site Add a Lab to a Site Add and Update Lab Normal Ranges

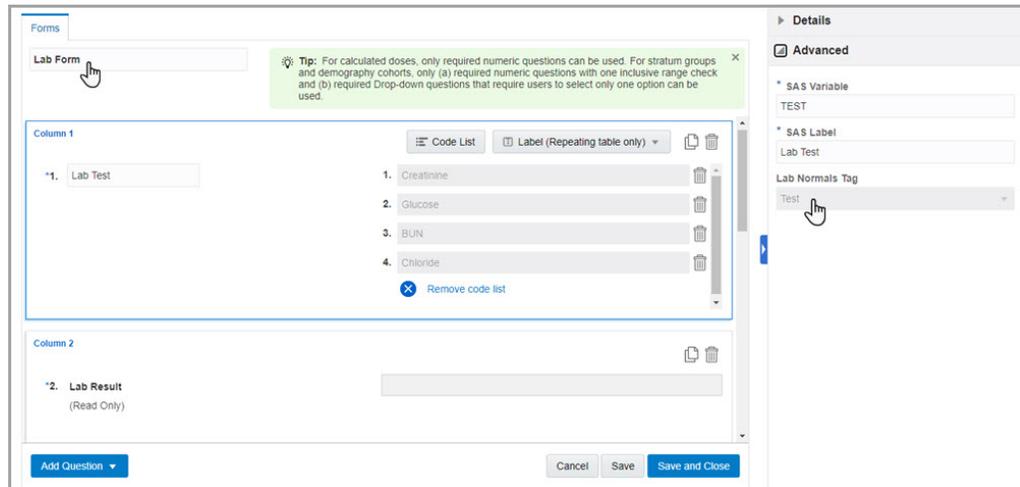
Details for study designers

Study designers can now create lab forms. To help accelerate your build time, lab forms contain predefined label items such as Lab Test, Lab Unit, Lab Results, and other items you would typically include in a lab form, as well as predefined code lists. You must update predefined and tagged code lists and lab tests to follow your study's protocol when defining lab normals and collecting lab results. Additionally, you can add other questions or items you find necessary for site users to collect lab data.

Typically, a lab form contains labels, drop-down questions, questions with checkboxes, text questions, number questions, read-only items, and other types of question or items that help data managers or site users define lab normals and collect lab data. This release introduces **Labels** which can also be used in lab forms. To learn more about **Labels**, see [Include predefined labels to create tabular forms](#).

Study designers can also add subject tags and lab tags for certain questions or items when the labs included in the study have different normals depending on gender or other demographic tags. For example, a subject tag is typically used in a demography form to tag questions on a subject's date of birth, race, or gender. Lab tags are used to tag items or questions in a lab form.

Figure 19-11 How a study designer creates a lab form



Details for data managers and site users

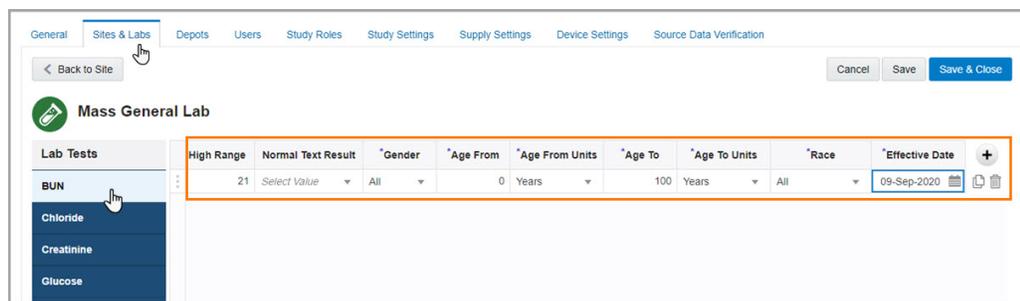
Data managers and site users can now create and manage their own labs during a study.

On the **Sites & Labs** tab, you can now create a lab in the context of a site, give it a name, and a short name or Lab ID. Every lab created in the context of a site is already associated with the respective site.

You can create, edit, or remove labs as required. Once your labs are added, you can start adding lab normals associated with the newly created laboratory. These are predefined standard values that site users can use to compare lab results they collect during a visit from a subject. You'll have to define lab normals for every lab collected in the study.

After finishing your lab, you can click **Save** or **Save & Close**.

Figure 19-12 How a user defines lab normals for a lab test



Details for site users

When it comes to your workflow, you can now collect lab results for subjects in a more integrated manner. What this means is that you can now select the lab that you are collecting data for and you can also apply the appropriate normal ranges to those results. Here's what you'll see new in the user interface:

- As part of the entry of lab results, you must select the lab from the **Select Lab** drop-down
- If you have the appropriate permissions, you can create a lab "on the spot" and define lab normals for that newly created lab, before entering data in the lab form. To do this, use the **Go to Sites & Labs** shortcut from the **Select Lab** drop-down

Figure 19-13 What a site user first sees in a visit when there's a lab form they must complete

The screenshot displays the Oracle Clinical One Platform interface. At the top, there are tabs for 'Subject', 'Adverse Events', 'Current Visit', and 'Previous Visits'. The 'Current Visit' tab is active, showing a 'Check 9' button and a list of previous checks (Check 8 through Check 1). On the left, a sidebar contains 'Forms', 'Vital Signs', and 'Cornea Image' sections. The main content area is titled 'Lab Form' and features a message: 'This is a lab form. Add an existing lab or create a new one below. See how it works!'. Below this message is a 'Select Lab' dropdown menu with a 'Go to Lab Settings' link and a 'Create Lab' button. The dropdown menu is open, showing a list of labs, including '001 - Quest Diagnostics North Andover'. Below the dropdown, there are five numbered fields: '1. Date of Data Collection' (YYYY), '2. Blood Pressure' (mmHg), '3. Temperature' (F), '4. Pupil size' (mm), and '5. Respiration' (BPM). At the bottom right, there are 'Save' and 'Save & Close' buttons. On the right side of the interface, there are sections for 'Answer History' (Value: 128/80, 03-Oct-2018, Lisa Smith) and 'Visit History'.

Already working in a live study?

As soon as the release upgrade is done, study designers can start creating lab forms and data managers or site users with the appropriate permissions can create labs and define their lab normals. For these changes in the study to become effective in Production, the updated study version must be moved to the Approved container.

Randomization and supplies

- [Deactivate kit lists](#)
Clinical supply managers now have the flexibility to deactivate a kit list that uploaded into the system.

Deactivate kit lists

Clinical supply managers now have the flexibility to deactivate a kit list that uploaded into the system.

What are the benefits?

Most of the times, kit lists can't be easily changed, as the physical investigational product is often packaged and ready to ship by the time the list is uploaded. And because a kit list contains unique kit numbers, clinical supply managers often times cannot make any changes to the list and they can't upload a new one with the same kit numbers, either. With this new feature, if you ever upload a kit list in error for a live study, you can now deactivate the kit list, rename it, and then re-upload it into the system.

Details for clinical supply managers

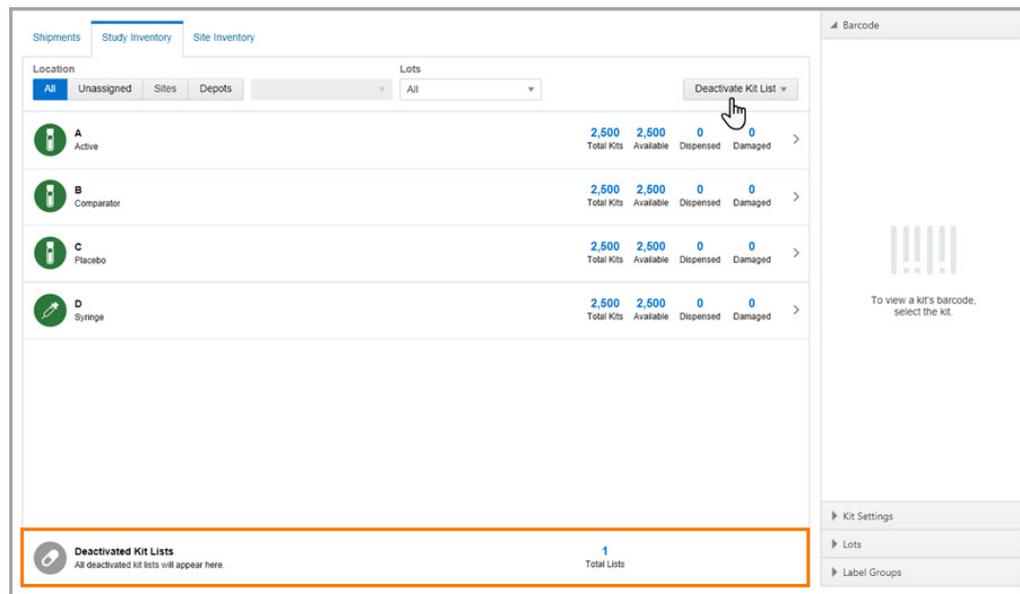
On the **Study Inventory** tab, you can now deactivate kit lists by clicking the **Deactivate Kit List** button and selecting a kit list that you want deactivated.

A kit list might take some time to be deactivated, so you'll receive a notification when the process is complete. Until then, you shouldn't upload another kit list or re-upload the one you just deactivated. Additionally, you can receive a notification if the kit list deactivation has failed.

Once a kit list is deactivated, it will appear under the active kit lists on the **Study Inventory** tab. You can deactivate as many kit lists as you want.

Lastly, the Kit Chain of Custody report will also contain a new column called **Status**, where you'll see the status of all uploaded kit lists in a study, whether they're **Deactivated** or **Active**.

Figure 19-14 How clinical supply managers can deactivate a kit list and view deactivated kit lists



Already working in a live study?

As soon as feature is released, you can start deactivating kit lists, if needed. Remember that you can deactivate a kit list in Testing, Training, and Production modes. A kit list can be deactivated during the study conduct period.

Reports and archives

- [Annotated Forms report](#)
Study designers and other users at a sponsor organization can now generate annotated case report forms to either review the study design and determine that it matches protocol requirements or for regulatory submissions.

Annotated Forms report

Study designers and other users at a sponsor organization can now generate annotated case report forms to either review the study design and determine that it matches protocol requirements or for regulatory submissions.

What are the benefits?

The Annotated Forms report contains blank case report forms with annotations pointing to the location of the data with the corresponding form names, as well as the names of variables included in the forms.

Details for study designers and other sponsor users

Typically, this report can be run by either a study designer, a randomization list manager, or a production administrator.

This new report can be found on the **Reporting** tab for every study and contains a section for every form designed in the study. In every section dedicated to a form, the following columns are displayed:

- **Question:** The exact text of the question, as well as the question's hint, if applicable
- **Reference ID:** A question's reference code
- **Answer:** A question's answer format, including type, length, or answer options
- **Validations:** A question's validation rules or rules related to dynamic questions and forms
- **Advanced:** A question's advanced properties such as SAS variables

Rules Management

- [Create rules to check for missing data](#)
Rule designers can now create rules to easily determine if data is missing from forms and visits.

Create rules to check for missing data

Rule designers can now create rules to easily determine if data is missing from forms and visits.

What are the benefits?

Rules now work as effective data monitors checking if data is missing from forms and raising a query every time a data field is found empty. This allows sponsor users to ensure study data is always complete and the study results are accurate and reliable.

Details for rule designers

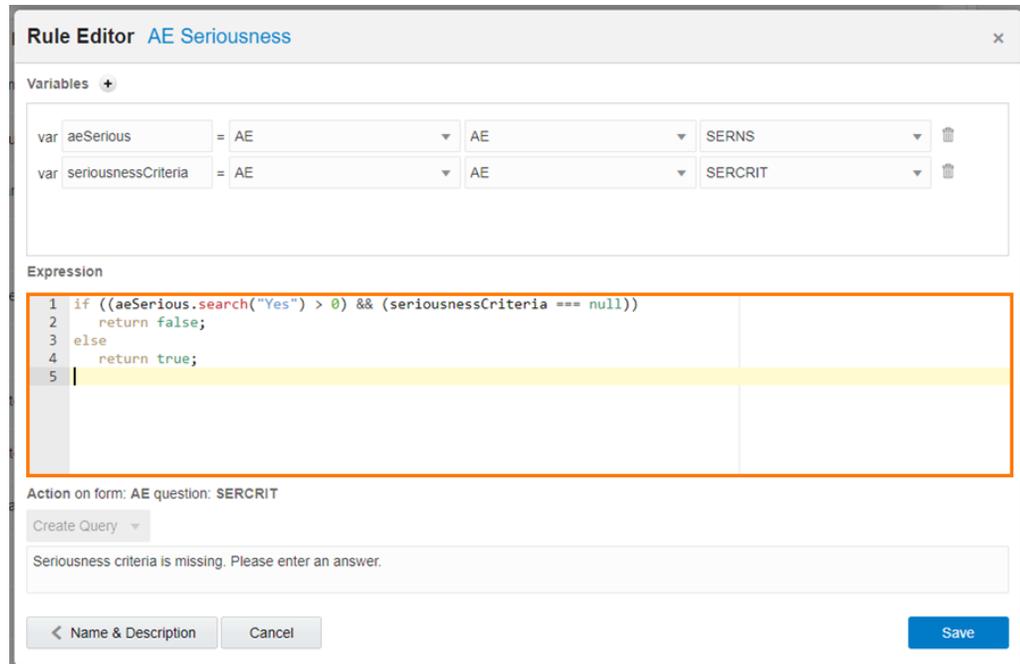
You can now create rules to verify collected data and raise a query anytime data in a form or a visit is incomplete. To detect missing data in forms you have to include the appropriate JavaScript expressions that:

- Check for empty data item(s)
- Check data item(s) across forms
- Check data item(s) across visits

- Use logical operators AND, OR, NOT to combine multiple checks
- Check all instances of a repeating form
- Check specific instances of a repeating form

Here's an example of a JavaScript expression that can be used in a form to ensure the seriousness criteria question is always completed when an adverse event is evaluated as serious:

Figure 19-15 A rule example for detecting missing data in a form



To learn more, see [Detect missing data](#).

Already working in a live study?

You can start creating rules to determine if data is missing from forms and visits as soon as the upgrade for this release is complete.

Fixed issues

- [Fixed issues for forms and visits](#)
- [Fixed issues for integrations](#)
- [Fixed issues for randomizations and kits](#)
- [Fixed issues for reports and notifications](#)
- [Fixed issues for site users and subject data](#)

Fixed issues for forms and visits

Date of Birth field is no longer editable when marked as read-only (former known issue)

Study designers: From now on, when you specify details for an Age type of question and then mark the Date of Birth field as read-only, a site user can no longer enter data in that field. Previously, when a Date of Birth field was marked as read-only, a site user could still enter a date.

Retracted workaround: None. (Issue **30643923**)

Action button now displayed for visits with dynamic questions in repeating forms

Site users: From now on, when you answer a dynamic question in a repeating form instance, the repeating form displays that form as complete and the action button for that visit is displayed, allowing you to save, screen, randomize, or dispense kits to a subject. Previously, when a dynamic question was included in a repeating form, the action button for that visit wasn't displayed as expected. (Issue **30976490**)

Button in Queries sidebar now works as expected (former known issue)

Site users and sponsor query managers: From now on, on the Queries sidebar, when you click the form icon to enter a repeating form assigned to another visit, the repeating form appears as expected. Previously, when you clicked the form icon, the repeating form either didn't appear or it contained blank fields, despite it being completed.

Retracted workaround: None. Issue **31081306**

Sign icon no longer overlaps with answer fields (former known issue)

Lead site users: From now on, when a subject is signed, the sign icon is displayed as expected. Previously, the sign icon overlapped with answer fields in a form. This behavior was only present in Internet Explorer.

Retracted workaround: None. However, we still recommend you use Google Chrome for a better product experience. (Issue **31204625**)

Forms with identical titles can now be copied from one study to another (former known issue)

Study designers: You can now copy a form from one study to another, despite the copied form having an identical title with another form in the study. Previously, when you attempted to copy a form that had the same title as an existing form in the study, you received an error message stating that the form and its rules couldn't be copied.

Retracted workaround: None. (Issue **31446152**)

A subject's adverse event no longer remains signed after data is modified (former known issues)

Lead site users: When data is modified for a signed subject's Adverse Event, that Adverse Event is unsigned. Previously, when data was modified for an Adverse Event, it remained signed.

Retracted workaround: You no longer have to refresh the browser page to display the Adverse Event as unsigned. (Issue **31484421**)

You can now create a form with a code list that contains special characters (former known issue)

Study designers: From now on, if you add a code list to a question and that code list contains special characters, you can save your form. Previously, whenever you added a code list, that contained special characters, to a question and attempted to save the form, an error message appeared stating that the system is unable to retrieve the details of the code list and create the form.

Retracted workaround: You no longer have to avoid using special characters when creating a code list. (Issue **31550571**)

Question used in two dynamic question rules now works in a repeating form (former known issue)

Study designers: Now, when you include the same child question in two rules for displaying dynamic questions in a repeating form, the child question's answer is processed in the system. Previously, the answer to a child question was not processed and it did not appear as answered in the repeating form instance.

Retracted workaround: None. (Issue **31673544**)

Fixed issues for integrations

Correct visit names appear in EDC systems integrated with Oracle Clinical One RTSM

 **Note:**

This fixed issue only impacts Oracle Clinical One Platform to EDC systems integrations.

Integration managers: For Oracle Clinical One Platform to EDC systems integrations, visit names now appear as expected in the EDC systems. Previously, visit names were populated with visit reference names used in the VisitComplete integration file. (Issue **31322182**)

Integration now sends kit replacement data as expected (former known issue)

 **Note:**

This fixed issue only impacts Oracle Clinical One Platform to EDC systems integrations.

Integration managers: From now on, when a kit is replaced in Oracle Clinical One Platform and the **Not Dispensed to Subject** reason is selected, the integration sends data for that kit replacement to the EDC system as expected.

Retracted workaround: None. (Issue **31512310**)

Reason for withdrawing a subject is sent to in Oracle InForm



Note:

This fixed issue only impacts integrations between Oracle Clinical One Platform and Oracle InForm.

Integration managers: From now on, when you withdraw a subject in Oracle Clinical One Platform and specify a reason for their withdrawal, this update is sent to Oracle InForm as expected. Previously, when a subject was withdrawn from a study in Oracle Clinical One Platform, the reason for their withdrawal wasn't sent and displayed in Oracle InForm as expected. The issue is now fixed after updating the integration file to properly send data to Oracle InForm. (Issue **31636210**)

Fixed issues for randomizations and kits

Updating a dispensed device to misallocated now works as expected (former known issue)

Site users: From now on, if you dispense a device type kit to a subject (Subject 1) and successfully register and activate the device for that subject, you can later on update the device's status from **Dispensed** to **Misallocated**, if needed. Previously, when you update a device's status, the device wasn't properly removed from the system and you couldn't dispense it to a new subject (Subject 2).

Retracted workaround: You no longer have to first deactivate the device, and then follow the workflow for misallocation. (Issue **31538783**)

Fixed issues for reports and notifications

Special characters used in code list now displayed in Study Design report (former known issue)

Study designers: From now on, if you use a code list with special characters for a question with multiple answer options (such as a drop-down question or a question with check boxes or radio buttons), the special characters are properly displayed in the Study Design report. Previously, special characters such as the ampersand symbol (&), comma, colon, the percentage sign (%), and the asterisk weren't properly displayed in this report.

Retracted workaround: None. (Issue **31485953**)

Date of Birth question label displayed with GUID in Subject Data report (former known issue)

Data managers: Now, when an age type of question is included in a form for a study, when you run the Subject Data report you'll notice that the question label for that type of question is displayed with its text label only, as expected. Previously, an age type of question was displayed in the Subject Data report along with a GUID, next to the text label.

Retracted workaround: None. (Issue **31503039**)

Fixed issues for site users and subject data

Error messages no longer appear when you enter dates in a form (former known issue)

Site users: From now on, when you manually enter a date in a form field, the calendar feature appears and you select the date from the pop-up. After selecting the date, no error messages appear. Previously, when you selected a date on the calendar, an error message appeared stating "Cannot read property 'value' of undefined". Moreover, after you clicked out of the date field, a warning appeared stating that the date you selected used an incorrect format.

Retracted workaround: You no longer have to press the Esc key on your keyboard, and then press Enter, to avoid the error messages. (Issue **30890560**)

Completed visits are now displayed after completing a repeating form

Site users: From now on, visit cards are displayed as expected at the top of the visit page, after you complete an instance of a repeating form that is assigned to multiple completed visits in a study. Previously, the visit cards weren't displayed at all.

Retracted workaround: You no longer have to refresh your browser's page or click **Return to All Subjects** to view all completed visits for a subject. (Issue **31313870**)

Data flags on radio buttons and checkbox questions no longer obscure the signed icon (former known issue)

Lead site users and Clinical Research Associates (CRAs): When signing and verifying subject data, you'll notice that data flags set on the checkboxes or radio buttons in a question group no longer obscure the response options and the signed icon.

Retracted workaround: You no longer have to clear the data flags to view the responses as needed. (Issue **31540397**)

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.2.3 (September 2020)

- [What's new](#)
- [Fixed issues](#)

What's new

- [Dispense calculated doses requiring multiple kits more efficiently](#)
Site users with the permission to see detailed dosing instructions receive clearer instructions when dispensing multiple kits for calculated doses.

Dispense calculated doses requiring multiple kits more efficiently

Site users with the permission to see detailed dosing instructions receive clearer instructions when dispensing multiple kits for calculated doses.

What are the benefits?

When you dispense investigational product with a calculated dose, the system now displays the kits in a separate table. The dosing instructions indicate the calculated dose only once for the combined kits. For example, if the calculated dose for one subject is 6 mg and each kit contains 5 mg of investigational product, you need to combine two kits to fulfill the order. When dispensing the kits to the subject, the system groups the two kits in a table and only mentions the calculated dose (6 mg) once, above the table. Previously, all kits to be dispensed were displayed in one table and the calculated dose (6 mg) was mentioned for each separate kit. This enhancement helps clarify the dosing instructions and enables site users to efficiently dispense kits with calculated doses.

Details for site users

Your workflow hasn't changed, but you will notice some updates in the way information is displayed in the Dispensation confirmation message and the Print Dispensation information. When you dispense kits, the system now displays kits without dosing instructions in one table at the top and kits that are used for calculated doses in separate tables below, with the dosing instructions displayed above each table.

The Dispensation notification is also updated. Now, under **Number of Kits**, the system displays kits without dosing instructions in one row section at the top followed by the kits without dosing instructions in separate rows below. Note that not all site user roles include the dosing instruction details.

Already working in a live study?

As soon as the upgrade for this release is complete, site users will start dispensing kits with calculated doses using the new dosing instructions.

Fixed issues

- [Fixed issues for integrations](#)

Fixed issues for integrations

Oracle InForm to Oracle Argus Safety integration: Job now runs as expected for fields in an SAE form



Note:

This behavior is only encountered in a Cloud Native Environment.

Integration managers: A job is now created in Oracle Clinical One Digital Gateway whenever values for fields in the Relevant Lab Tests section of the Oracle InForm SAE form are submitted. The data you enter in Oracle InForm for that SAE form section is then processed as expected. Previously, whenever you entered any value in the Relevant Lab Tests section

of the SAE form, the data was not successfully submitted and a job was not created in Oracle Clinical One Digital Gateway. (Issue **31811750**)

Oracle Clinical One Platform 20.2.2 (August 2020)

- [What's New](#)
- [Fixed Issues](#)

What's New

- [Integrate Oracle Clinical One Platform with Oracle Central Coding](#)
You can now integrate studies from Oracle Clinical One Platform with Oracle Central Coding to code (autocode and manually code) terms collected throughout the study.
- [Enable site users to manually enter subject numbers](#)
Study managers can now configure a study for site users to manually enter subject numbers in the system using a pre-specified subject numbering format.
- [Add multiple unscheduled visits to your study](#)
Study designers can now create multiple and diverse unscheduled visits in a study and site users can collect data more efficiently and dispense kits and devices during those visits.

Integrate Oracle Clinical One Platform with Oracle Central Coding

You can now integrate studies from Oracle Clinical One Platform with Oracle Central Coding to code (autocode and manually code) terms collected throughout the study.



Note:

This enhancement is introduced in the 20.2.2 release.

In December 2019, we introduced the ability to create and include coding questions in forms meant to collect data on adverse events, concomitant medications, and more. These coding questions would be used to collect verbatim terms (such as Headache or Advil) and allow for the return of the coded terms with the ultimate goal of integrating studies and forms with a medical coding product.

While study designers could create coding questions, these questions could not be integrated with a medical coding product where the verbatim terms entered in a study could be taken through the medical coding process, and coding results could automatically be returned to the study.

For this release, Oracle Central Coding 6.3.1.0 includes updates that allow Oracle Clinical One Platform studies to be integrated with Oracle Central Coding.

If you want to learn more about how to integrate the two products, reach out to your Oracle Project Manager.

Enable site users to manually enter subject numbers

Study managers can now configure a study for site users to manually enter subject numbers in the system using a pre-specified subject numbering format.

Note:

This new feature is introduced in the 20.2.2 release.

What are the benefits?

Site users can now manually enter subject numbers. Previously, the subject number was automatically generated by the system. This new feature lets site users assign predetermined subjects numbers that were received outside Oracle Clinical One Platform. This also helps provide consistency across subject numbers at each location.

Details for study managers

When it comes to your workflow, there are some new settings that you can use to control how subject numbers are assigned. On the **Study settings** tab, now you can:

- Allow sites to enter subject numbers in a study
- Define the format that site users must use when entering subject numbers.

Note:

The subject number format allows alphanumeric characters and the dash (-) character.

Figure 19-16 How a study manager sets subject numbering settings

The screenshot shows the 'Study Settings' configuration page. The 'Testing Settings' tab is selected. Under 'Study Settings', the following options are visible:

- Allow Subjects to be Manually Added: Yes No
- Allow Site to Select Subject Number: Yes No
- Include Hyphen in Subject Numbers: Yes No
- Leading Zeros in First Subject Number: 1
- Subject Number Format: [0-9][0-9][A-Z][a-z]
- Withdraw Subjects After Code Break: Yes No

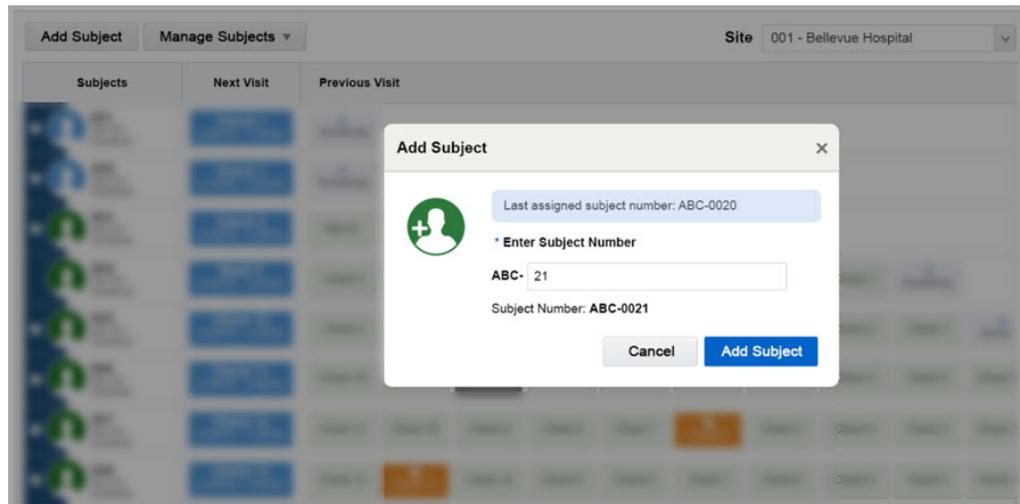
Details for site users

When you add a new subject, the **Add Subject** pop-up appears where you can enter the subject number. The system displays the last subject number that was assigned so you can ensure continuity among subjects.

 **Note:**

The subject number that you enter must comply with the format that was set in the study.

Figure 19-17 Site users can enter subject numbers when adding new subjects



Already working in a live study?

As soon as the upgrade is done, study managers can configure their studies to let site users enter subject numbers.

Add multiple unscheduled visits to your study

Study designers can now create multiple and diverse unscheduled visits in a study and site users can collect data more efficiently and dispense kits and devices during those visits.

 **Note:**

This new feature is introduced in the 20.2.2 release.

What are the benefits?

For study designers: With this new feature you can create multiple unscheduled visits and name each visit according to the purpose for which the data is collected. For instance, you can create unscheduled visits to collect lab results or additional data for vital signs or adverse events. Or you can create an unscheduled visit to follow up on your subjects even after the last dose of the product was dispensed. By creating multiple unscheduled visits you can expand your data and get a more in-depth view of your study findings.

For site users: You can now better manage subject events that occur outside the visit schedule and easily access forms, collect data, and dispense kits and devices.

Details for study designers

You can create as many unscheduled visits as needed in the **Unscheduled Visits & Events** section. You can include one or more forms in each visit to collect various types of data. Moreover, you can add kits and devices to be dispensed during those visits, the same way as for a scheduled visit.

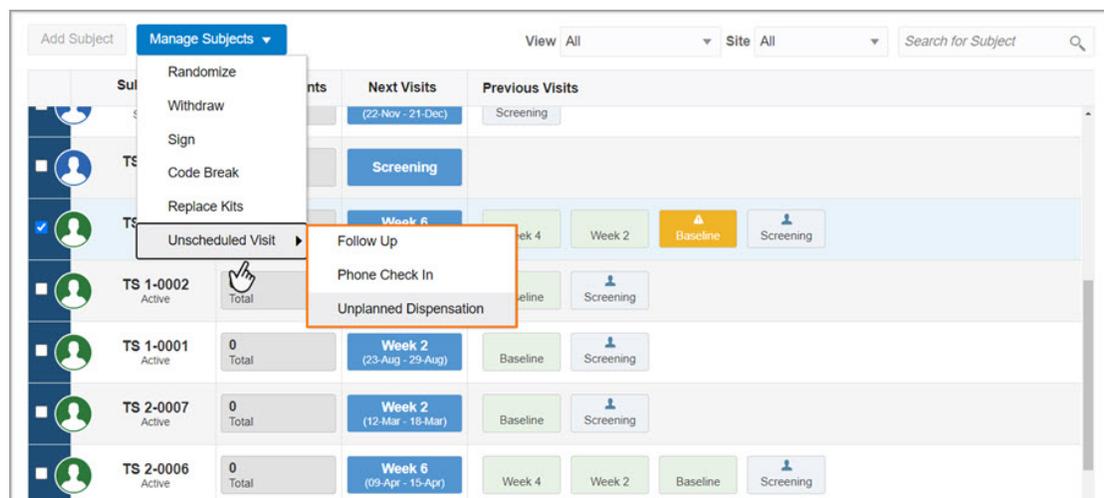
Remember that how you name your unscheduled visits is how site users will see them during the study conduct period.

Details for site users

On the **Subjects** tab, on the **Manage subjects** drop-down you now have new options for unscheduled visits. For example, when you hover over **Unscheduled Visits**, you may see new options for multiple unscheduled visits, such as Follow-Up, Phone Check-In, or more, if your study was designed to include different unscheduled visits.

You just have to select the visit that corresponds to the subject's reason for coming to the site, enter data in the forms that are listed on the left pane, and dispense kits or devices, if they are included in the visit.

Figure 19-18 New drop-down for Unscheduled visits on the Subject tab



Already working in a live study?

As soon as the upgrade for this release is complete, study designers can add multiple unscheduled visits to their study in the **Unscheduled Visits & Events** section. Once the study version is updated, site users can collect data by selecting the appropriate unscheduled visit from the **Manage subjects** drop-down.

Fixed Issues

- [Fixed issues for forms and visits](#)
- [Fixed issues for sites, depots, settings, and user management](#)
- [Fixed issues for site user and subject data](#)

Fixed issues for forms and visits

Copied dynamic forms to a new study now work as expected (former known issue)

Study designers: From now on, when you copy forms from one study to another, and a dynamic form is set, the dynamic form target remains set as a dynamic form. For example, if you have a study with Form A and Form B, and Form A has a Show Form rule on a question that points to Form B, when you copy both forms to a new study, the Show Form rule is now copied along with them. Previously, when you copied a dynamic form from one study to another, the dynamic target form was still dynamic even though the Show Form rule in the dynamic source form wasn't copied.

Retracted workaround: You no longer have to manually set the Show Form rule again for the dynamic target form. (Issue **31535813**)

Duplicate SAS variables no longer stop you from saving a form (former known issue)

Study designers: From now on, when you create multiple questions of the same type and update one of their reference codes, you'll be able to save the form without having duplicate SAS variables for the question types. Previously, when you attempted to save the form, an error message appeared stating that the form cannot be saved due to duplicate SAS variables.

Retracted workaround: You no longer have to update the questions' SAS variables. (Issue **31483324**)

Questions with checkboxes or radio buttons now properly displayed in question groups (former known issue)

Study designers: From now on, you can include a question with checkboxes or radio buttons with over 19 answer options, in a question group. The answer options will be displayed as expected. Previously, whenever you included so many answer options in a question group, the answer options didn't display as expected.

Retracted workaround: You no longer have to use drop-down questions as an alternative. (Issue **31527051**)

Question used in two dynamic question rules now works in a repeating form

Study designers: From now on, when you include the same target question in two rules for displaying dynamic questions in a repeating form, that target question's answer will get processed in the system. For example:

1. Create a drop-down question 1, with two answer options: A and B.
2. Create three other questions: 2, 3, and 4.
3. Set a **Show Question** rule for answer option A in question 1. If answered using option A, the form displays questions 2 and 3.
4. Set a **Show Question** rule for answer option B in question 1. If answered using option B, the form displays questions 3 and 4.

Whether a site user answers question 1 using answer option A or B, the answer for question 3 will now appear in the repeating form table.

Retracted workaround: None. (Issue **31673544**)

Form containing duplicate question groups can now be saved (former known issue)

Study designers: From now on, when you create a question group, duplicate it and rename it, you will be able to save the form containing these question groups, as well as the duplicate and renamed question group. Previously, you couldn't save the form and you received an error message stating that there was an issue with processing your changes.

Retracted workaround: None. (Issue **31635470**)

Fixed issues for sites, depots, settings, and user management

Designer role can now create scheduled visits (former known issue)

User administrators, global user managers, and study designers: When assigned a custom study designer study role, study designers can now create scheduled visits. Moreover, when saving a scheduled visit, they will no longer receive a confusing error message. Previously, study designers who were assigned a custom designer study role, noticed they were unable to create or save scheduled visits.

Retracted workaround: User administrator or global user managers no longer have to assign study designers the predefined Designer study role template created by Oracle. Instead, they can create whatever study role best fits their study's needs, either at a study level or at an organization level. (Issue **31666358**)

Fixed issues for site user and subject data

Canceling a reason for change update doesn't affect dynamic forms anymore (former known issue)

Site users: From now on, when you select the answer that triggers the appearance of a dynamic form and then update that answer, the **Reason for Change** text field appears and the dynamic form is still displayed, even after clicking **Cancel**. Previously, whenever you followed these steps, you noticed the dynamic form disappeared.

Retracted workaround: You no longer have to refresh you browser's page. (Issue **31515149**)

Confirm dispensation button appears after a page refresh (former known issue)

Clinical supply managers: From now on, if a study's setting to confirm dispensation of kits is set from No to Yes while the study is live, site users will see the Confirm Dispensation button for kits without refreshing the page.

Retracted workaround: Site users no longer have to refresh the page to see the Confirm Dispensation button or contact their Clinical Research Associate (CRA). However, we do still recommend that you use Google Chrome for a better user experience. (Issue **31524481**)

Unable to save rule when question is removed in a new study version (former known issue)

Rule designers and rule testers: From now on, you can save a rule when a question or an item is removed in a new study version, if you use the operand null check comparison in the JavaScript expression for that rule. Previously, if you removed a question or item that were impacted or referenced in a rule, in a new study version, you weren't able to save the rule.

Retracted workaround: None. (Issue **31515186**)

Re-running a calculation rule no longer updates a subject as unsigned and unverified (former known issue)

Rule designers and rule testers: From now on, when you re-run a calculation rule for a read-only item that was already signed and verified in a study, you'll no longer notice that subjects whose value was automatically calculated are marked as unsigned and unverified in the system. Previously, after re-running the rule, subjects were unsigned and unverified.

Retracted workaround: None. (Issue [31513382](#))

Oracle Clinical One Platform 20.2.1.2 (August 2020)

- [Fixed issue for rules](#)

Fixed issue for rules

 **Note:**

This issue is now fixed in the current 20.2.1.2 release.

Read-only target items are now automatically updated for items where the rule's operands are on a different visit

Rule testers: The value of a target item is now automatically updated even when the rule's operands and the target item are on forms assigned to different visits. Previously, when the target item was on a different visit from the rule's operands, you had to manually refresh the form with the target item before it was updated with the correct value. (Issue [31720906](#))

Oracle Clinical One Platform 20.2.1.1 (August 2020)

- [Fixed issue for resupply strategy](#)

Fixed issue for resupply strategy

Users with the Clinical Supply Manager role are now able to see their resupply strategy

Clinical supply managers: From now on you will be able to assign a resupply strategy to a site and the strategy will remain visible even when you navigate away from the resupply screen and return at a later time. Previously, when you assigned a resupply strategy to a site, it was assigned successfully but once you navigated away from the resupply screen, the strategy was no longer visible and could not be retrieved. (Issue [31687688](#))

Oracle Clinical One Platform 20.2.1 (July 2020)

- [What's new](#)

- [Fixed issues](#)

What's new

- [Create and assign study roles](#)
Getting access to Oracle Clinical One Platform and performing your tasks in the product is now easier thanks to study roles!
- [Manage sites more efficiently](#)
Site managers can now limit the activities a site can perform, such as enrollment, screening or dispensation.
- [Randomize into cohorts](#)
- [Create queries](#)
- [Improved calculated doses](#)
- [New Study Enrollment report](#)

Create and assign study roles

Getting access to Oracle Clinical One Platform and performing your tasks in the product is now easier thanks to study roles!

What are the benefits?

Creating a study role allows you to group the permissions commonly assigned to a particular user (such as a CRA) and then use that role for users across your study, or even across your organization. This provides a consistent set of rights for key user types and allows you to assign that role without the hassle of dealing with individual permissions settings. We even help you get started by providing predefined templates for common user roles!

These different levels offer you even more flexibility for your role assignments. For example, if CRAs generally perform the same tasks in every study, you might create a CRA role for your entire organization, so that it's available in every study. And if the CRA in a particular study has additional tasks, you can create a study role just for that study, and you won't have to worry about accidentally assigning it in other studies.

Details for global user managers and user administrators

Here's what you need to know about study roles:

- You can make study roles available in two different places:
 - In every study owned by your organization, as a global user manager
 - In just one study, as a user administrator
- As part of the new study roles feature, we provide you with a set of predefined roles that you can use to get started. You can use these predefined roles as they are, or copy them and use them as a starting point for your own custom roles. Predefined roles are based on common user types and commonly combined permissions and include:
 - Designer Study Roles (such as Study Designer or User Administrator)
 - Study Management Study Roles (such as CRA or Site Administrator)
 - Site Study Roles (such as Pharmacy User or Site User)

Create a study role at the organization level

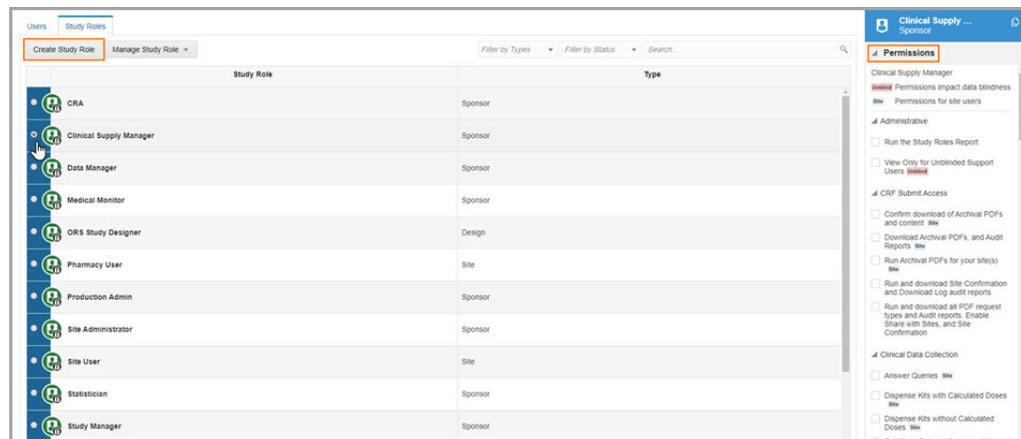
As a global user manager, you can create study roles at the organization level. These roles are automatically propagated to any new studies that are created within your organization. Once a study begins, you can further customize roles at the study level.

To create an organization-level role, you can access the new Study Roles tab from **Global Settings**. Three study role types are available:

-  Predefined read-only study roles provided by Oracle
-  Study roles defined by your organization
-  Study roles defined by your organization and retired. A retired study role can be activated again and also duplicated

You can select any existing role and view the permissions assigned to that role. You can also create new study roles by clicking **Create Study Role** and providing the required details.

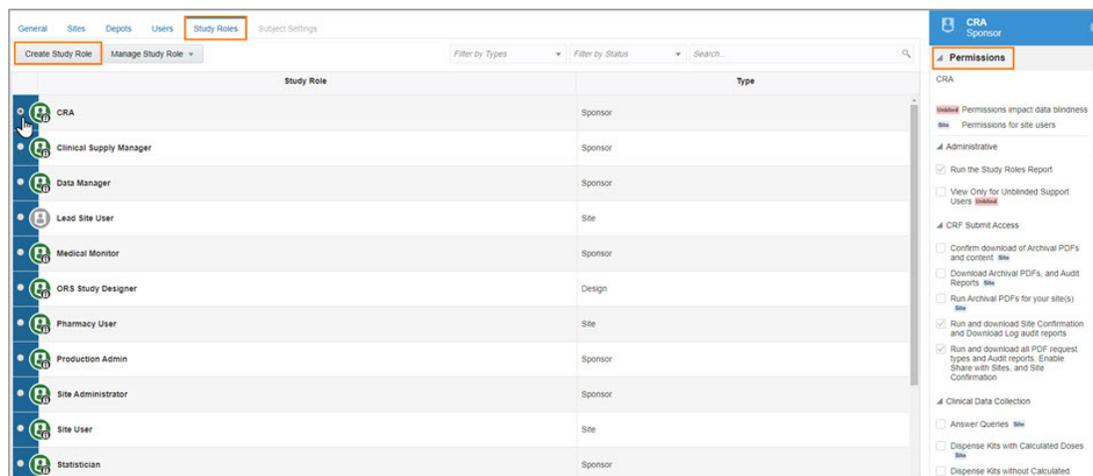
Figure 19-19 How global user managers see the new Study Roles tab



Create a study role at the study level

As a user administrator, you can create study roles at a study level. When you create or modify a study role at the study level, your changes are kept within the scope of the study. This allows you to create and customize roles for your specific study needs.

To create a study-level role, you can access the new **Study Roles** tab from **Study Settings** page.

Figure 19-20 How user administrators see the new Study Roles tab

Need to update a study role that's already been assigned?

Update a study role at any time, even if it's assigned to one or more users. New study roles and changes to existing organization-level study roles do not automatically propagate to existing studies. Instead, updates to the organization-level roles will only become effective in newly created studies. This is to avoid any potential unblinding of subject data due to a change in role permissions.

Reporting changes

There are some changes in an existing report, but there are also new reports that you can run and download to view data about study roles.

- The **User Assignment** and **User Assignment by Site** reports now contains a new column called "Study Role". The column displays study roles assigned to a user either at a site or sponsor level.
- There are also two new reports that you can run to inspect valuable data on study roles:
 - **Study Roles Report by Study**: This report shows all groups of permissions for each study role created at a study-level. This report is available in HTML and PDF formats.
 - **Global Study Roles**: This report shows all groups of permissions for each study role created at the organization-level. This report is available in CSV, HTML, and PDF formats.

Manage sites more efficiently

Site managers can now limit the activities a site can perform, such as enrollment, screening or dispensation.

What are the benefits?

With this new feature, you can stop the enrollment of new subjects and cease screening, randomization or dispensation, at one or multiple sites at once. For instance, if you need to have a balance between subjects enrolled at different sites and you notice that one site is approaching its limit for randomized subjects, you can prevent site users at that site from adding more subjects, screening, or randomizing them. Or, if one of the sites in your study

requires additional protocol training, you might need to suspend dispensing to all subjects. These restrictions allow you to have a better control over site activities.

Details for site managers

On the **Sites** tab, when you edit a site, you can now allow or prevent site users from performing certain actions at a site. Site permissions are displayed as toggle buttons for the following site tasks:

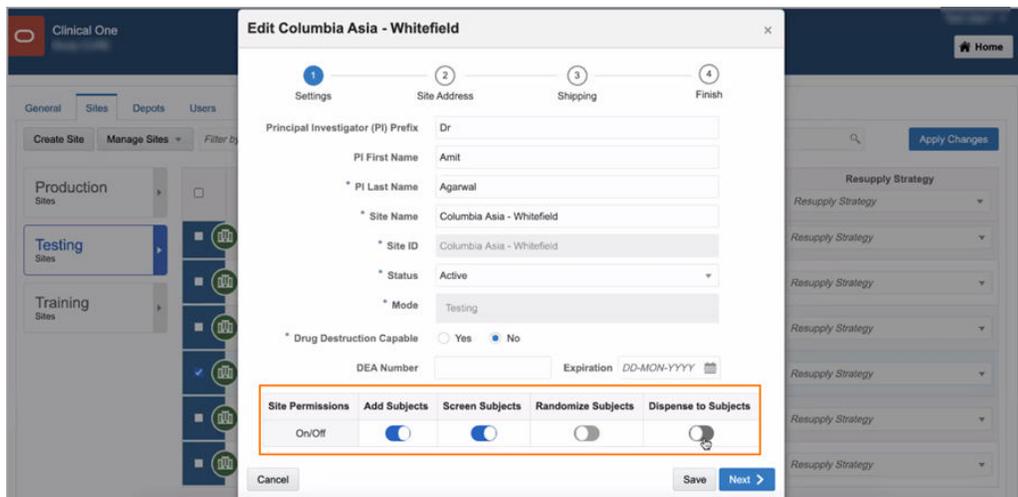
- Add Subjects
- Screen Subjects
- Randomize Subjects
- Dispense to Subjects.



Note:

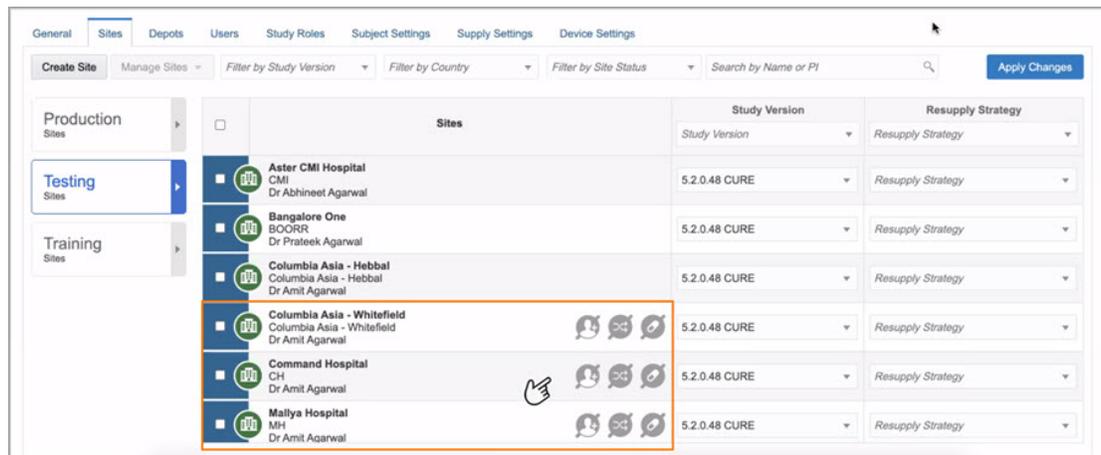
Toggle buttons for site permissions are available only for active sites.

Figure 19-21 How site managers see the Site permissions toggle buttons



Additionally, there are new icons that appear next to each site to indicate the restrictions that are set for that specific site.

Figure 19-22 How site managers the Site permissions icons



Details for site users

Your workflow hasn't changed. However, if you try to add, screen or randomize subjects, or dispense kits to patients and the permission to perform that action is turned off for your site, you receive a message informing you of the restriction.

Already working in a live study?

As soon as the upgrade is done, site managers can use the new **Site permissions** toggle buttons to allow or prevent site users from adding, screening and randomizing subjects, as well as dispensing kits to them. The feature is available in all three modes: Testing, Training, and Production.

Fixed issues

- [Fixed issues for reports](#)
- [Fixed issues for site users and subject data](#)
- [Fixed issues affecting all users](#)
- [Fixed issues for forms and visits](#)
- [Fixed issues and enhancements for integrations](#)
- [Fixed issues for reports and notifications](#)
- [Fixed issues for site users and subject data](#)
- [Fixed issues for randomization and kits](#)

Fixed issues for reports

The Subject Visits (Unblinded) report is now generated as expected

Clinical supply managers: From now on, anytime you run the Subject Visits (Unblinded) report, the report will be generated as expected in any format you selected. Previously, when you sometimes ran this report, you may have noticed that the report either wasn't generated at all or it encountered errors in visualizing the study's data. This issue happened due to a performance limitation that is now fixed. (Issue **31521406**)

Fixed issues for site users and subject data

Browser page no longer freezes when multiple dynamic forms or questions are used (former known issue)

Site users: From now on, if there are multiple dynamic forms and dynamic questions which appear based on your answer selections, you will no longer notice any irregularities or your browser freezing. Moreover, you'll be able to answer any of the questions displayed in a form. Previously, you could have encountered the above-mentioned issues for questions with radio buttons, especially when you attempted to clear answers or select different answers in a dynamic form, or for a dynamic question.

Retracted workaround: You no longer have to refresh the page in your browser and attempt to answer all question on a form again. (Issue **31553924**)

You can now save the updated answer for a question with checkboxes (former known issue)

Site users: From now on, whenever you attempt to change your initial answer and save the update for a question with checkboxes, the **Reason for Change** text field appears, as expected. Previously, an error message appeared stating that your change cannot be saved because someone else saved a change on the same page after you opened it.

Retracted workaround: You no longer have to first apply a data flag to the question and then update its answer. (Issue **31549455**)

Validation error message now appears for Reason for Change dialog box (former known issue)

Site users: From now on, when you delete a repeating form instance and you enter a reason for this change, that doesn't follow the guidelines for minimum or maximum numbers of characters, a validation error appears. Previously, no error message was displayed, generating confusion as to what the problem with your text input was.

Retracted workaround: None. (Issue **31452209**)

Open query message displayed once in Answer History (former known issue)

Rule testers: From now on, when you create a rule that raises a query related to two fields in a form, a single message appears in the Answer History pane. Previously, if you created an automated query related to two fields in a form, duplicate messages appeared in the Answer History.

Retracted workaround: None. (Issue **31052105**)

Oracle Clinical One Platform & Oracle Clinical One Digital Gateway 20.2 (July 2020)

- [What's new](#)
- [Fixed issues](#)

What's new

This is the start of your topic.

- [Data collection](#)
- [Data extraction](#)
- [Integrations](#)
- [Randomization and supplies](#)
- [Reports](#)
- [REST APIs and development](#)
- [Rules management](#)
- [User experience](#)

Data collection

- [Add SAS properties to improve data analysis](#)
Study designers can now include SAS variables and labels in forms to make data readily available for extraction and analysis.
- [Copy and re-use forms from other studies](#)
Study designers can now copy forms from other studies and duplicate forms within the existing study.
- [Collect data on adverse events faster and more efficiently](#)
Study designers can now create a new type of event, so site users can easily collect data on adverse events or concomitant medications for subjects.
- [Create and use partial dates in forms](#)
Study designers can now enable the use of partial dates in forms and site users can enter partial dates during visits.
- [New question types for a better form design](#)
Study designers can now add questions with radio buttons and checkboxes to their forms to better define how data is collected.
- [Streamline form design and improve study data with code lists](#)
Study designers can now add code lists to their forms to streamline form design and ensure collected data is easy to retrieve and analyze.

Add SAS properties to improve data analysis

Study designers can now include SAS variables and labels in forms to make data readily available for extraction and analysis.

What are the benefits?

SAS variables and labels are displayed in data extracts and play an important role in statistical analysis. By adding SAS properties to questions in a form, study designers ensure data is easy to review and analyze, according to the industry's standards.

Want to know more about data extracts? See [Augment data collection processes with data extracts](#).

Details for study designers

When you add a question in a form, two new fields appear on the **Advanced** pane: **SAS Variable** and **SAS Label**.

Both fields are required and completed by default with the question's Reference Code and the question's label, respectively. While you're designing a study, you can modify these labels.

Already working in a live study?

As soon as the upgrade for this release is complete, study designers can start adding SAS properties to forms while working on a study version in Draft mode. In existing studies, SAS fields remain blank. In a future release, in studies with blank SAS fields, Data Extract will automatically use the question's Reference Code and Label as a SAS Variable and SAS Label, respectively.

Copy and re-use forms from other studies

Study designers can now copy forms from other studies and duplicate forms within the existing study.

What are the benefits?

Designing a study can now be easier, faster and more efficient. By simply copying forms from other studies or duplicating forms in the existing study, you are able to ensure consistency across studies, maintaining your data collection strategy, and saving time.

Details for study designers

On the **Data Collection** tab, you now have a new **All forms** tab where you can:

- View all forms that are created in all the studies that you are assigned to, as a study designer
- Copy forms from other studies in your current study or duplicate a form within the same study
- Filter your view by the study in which the form was created, therapeutic area, or search for a form

Note:

In the process of copying forms, rules won't be copied.

Additionally, forms that are copied from another study are displayed on the **Forms** tab and are marked with a copied icon (). Copied forms that are edited are also marked with a copied and edited icon () , so you can easily distinguish between the two types of copied forms.

Already working in a live study

As soon as the upgrade for this release is complete, you can start copying forms when working on a study version in Draft mode. Copied and edited forms can only be used by site users after the study version is updated.

Collect data on adverse events faster and more efficiently

Study designers can now create a new type of event, so site users can easily collect data on adverse events or concomitant medications for subjects.

What are the benefits?

For study designers: On the **Data Collection** tab, an adverse events visit type appears by default in a new section for **Unscheduled Visits & Events** so you can now easily add forms for collecting data. This way the stage is already set for you to quickly prepare a more intuitive and faster data collection process for adverse events.

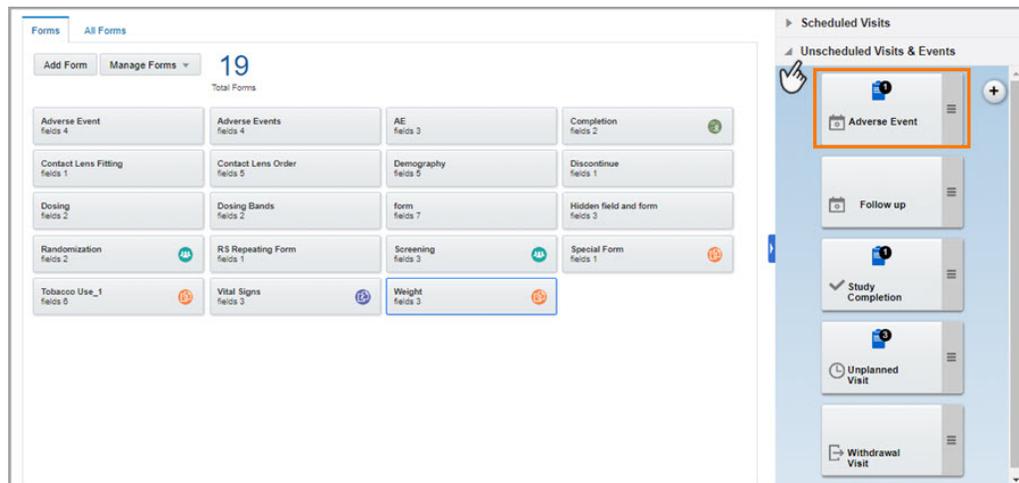
For site users: There is a new column for **Adverse Events** on the **Subjects** tab that you can click to quickly access forms and enter data. With the new event readily available, adverse events are now recorded faster and easier.

Details for study designers

The scheduled and unscheduled visits and events are now displayed in separate sections, on the right side of the screen. Scheduled visits, such as screening or scheduled dispensation visits are created and displayed in the **Scheduled visits** section. Unscheduled visits and events, such as an Adverse Event or a Study Completion visit are displayed in the **Unscheduled Visits & Events** section.

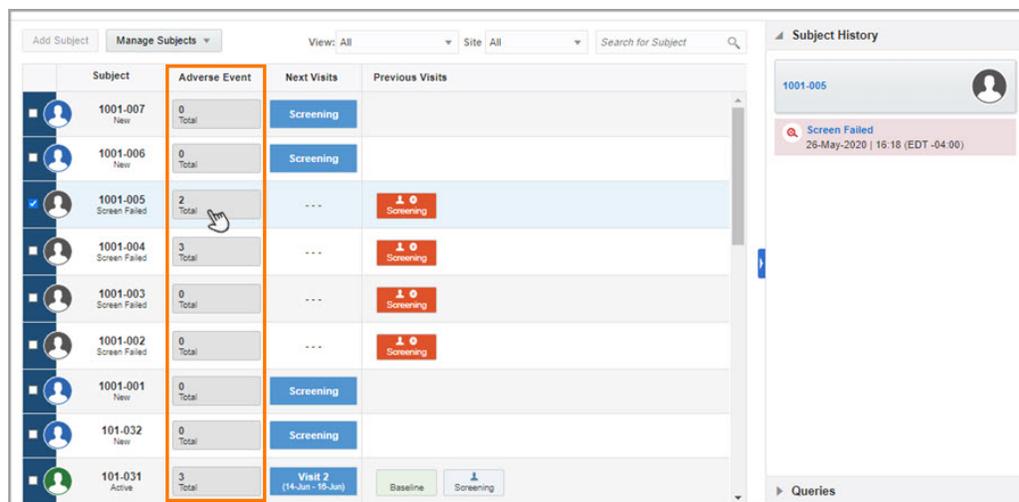
In terms of workflow, you can now directly add the appropriate forms to the Adverse Event visit displayed under **Unscheduled Visits & Events**. You can collect various types of data in this visit using one or more forms. For instance, alongside the forms for recording data on adverse events, you can also include forms to collect data on concomitant medications or hospitalizations. As an added benefit, the **Adverse Event** column on the **Subjects** tab will display the number of repeating form instances that were completed for each subject. In order for this count to reflect the number of form instances correctly, the Adverse Event form must be placed as the first form in the visit, during design.

You can also rename or remove the adverse event from the **Unscheduled Visits & Events** section. The name of the event will appear at the top of the new column on the **Subjects** tab. If you remove the event, the **Adverse Event** column will not show on the **Subjects** tab.

Figure 19-23 How study designers see the new Adverse Event visit**Details for site users**

On the **Subjects** tab, you now have a new column called Adverse Event that you can use to collect data on a subject's adverse events, concomitant medication, hospitalizations, and more.

Whenever a subject reports an adverse event, you need to go to the Adverse Event column, click the tile that corresponds to that particular subject, and enter data in the forms that are listed on the left pane. As data for adverse events is collected, the column will display the number of repeating form instances that are completed for each subject, provided the AE form is the first form in the visit.

Figure 19-24 How site users see the Adverse Event column**Already working in a live study?**

As soon as the upgrade for this release is complete, study designers can add the Adverse Event type of visit to their study in the new **Unscheduled Visits & Events**

section. Once the study version is updated, site users can collect data by accessing the **Adverse Event** visit column.

In new studies, Adverse Event appears by default in the **Unscheduled Visits & Events** section.

Create and use partial dates in forms

Study designers can now enable the use of partial dates in forms and site users can enter partial dates during visits.

What are the benefits?

Partial dates are particularly useful for collecting historical data without running the risk of leaving dates completely unknown. There might be situations when only the month and year are known by the site user or subject. For example:

- When a subject doesn't remember the exact start date of a concomitant medication they've been taking for a number of years
- When a study's or country's personally identifiable information (PII) regulations require only the month and year to be collected for a subject's date of birth

Details for study designers

When it comes to your updated workflow, here's what you need to know for date/time questions:

- If you select **DD-MON-YYYY** or **MON-YYYY** as the format, you can then enable a setting called **Accept Partial Date**
- You then can select a format for the **Minimum Date Answer**, such as **MON-YYYY**. This is what's required to be entered, at a minimum, by a site user

Figure 19-25 How study designers see the new Accept Partial Date toggle button

Details

* Reference Code
DATETIME_09

Question Hint
Hint Text

Required

Read Only

Format DD-MON-YYYY

Accept Partial Date

Minimum Date Answer
MON-YYYY
MON-YYYY
YYYY

Details for site users

When it comes to your workflow, if partial dates are enabled in a form, you can select a separate value for the day, month, and year. If you don't know the day or month of a date, you can select a value of **UNK** for that element, depending on what the allowed date format is. If you omit the day, month, or year from a date question, you'll receive validation messages that indicate what fields you need to complete. Also, keep in mind that it is not possible to have a known Day part but an unknown Month part. In this case, a validation error will appear alerting you to correct the data.

Figure 19-26 How site users see a partial date in a form

Already working in a live study?

As soon as the upgrade for this release is complete, study designers and site users can start using this feature. Remember that the setting for partial dates is set to **No**, by default. Study designers must first enable the setting in Draft mode and update the study version in the Approved container, for site users to start collecting partial dates in the live study.

New question types for a better form design

Study designers can now add questions with radio buttons and checkboxes to their forms to better define how data is collected.

What are the benefits?

By including checkboxes and radio buttons in the forms, study designers allow site users to expand or restrict the quantity of data collected for each subject. For instance, by using checkboxes for the Race question the study designer allows site users to select one or more answers from the available options: "American Indian and Alaska Native", "Asian", "Black or African American", "Hispanic or Latino", "Native Hawaiian and Other Pacific Islander", and "White". Moreover, by using radio buttons for the Gender question, the study designer restricts the answer choices to just one option: "Male" or "Female".

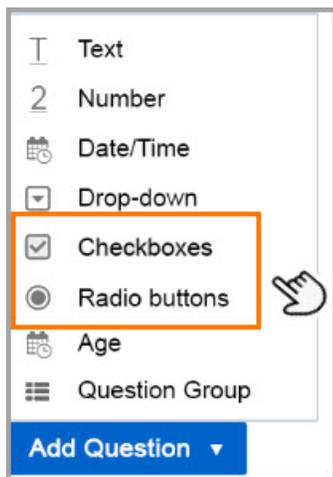
With these new question types included in forms, study designers can allow site users to collect data more efficiently.

Details for study designers

When you add a question in a form, in the **Add question** drop-down, two new options appear for **Checkboxes** and **Radio buttons**.

Checkboxes allow site users to select one or more answers for one single question, while radio buttons restrict the options to only one answer.

Figure 19-27 Checkboxes and Radio buttons now appear in the Add Question drop-down



Details for site users

Your workflow doesn't change. However, you need to be aware that from now on, for questions that have a checkbox answer type you can select one or more options, while for questions that include radio buttons only one answer can be selected.

Figure 19-28 How site users see checkboxes and radio buttons questions

A screenshot of a 'Demography' form. The form is titled 'Demography' and has a light gray background. It contains several fields: 'Gender' with radio buttons for 'Male' (selected) and 'Female'; 'Race' with checkboxes for 'American Indian', 'African American', 'Native Hawaiian or Other Pacific Islander', 'Asian' (checked), 'White', and 'Other'; 'Date of Birth' with a text input field showing 'DD-MMM-YYYY' and a calendar icon; and 'Age' with a text input field showing '0'. A hand cursor is pointing at the 'Asian' checkbox.

Already working in a live study?

As soon as the upgrade for this release is complete, study designers can start adding questions with checkboxes and radio buttons to the forms. After the study version is updated and live, site users can start collecting data using these new features.

Streamline form design and improve study data with code lists

Study designers can now add code lists to their forms to streamline form design and ensure collected data is easy to retrieve and analyze.

What are the benefits?

A code list is a set of standard data that study designers can automatically add as a list of answer options to a drop-down, checkboxes or radio buttons type of question in a form. For instance, for a question assessing the subject's gender, instead of adding each option one by one, the study designer can now add a predefined code list that includes all the standard answers for this type of question, as well as their standard codes for data analysis. This allows them to streamline form design and improve the quality of collected data. Moreover, with code lists, sponsor users can easily extract and analyze data, and ultimately optimize the study results. For more details on data extracts, see [Augment data collection processes with data extracts](#).

Details for user managers

Your workflow hasn't changed. However, there are some new permissions that you need to be aware of.

If the user that is creating and managing code lists already has a role that includes the appropriate permissions, no action is required. The user will be able to start working immediately after the system update.

The following new permissions let study designers create and manage code lists:

New permission	Tasks that users with this permission can perform	Roles that include this permission
View code list	View and add a code list to a drop-down, check box or radio button type of question.	Unblinded study designer



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New permission	Tasks that users with this permission can perform	Roles that include this permission
		h c o d e l i s t s .
Edit code lists	<ul style="list-style-type: none"> Create a code list Edit a code list 	Unblinded study designer
Delete code lists	Delete a code list	Unblinded study designer

Details for study designers

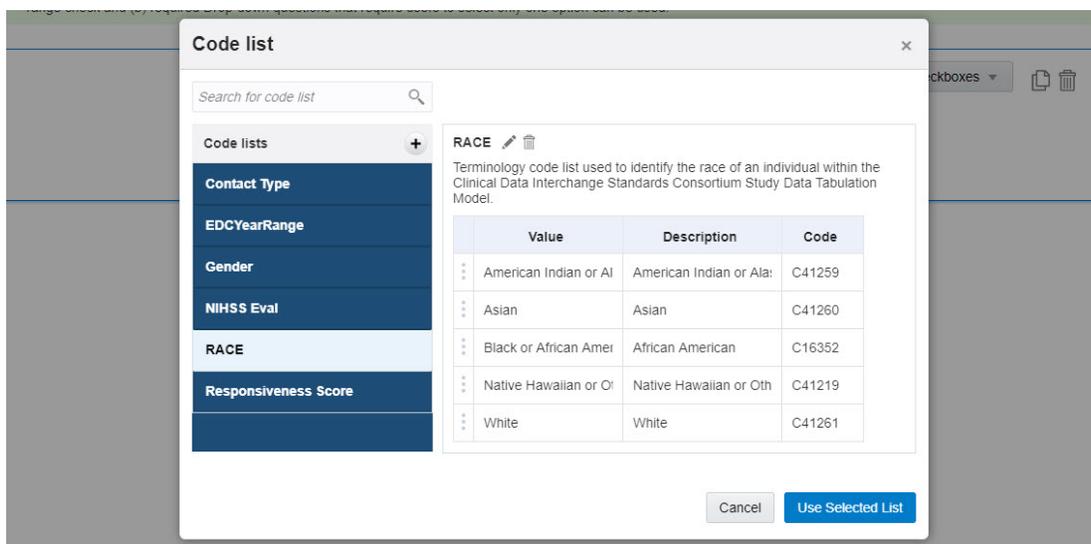
When you add a drop-down, checkboxes or radio buttons type of question, a new **Code list** button appears next to the **Rules** button.

Depending on the permissions that are assigned to you, when you click the **Code list** button on a question you can:

- Add a code list as a list of answer options for that question
- Edit an existing code list to add or remove standard data
- Delete a code list
- Create a code list

Code lists are created at an organization-level, so you can use them across all studies.

Figure 19-29 How study designers see the new Code list dialog window



Already working in a live study?

As soon as the upgrade for this release is complete and you have the appropriate permissions you can start including code lists in your forms. The feature can be used in Draft mode.

Data extraction

- [Augment data collection processes with data extracts](#)
Data managers can now extract subject data from a study. The Subject Data Extract (Unblinded) contains all form data collected for subjects during a study.

Augment data collection processes with data extracts

Data managers can now extract subject data from a study. The Subject Data Extract (Unblinded) contains all form data collected for subjects during a study.

What are the benefits?

With this new feature, you now have the ability to extract clinical data stored in the Oracle Clinical One Platform repository in a different format that is useful for data analysis or regulatory reporting. In turn, this further enhances the data collection processes in the study you work in, improving the quality of data and the efficacy of the study. For this data extract, we've adopted the Study Data Tabulation Model (SDTM), part of the Clinical Data Interchange Standards Consortium (CDISC) to make sure we're following the industry's top standards in terms of code lists and data sets.

In a future release, data extracts will also include SAS properties, so work with your study designer to make sure those fields are specified correctly within the study. For more details on SAS properties, see [Add SAS properties to improve data analysis](#).

Besides all form data that will be included in a data extract, note that data extracts will also contain codes configured in [code lists](#).

Details for user administrators

Your workflow hasn't changed. However, there is a new permission that you need to be aware of.

If the user that is extracting data already has a role that includes the appropriate permissions, no action is required. The user will be able to start working immediately after the system update.

The following new permission allows data managers and statisticians to extract data:

Table 19-3 New permission for extracting data

New permission	Tasks that users with this permission can perform	Existing role that should get this permission assigned to them
Run the Subject Data Extract Unblinded report	Extract both blinded and unblinded subject data from your study	Data manager

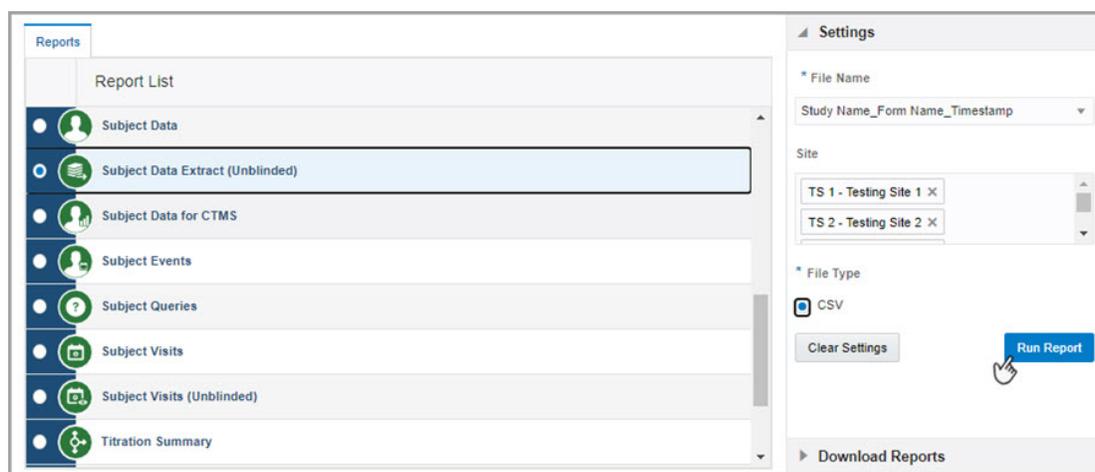
Details for data managers

Here's what's new in your workflow if you're assigned the task of performing data extracts:

- On the Reports tab, with the appropriate roles and permissions, you can extract blinded and unblinded subject data using the new **Subject Data Extract (Unblinded)**
- The Subject Data Extract (Unblinded) is a ZIP archive containing a CSV file per each form created in a study. Subject data can be extracted for either a selection of sites or all sites, depending on how you configure the extract's settings

More details on what exactly you'll see in a data extract will be coming soon.

Figure 19-30 How data managers can extract data in the system



Already working in a live study?

As soon as the upgrade for this release is complete, with the appropriate role and permissions, you can start extracting subject data in Testing, Training, or Production mode.

Integrations

- [Send partial dates to Oracle InForm and other electronic data capture systems](#)
 With the newly introduced feature, integration managers can now send partial dates from Oracle Clinical One Platform to Oracle InForm or other third-party electronic data capture systems.
- [Define and manage new integration types using the integration builder feature](#)
 New types of integrations can now be defined by the Oracle Services team using the new integration builder feature in the Oracle Clinical One Integration Hub user interface.

Send partial dates to Oracle InForm and other electronic data capture systems

With the newly introduced feature, integration managers can now send partial dates from Oracle Clinical One Platform to Oracle InForm or other third-party electronic data capture systems.

How does this work?

In short, if the partial dates feature is enabled in a Oracle Clinical One Platform study and the date formats are compatible and properly configured in the integration template, you can send data to Oracle InForm or other third-party electronic data capture systems.

To send partial dates through your integration, reach out to your Oracle Project Manager.

For more information on how partial dates work in Oracle Clinical One Platform, see [Create and use partial dates in forms](#).

Define and manage new integration types using the integration builder feature

New types of integrations can now be defined by the Oracle Services team using the new integration builder feature in the Oracle Clinical One Integration Hub user interface.

This new feature does not impact your existing and running integrations.

How does this work?

If you're currently managing integrations between Oracle InForm and Oracle Argus Safety, you'll notice a new option called **Other**, on the **Upload Integration File** pop-up. Upon selecting that option, you will be able to configure new integration types as they are registered in your environment by the Oracle Services team.

If you want to understand more about new integration types, reach out to your Oracle Project Manager.

Randomization and supplies

- [Define kits that can only be dispensed by a pharmacist or unblinded site user](#)
Study designers can now define kits with an Unblinded Pharmacist distribution type. These are kits that can only be dispensed by an pharmacist or unblinded site user to subjects in the study.
- [New option for replacing kits and devices](#)
Site users and clinical supply managers now have an improved process for replacing kits and making them available for dispensation again.
- [Track the full chain of custody with a depot reconciliation workflow](#)
Clinical supply managers can now have full control over the study's chain of custody for shipments that need to be destroyed at a depot facility. Additionally, depot users can now receive, destroy, and confirm the destruction of reconciliation shipments raised by site users.

Define kits that can only be dispensed by a pharmacist or unblinded site user

Study designers can now define kits with an Unblinded Pharmacist distribution type. These are kits that can only be dispensed by an pharmacist or unblinded site user to subjects in the study.

What are the benefits?

For example, if you're designing a double-blinded study, perhaps one where investigational products need to be reconstituted by a pharmacist before being consumed by subjects, then this feature will help you.

Unblinded Pharmacist kits that can only be dispensed by a pharmacist or unblinded site user increase the study's efficacy and ensure the study's blind.

Details for user administrators

Your workflow hasn't changed. However, there is a new role that you need to be aware of.

The following new role allows users to dispense and monitor kits that can only be dispensed by an Unblinded Pharmacist.

Table 19-4 New role for viewing and managing kits that can only be dispensed by an Unblinded Pharmacist

New role	Tasks that users with this role can perform	Users that should get this role
View Unblinded Pharmacist kits in study	Monitor, verify, or dispense Unblinded Pharmacist kits to subjects	Typically, you assign this role along with the following other roles in the system, to make sure these users can monitor and dispense Unblinded Pharmacist kits: <ul style="list-style-type: none"> • Unblinded site user or pharmacist: this user receives the <i>Site User</i> or <i>Lead Site User</i> and <i>View Unblinded Pharmacist kits in study</i> roles. With these roles assigned, they can view and dispense unblinded kits or Unblinded Pharmacist kits • Unblinded Clinical Research Associate: this user receives the <i>Clinical Research Associate</i> and <i>View Unblinded Pharmacist kits in study</i> roles. With these roles assigned, they can monitor and review unblinded kits and Unblinded Pharmacist kits

Details for study designers

On the **Kits** tab, you can now define kit types using **Unblinded Pharmacist** as an option for their distribution type. When a kit is of the Unblinded Pharmacist distribution type, unblinded

site users or pharmacists can see the kit's number and description. Blinded site users can't see the kits in the system.

Details for blinded site users

For Unblinded Pharmacist kits, you'll receive appropriate instructions to reach out to the pharmacist or unblinded site user in your study, so they can dispense the kits. If during the same visit, there are blinded kits and unblinded kits that can only be dispensed by a pharmacist or unblinded site user, you can only dispense the blinded kits to the subject.

After the dispensation is done, you'll receive a notification that contains information about the blinded kits you dispensed and another notice to see your pharmacist for the kits that only they can prepare and dispense to subjects.

Details for pharmacists or unblinded site users

When it comes to your workflow, you will now receive a notification that indicates the exact kits that you need to prepare and dispense to subjects in a study. Additionally, with the right role, you're able to see and dispense unblinded kits in the system.

Details for unblinded Clinical Research Associates

When it comes to your workflow, with the right role, you'll be able to monitor and review Unblinded Pharmacist kits in the system.

Details for clinical supply managers and unblinded depot users

When it comes to your workflow, nothing has changed. You can see all kit types within the system, as well as manage them.

Already working in a live study?

As soon as the upgrade is done, study designers can design new kits with an Unblinded Pharmacist type of distribution. Only newly created kits can be designed as Unblinded Pharmacist kits. After the study version is updated, pharmacists or unblinded site users can then prepare and dispense those kits, as long as the kits are available in the live study.

New option for replacing kits and devices

Site users and clinical supply managers now have an improved process for replacing kits and making them available for dispensation again.

What are the benefits?

For both site users and clinical supply managers, the process for replacing a kit, particularly a device, is now better and more straightforward. Site users can now easily replace a kit or a device and properly update its status, whereas clinical supply managers can easily make that kit Available again in a site's inventory. This new workflow is also available for IoT-enabled devices managed with Oracle Health Sciences mHealth Connector Cloud Service.

Details for site users and clinical supply managers

For site users:

- When replacing a device that was dispensed to a subject or marking a kit that was never dispensed in the first place, you can now update the kit's status to **Not Dispensed to Subject**.

For clinical supply managers:

- You can now update a kit's status from **Not Dispensed to Subject** to **Available**, so the kit can be dispensed to another subject in the study.
- Kit status updates for misallocated or not dispensed kits should only be performed on the Site Inventory page for a better, more detailed view of the subjects that initially got these kits.

Already working in a live study?

As soon as the upgrade for this release is complete, you can start replacing kits and devices using the new status option.

Track the full chain of custody with a depot reconciliation workflow

Clinical supply managers can now have full control over the study's chain of custody for shipments that need to be destroyed at a depot facility. Additionally, depot users can now receive, destroy, and confirm the destruction of reconciliation shipments raised by site users.

What are the benefits?

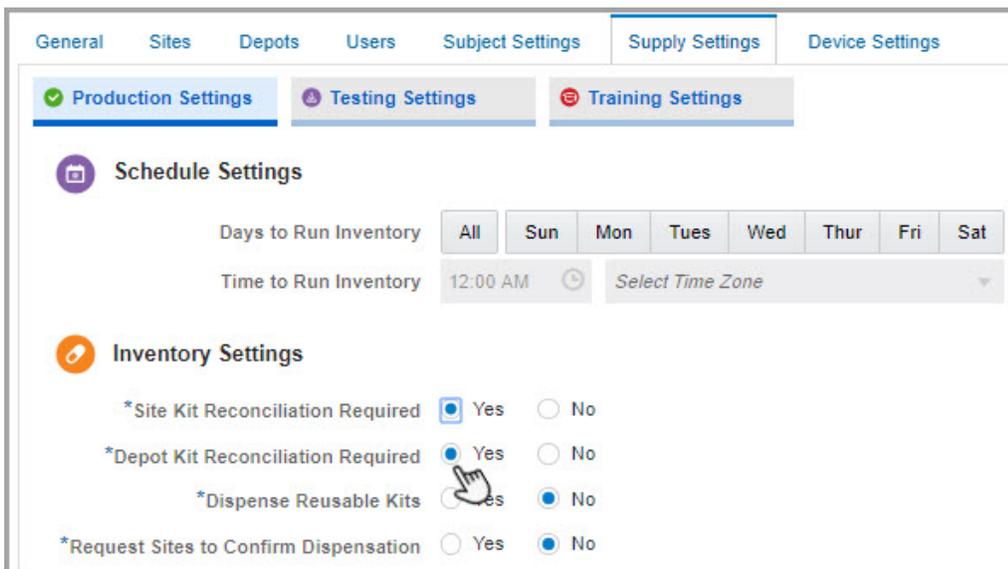
As a clinical supply manager, you can now enable kit reconciliation at a depot level. In turn, this allows you to properly track the depot reconciliation process of shipments and kits that have to be received for destruction. Tracking this entire process within the same system gives you better control over your study's chain of custody and makes way for a better, more transparent reconciliation process.

Additionally, depot users now have a clear and user friendly workflow to make sure they keep track of every shipment and kit that they have to receive and destroy for reconciliation purposes.

Details for clinical supply managers

What's new in your workflow is that you can now enable depot kit reconciliation as required in a study, on the Supply Settings tab. When you make depot reconciliation required, depot users must confirm they've received each kit in a destruction shipment, one by one, before destroying them.

Figure 19-31 How clinical supply managers see the new setting on the Supply Settings tab

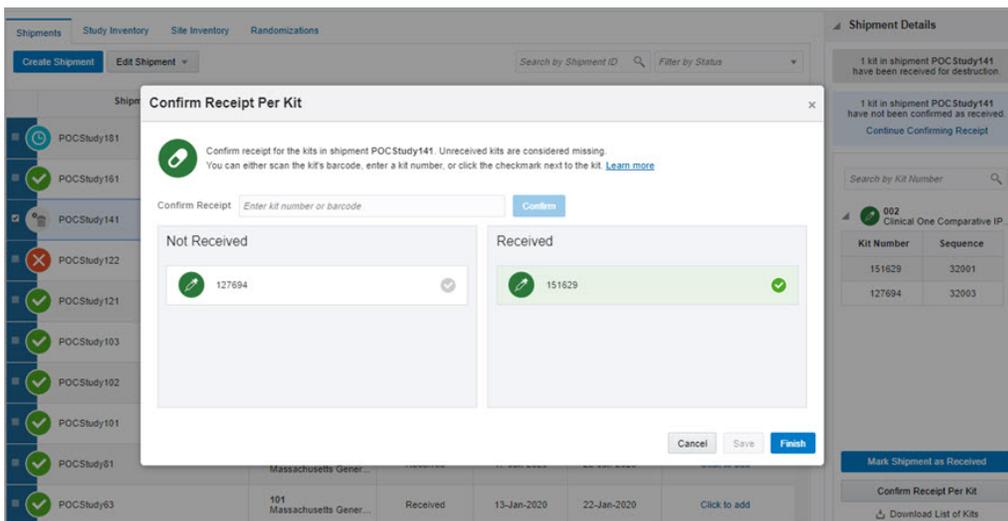


Details for depot users

Now here's what's new for you, as a depot user. Depending on your study's settings, on the Shipments tab, you can:

- Receive and destroy entire shipments
- Receive kits one by one, specify their returned units, and then destroy the shipment

Figure 19-32 How a depot user sees the Confirm Receipt Per Kit pop-up when they have to confirm receipts per each kit



Already working in a live study?

As soon as the upgrade is complete, clinical supply managers can update an existing study to require depot reconciliation. Shipments pending destruction can be received by depot users in existing studies. Any existing destruction shipments that were raised prior to this upgrade can be marked as **Received for Destruction** and subsequently destroyed by a depot user.

Reports

- [New archives and reports from Oracle CRF Submit](#)
Oracle CRF Submit archives and reports are now available for download on the Oracle Clinical One Platform. Sponsor and site users can now generate and download archives and reports from Oracle CRF Submit for mid-study reviews and end-of-study requirements, for example.
- [New reports to keep track of your rules and shipments](#)
The Rules report now provides you with key information about all rules in a study and the Shipment Order Summary report displays valuable data on your shipment orders, such as statuses in each study.

New archives and reports from Oracle CRF Submit

Oracle CRF Submit archives and reports are now available for download on the Oracle Clinical One Platform. Sponsor and site users can now generate and download archives and reports from Oracle CRF Submit for mid-study reviews and end-of-study requirements, for example.

Details for user administrators

Your workflow hasn't changed, but there are some role updates that you need to be aware of. For sponsor or site users to generate and download Oracle CRF Submit archives or reports, you must first make sure the following roles are assigned accordingly to users on the study and site team:

Users at a sponsor	Users at a site
<p>The following roles can generate Oracle CRF Submit archives and reports:</p> <ul style="list-style-type: none"> • Study manager • Data manager • Clinical Research Associate (CRA) 	<p>The following role can download Oracle CRF Submit archives and reports:</p> <ul style="list-style-type: none"> • Site user

Details for sponsor users

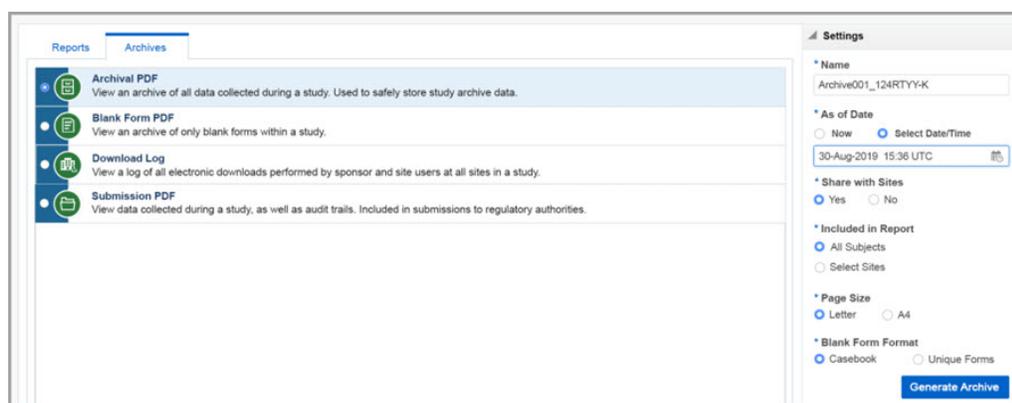
As a sponsor user, you can generate and download the following Oracle CRF Submit archives and reports that will only contain blinded data:

- **Submission PDF**
This is an archive that contains blinded data collected during a study, as well as audit trails, and is included in submissions to FDA and other regulatory authorities at the conclusion of a clinical trial. The information is automatically compiled and formatted according to the regulators' requirements.
- **Archival PDF**

This consists of an archive of all the blinded data that was collected during the study. Typically, this report is generated mid-study or at the end of the study in order to safely store study archive data that you can later make available to auditors, sponsor users, site users, and other regulatory organizations.

- **Download Log**
This report contains a log of all the electronic downloads performed by sponsor and site users at all sites in the study. The log is saved in a CSV format and is available until the trial is decommissioned. This report is especially useful when you choose to share the Archival PDF with site users.
- **Blank Form PDF**
This consists of an archive containing only blank forms within a study. The archive contains annotations that document the location of forms and variables included in these forms, as well as corresponding names.

Figure 19-33 How the new archives and reports appear to sponsor users



Details for site users

As a site user, you can now generate and download the Archival PDF. This archive can be generated at any time but typically it is generated mid-study or at the end of the study, and consists of an archive of all the blinded data that was collected during the study.

New reports to keep track of your rules and shipments

The Rules report now provides you with key information about all rules in a study and the Shipment Order Summary report displays valuable data on your shipment orders, such as statuses in each study.

The Rules report

This report gives you a detailed view of all the rules that were created in a study, along with an audit trail of all the changes that were performed for each rule. With all this information available in one report, study designers and data managers can have an accurate understanding of the impact each rule has on the study and make data-informed decisions.

Who can run this report?

To run the Rules report, users need the Run the Study Rules report permission. Typically, this permission is assigned to users with a role of Study Designer, Rule Designer, Rule Tester, Rule Publisher, and View Only - Support.

What data does it contain?

The Rules report is available in Testing, Training and Production, and contains details about each rule created in the study such as:

- Target item
- Rule name
- Rules description
- Rule expression
- Rule version
- Action type
- Action properties
- Rule state
- Mode
- Type of change
- Last modified by
- Validity
- If the rule is enabled or disabled
- The date the rule was last modified

The Shipment Order Summary report

This report provides summary details about the status of each order made in a study. This way sponsor users and site users have a complete view of all kits that were ordered in a study and their corresponding shipments.

Who can run this report?

To run this report users need the Run the Shipment Order Summary report permission. Typically, this permission is assigned to users with a role of Clinical Supply Manager, Site Inventory User, Clinical Research Associate (CRA), and View Only - Support.

What data does it contain?

The Shipment Order Summary report is available in Testing, Training, and Production, and contains details about each order in the study, including:

- The depot or site that shipped the order
- The depot or site that received the order
- Shipment ID
- Shipment type
- Shipment status
- The date when the order was requested
- The date when the order was received

- Date Outstanding (calculation of the time between shipment creation and current date)
- Kit count
- Kit numbers in shipment

REST APIs and development

- [Check the list of deprecated APIs and plan your work ahead](#)
Developers should now consult the new list of deprecated API endpoints and see which versions they are currently using to plan their API work.

Check the list of deprecated APIs and plan your work ahead

Developers should now consult the new list of deprecated API endpoints and see which versions they are currently using to plan their API work.

What do I have to do with this list?

If you're using any API endpoints that might be deprecated, you need to consult the list of deprecated endpoints and see which new versions you can use from now on. The deprecated API endpoints will no longer retrieve, update, upload, or remove the latest code from the product, so if you're using any deprecated versions you need to make sure you're planning your code work to use the latest versions of those API calls.

Where can I find a complete list of the deprecated API requests?

All deprecated API endpoints will be listed in the [REST API Guide](#) in an upcoming release.

Rules management

- [Control rule execution by study version and achieve better results](#)
Rule designers can now control the execution of each rule by study version and ensure rules always apply to the right data.
- [Create new rules and optimize the quality of your data](#)
Rule designers can now create rules to detect any duplicate entries that were entered in error.
- [Re-run modified rules and automatically update their results](#)
Rule publishers can now update rules faster and more efficiently. When they modify a rule, they can re-run that rule and update their results automatically, including data that was already entered.

Control rule execution by study version and achieve better results

Rule designers can now control the execution of each rule by study version and ensure rules always apply to the right data.

What are the benefits?

Study version changes can have an impact on the applicability of rules. For instance, if a new question is added or removed from a form in a new study version, this change can render a rule invalid or non-applicable. When rule developers control rule execution based on a specific study version, they ensure only valid rules run in a study

version and these rules always apply to the right data, and ultimately generate reliable results.

Details for rule designers

Rule designers can now add a new command in the rule expression to ensure the rule executes only in a certain study version or several versions. The built-in JavaScript function **isStudyVersion()** can be used to have different results based on the study version. In the example below, the rule is a calculation that returns num1*10 for study version 1.0.0.5 and greater and num1 for version below 1.0.0.5. :

```
if (isStudyVersion(">=", "1.0.0.5")) {  
    return num1*10;  
} else {  
    return num1;  
}
```

Already working in a live study?

As soon as the upgrade for this release is complete you can control rule execution by one or more study versions. This feature is available in Testing and Production mode.

Create new rules and optimize the quality of your data

Rule designers can now create rules to detect any duplicate entries that were entered in error.

What are the benefits?

Rules work like guardians that oversee the quality of your study data. Rule designers can write rules to scan the collected data and raise a query anytime duplicate data is found in a repeating form. You can do this by writing several Javascript expressions to:

- Compare newly entered data against data entered in previous instances of a repeating form
- Compare one or more data item(s)

Already working in a live study?

As soon as the upgrade for this release is complete you can start creating rules to check for duplicate entries in repeating forms.

Re-run modified rules and automatically update their results

Rule publishers can now update rules faster and more efficiently. When they modify a rule, they can re-run that rule and update their results automatically, including data that was already entered.

What are the benefits?

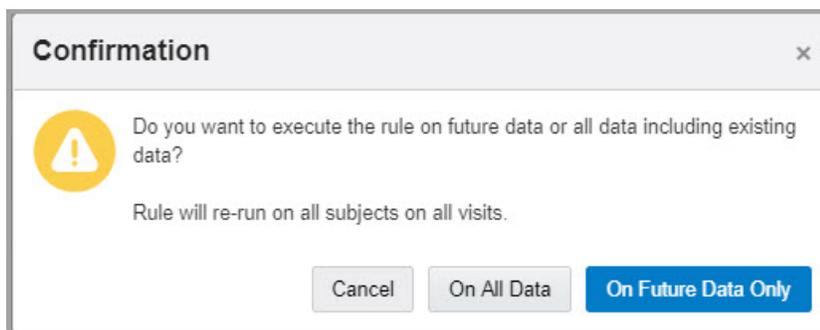
Rule publishers can now re-execute modified rules much easier and faster, without manually re-running every modified rule for previously entered data. For instance, if a query is opened as a result of an already created rule and the rule designer modifies that rule making that query obsolete, when the rule publisher re-runs the modified rule the query is automatically re-evaluated and closed. This saves rule designers a lot of time and ensures rules always generate proper results.

Details for Rule publishers

When you publish a modified rule, a confirmation message appears asking you to choose if you want to execute the rule only on future data or on all data including data that was already collected. When you click **On All Data**, the rule re-runs for all subjects for which it has previously run. For example, if the rule is a calculation for Body Mass Index (BMI) and has previously calculated the value for two subjects, then the rule will re-run and re-calculate BMI for these two subjects. The rule will also run for data captured in the future.

When the rule re-run is completed, you receive a notification.

Figure 19-34 Confirmation message for re-running a rule



Already working in a live study?

As soon as the upgrade for this release is complete, you can start re-running modified rules. This feature is available in all 3 modes.

User experience

- [More data at a glance with the study dashboard](#)
More study data with just one click! The new study dashboard now lets you access important information about your subjects, queries, and shipments in a fast and easy way.

More data at a glance with the study dashboard

More study data with just one click! The new study dashboard now lets you access important information about your subjects, queries, and shipments in a fast and easy way.

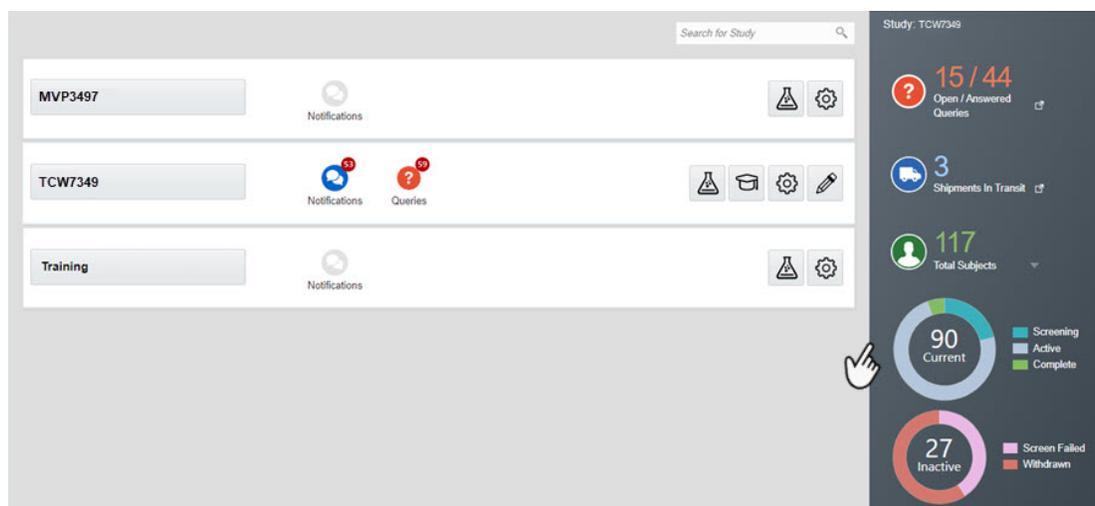
How does it work?

From now on, all you need to do is click once on the study row, next to the study ID, and data about your subjects, shipment or queries instantly becomes available to you. The dashboard appears on the home page, on the right. The data is displayed according to the roles and permissions that are assigned to you. Read below to learn more about what type of data you can see in the dashboard.

What do I have to do to have access to the study dashboard?

The study dashboard only shows the data that you have permission to see according to your assigned roles in the study. For instance, if you don't see shipments with an **In Transit** status, you might not have the right roles assigned. Additionally, you only see data for sites that you're assigned to. For example, you only see the total number of subjects enrolled at a site that you're assigned to.

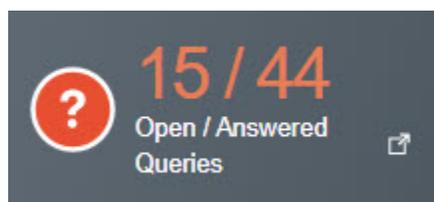
Figure 19-35 How the study dashboard is displayed on the home page



Open/Answered Queries

This section shows the total number of queries with an **Open** and **Answered** status for all the sites that you're assigned to. To access the queries just click the **Open/Answered Queries** button. The Subjects tab opens in Production mode. From the Sites drop-down, select a site. A list of all open and answered queries for that site will be displayed on the right sidebar.

Figure 19-36 How you see the Open/ Answered Queries section on the study dashboard



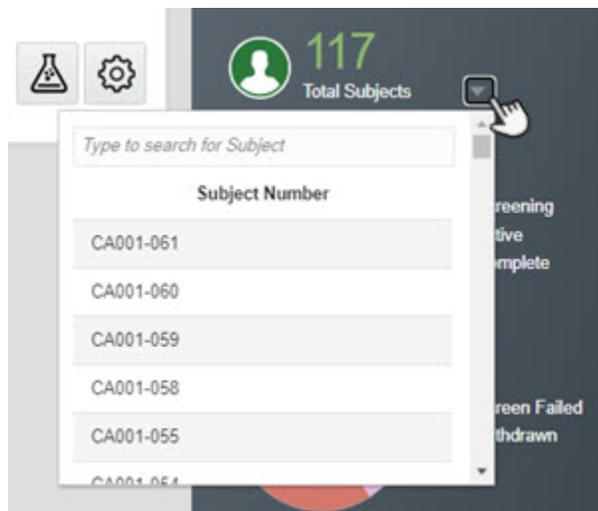
Total Subjects

This section shows the total number of subjects for all the sites that you're assigned to and acts as a shortcut to the main **Subjects** page. To browse through the list of subjects, click the drop-down on the right. If you want to find out more about one subject in the list select the subject's ID from the drop-down or type the subject's ID in the search field above the subjects

list. The **Subjects** tab opens in Production mode with the subject you chose selected and the Subject History pane displayed on the right.

The **Total Subjects** section also includes charts that show you the way subjects with different statuses are distributed in the study. One chart displays the number of current subjects with **Screened**, **Active**, **Enrolled**, and **Complete** statuses, while the second graphic shows the number of inactive subject with **Screen Failed** and **Withdrawn** statuses.

Figure 19-37 How you see the Total Subjects section on the study dashboard



Shipments In Transit

This section shows the number of shipments with an **In Transit** status for all the sites that you're assigned to. When you click the **Shipments In Transit** section, the **Shipments** tab opens and a list of all shipments is displayed.

Figure 19-38 How you see the Shipments In Transit section on the study dashboard



Already working in a live study?

As soon as the upgrade for this release is complete, the new study dashboard will display data for your live studies.

Fixed issues

- [Fixed issues for reports](#)
- [Fixed issues for site users and subject data](#)
- [Fixed issues affecting all users](#)
- [Fixed issues for forms and visits](#)
- [Fixed issues and enhancements for integrations](#)
- [Fixed issues for reports and notifications](#)
- [Fixed issues for site users and subject data](#)
- [Fixed issues for randomization and kits](#)

Fixed issues affecting all users

What's new video no longer part of the mandatory training for site users

The What's New video, that is presenting an overview of all new features introduced in a release, is no longer part of the mandatory training for site users. Previously, the What's New video was listed as part of mandatory training and appeared as incomplete training for site users in a study. (Issue **31434105**)

Fixed issues for forms and visits

Question labels for age questions are now displayed as expected (former known issue)

Rule designers: On the Rule Editor, the question label for an age type of question is now properly displayed. Due to the age type of question being a smart object, whenever you selected a variable for this type of question, you didn't know what to choose: whether the Age read-only item or the date/time type of question that represented the date of birth.

From now on, an age read-only item will be displayed with an "_AGE" appendix, and the date/time type of question will be displayed with a "_DOB" appendix.

Retracted workaround: None. (Issue **30969430**)

Repeating forms now work in Microsoft Edge (former known issue)

Site users: You can now add and complete instances of a repeating form in Microsoft Edge. Previously, whenever you added instances of repeating forms, the screen froze, and the browser page stopped responding.

Retracted workaround: Although the issue is now fixed in Microsoft Edge, we still recommend using Google Chrome for a better product experience. Issue (**30668867**)

Automated query now closes when resolved (former known issue)

Rule testers: From now on, when an automated query is raised for a question on a form assigned to another visit, the query is closed, after data is corrected. Previously, even though a site user corrected the value, the automated query still appeared as if the data for that field was still incorrect.

Retracted workaround: None. (Issue **31310661**)

Reference code can now be updated for dynamic question in Draft mode (former known issue)

Study designers: You can now update a dynamic question's reference code in Draft mode without an error message appearing.

Retracted workaround: None. (Issue **31208843**)

Information message no longer appears when clearing answer to a dynamic question (former known issue)

Site users: From now on, when you clear the answer to a question that contains a Show Form rule, an information message no longer appears prompting you to first clear answers for any dynamic questions, even though you already did that.

Retracted workaround: None. (Issue **31083837**)

Fixed issues and enhancements for integrations

Data on events is now properly displayed in the EDC system when FreezeDataItem is set to False **Note:**

This fix impacts integrations between Oracle Clinical One Platform and a third-party EDC system.

Integration managers: Now, when you send data for a subject event from Oracle Clinical One Platform, that data is properly reflected in the EDC system when the indicator is set to **False** for the FreezeDataItem in the integration template. Previously, data sometimes wasn't displayed as expected in the EDC system. For example:

- For a withdraw event, the reason for withdrawing a subject was cleared from the EDC system although it shouldn't have.
- For a randomization event, data was cleared for a form associated with another visit, instead of the randomization visit.

(Issue **31041701**)

Cohort data can now be sent to Oracle InForm **Note:**

This enhancement impacts integrations between Oracle Clinical One Platform and Oracle InForm.

Integration managers: If your Oracle Clinical One Platform study uses cohorts, you can now include a cohort's name in the data you send to Oracle InForm related to randomization events, using the integration template. (Issue **31125199**)

Integration with Catalent Clinical Supply Services now fulfills shipment requests for mapped depots only

Integration managers: From now on, when configuring the integration, you can choose whether a shipment request sent to an unmapped depot should result in an error, highlighting the missing depot that needs to be mapped, or omit any shipment requests coming from an unmapped depot. Typically, you would choose for the integration to omit any shipment requests coming from an unmapped depot, if the sponsor user uses any alternate shipment means, such as creating a manual shipment.

Previously, it was expected that Oracle Clinical One Digital Gateway would fulfill all shipment requests coming from all study depots through the integration with Catalent Clinical Supply Services. When a depot wasn't mapped in the integration template, the jobs would fail.

(Issue **31030363**)

Job retry attempts now take place in the expected number



Note:

This fix impacts all integrations between Oracle Clinical One Platform and Fisher Clinical Services, Catalent Clinical Supply Services, and Oracle InForm.

Integration managers: From now on, retry attempts for jobs work as expected and configured in the user interface. Previously, more retry attempts than expected took place for existing jobs when another shipment was created during the retry process. (Issue **31005991**)

Kit type package now displayed as expected (former known issue)

Integration managers: Now, when you send kit replacement data from Oracle Clinical One Platform to Oracle InForm, the value for Kit Type Package is displayed as expected, instead of displaying it in the Kit Type Name field, in Oracle InForm.

Retracted workaround: None. (Issue **31224193**)

Error message when enabling integrations now displayed as expected

Integration managers: From now on, when you attempt to enable an integration, the correct error message is displayed. Occasionally, an incorrect error message was displayed stating that the scheduler service was down. (Issue **30416913**)

Fixed issues for reports and notifications

Questions in the Study Design report are now properly ordered (former known issue)

Study designers: Now, when you run the Study Design report, questions are displayed in the correct numeric order. Previously, questions were displayed in order of the first numeral in a number, rather than the number as a whole.

Retracted workaround: None. (Issue **31038725**)

Study Design report now shows the expected last modified dates and users (former known issue)

Study designers: Now, when you update a question in a form and run the Study Design report, data for the Last Modified and Last Modified User columns appears as expected. Previously:

- The date when a study version was last created appeared in the Last Modified Date column for a modified question, instead of the last date you modified the question
- In the Last Modified User column, your user name might have appeared for every question in a form, even though you didn't update all of the questions in that form

Retracted workaround: None. (Issue **31233311**)

Subject numbers are now displayed in Kit Chain of Custody report (former known issue)

Clinical supply managers: The Kit Chain of Custody (Unblinded) report now displays numbers of subjects who initially received kits that are marked as **Pending Destruction** or **Returned to Site**, in the inventory.

Retracted workaround: None. (Issue **31204320**)

Fixed issues for site users and subject data

Dispensed devices can now be registered and dispensed again (former known issue)

Clinical supply managers and site users: From now on, you can register and re-dispense a device from one subject to another within the study. Previously, if a clinical supply manager updated a device's status from **Dispensed** to **Available** and the site user attempted to re-dispense that device, they received an error message. (Issue **30775867**)

This fix also applies to kits containing an investigational product that should be replaced. For more details on the new process for replacing kits and devices, see [New option for replacing kits and devices](#).

Retracted workaround: None.

Fixed issues for randomization and kits

Latest sponsor messages appear in Testing Mode

Study designers: Now, when you update the messages that should appear to site users who want to titrate but can't, the latest message appears only for sites using the latest study version. Previously, even sites that were using an earlier study version received this message.

Retracted workaround: None. (Issue **29708022**)

Oracle Clinical One Platform 20.1.1.1

- [Fixed issues for reports and notifications](#)

Fixed issues for reports and notifications

Subject Events report filters now work as expected

Study team members and site users: When you select **Screened** for the **Event Type** filter, the report is now generated successfully in all formats. Previously, when you selected the Screened event type as a filter option, the report couldn't be generated. This was due to a system limitation with the number of screened subjects that can be displayed in the Subject Events report. The limitation is now fixed. (Issue **31379752**)

Reporting filters now work in the training report

Training managers: Now, when you run the Health Sciences Learn Training report for all studies setting a default start-up date and continuing through the present date, the filtering options work. Previously, some filters didn't work which resulted in blank fields in the CSV version of the report. (Issue **31386639**)

This fix is associated with another Oracle Health Learn Manager former known issue. For more details, see Fixed issues in this release.



Note:

If you had issues with these reports recently, we recommend you re-run the reports to make sure filters are working as expected and data is properly displayed.

Oracle Clinical One Platform and Oracle Clinical One Integration Hub 20.1.1 (May 2020)

- [What's new](#)
- [Fixed issues](#)

What's new

- [Sign and verify data in a study](#)
Principal investigators can now sign data at a subject level and Clinical Research Associates (CRAs) can now verify data to make sure the information collected in a study is accurate.
- [Add customized fields to the Subject Events report](#)
Clinical Research Associates (CRAs), data managers, study managers, lead site users, and site users can now customize their Subject Events report with specific fields.
- [Send kit replacement and kit re-dispensation data to Oracle InForm](#)
Integration managers can now send more data about additional kit-related events from Oracle Clinical One Platform to Oracle InForm.

Sign and verify data in a study

Principal investigators can now sign data at a subject level and Clinical Research Associates (CRAs) can now verify data to make sure the information collected in a study is accurate.

What are the benefits?

With this new feature, principal investigators can sign data and Clinical Research Associates (CRAs) can perform source data verification to reduce error rates of study data, and make sure it is always accurate and reliable for the study's findings.

Details for user administrators

Your workflow hasn't changed. However, there are some new permissions that you need to be aware of. Principal investigators and Clinical Research Associates (CRAs) must have the correct permissions and roles assigned to them in order to sign and verify data, respectively.

If the user that is signing or verifying data already has a role that includes the appropriate permissions, no action is required. The user will be able to start working immediately after the system update.

The following new permissions allow principal investigators to sign data and Clinical Research Associates (CRAs) to verify data.

Table 19-5 New permissions for signing and verifying data

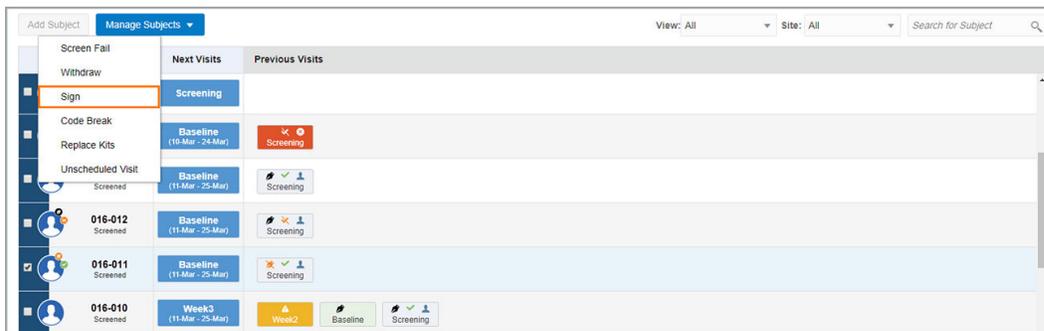
New permission	Tasks that users with this permission can perform	Roles that include this permission
Verify site-entered subject data	Verify data at a visit, form, and question level.	Clinical Research Associate (CRA)
Approve and sign subject data	Sign off on data at a subject level.	Lead site user or site user

Details for principal investigators

You can now sign off on data in a study, at a subject level, to make sure data in a study is properly collected and accurate. Additionally, you can also re-sign changed data for a subject. When it comes to your workflow, there are a couple of changes that you should be aware of. From now on, on the Subjects tab, you can:

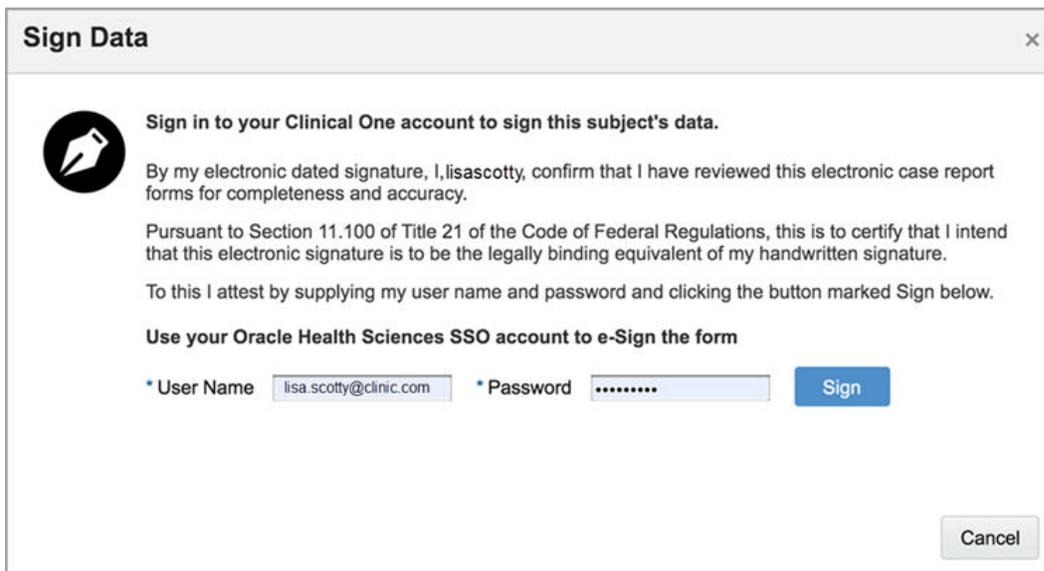
- Filter your search to find subjects that are **Ready to Sign**.
- Select a subject, click **Manage Subjects**, and select **Sign** to sign a subject's visits and forms at once.

Figure 19-39 How lead site users see the new Sign option



- Sign a subject's data using an electronic signature based on your Oracle Clinical One Platform credentials, that you typically use to sign in the system.

Figure 19-40 How a principal investigator sees the Sign Data pop-up



- When all visits for a subject are signed, a black fountain pen icon appears next to a subject's icon.

Figure 19-41 Signed subject icon



Details for Clinical Research Associates (CRAs)

You can now verify forms in a study to make sure data collected at a visit, form, or question level is accurate and reliable for the study. When it comes to your workflow, there are a couple of changes that you should be aware of. From now on, on the Subjects tab, you can:

- Filter your search to find subjects that are **Ready to Verify**.
- Click a visit and verify its data entirely, at a form, or a question level.

Figure 19-42 How users see a signed and verified visit

The screenshot displays the Oracle Clinical One Platform interface for a subject named CA Hebbal-038. The main area shows the 'Basic Details' form for a visit on 11-Mar-2020. Fields include Name (Akash), Gender (Unknown X), Date of Birth (21-Oct-1991), Age (28 Years), Patient Id (10001), and Patient Type (New X). Each field has a green checkmark icon indicating it is verified. The right sidebar shows the 'Answer & Visit History' section, listing various visits with their status (Signed, Unsigned, Verified) and dates.

- When all visits for a subject are verified, a green check mark appears next to a subject's icon.

Figure 19-43 Verified subject icon



Add customized fields to the Subject Events report

Clinical Research Associates (CRAs), data managers, study managers, lead site users, and site users can now customize their Subject Events report with specific fields.

What are the benefits?

With customized fields in the Subject Events report, sponsor and site users can now consolidate reporting data for their studies. Moreover, they can make data-driven decisions and achieve better outcomes when it comes to subjects and their events, such as screening visits, randomizations, dispensations, or unscheduled visits.

Details for users at a sponsor and site users

If you have one of these roles, you can now add up to 20 new customized fields in the Subject Events report by clicking the **Advanced** button.

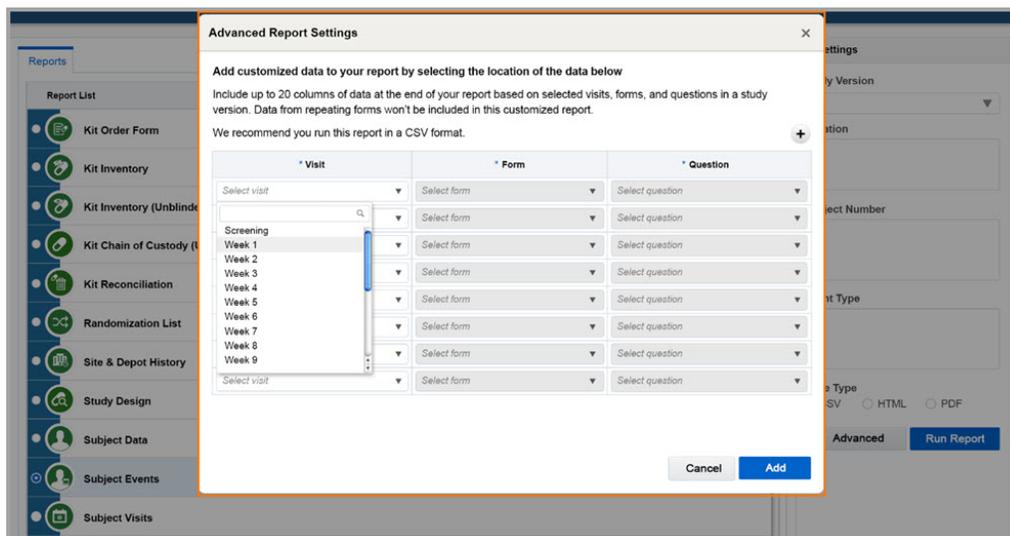
Figure 19-44 Fig. 1-1 Click the Advanced button to add customized fields in the Subject Events report

The screenshot shows a settings panel for a report. At the top is a 'Settings' header with a right-pointing arrow. Below it are several configuration sections: 'Study Version' with a dropdown menu showing 'All'; 'Location' with a text input field showing 'All'; 'Subject Number' with a text input field showing 'All'; and 'Event Type' with a text input field showing 'All'. Below these is a 'File Type' section with three radio buttons: 'CSV' (selected), 'HTML', and 'PDF'. At the bottom of the settings area are two buttons: 'Advanced' (with a gear icon, highlighted by an orange border and a hand cursor) and 'Run Report' (in blue). At the very bottom of the panel is a 'Download Reports' header with a right-pointing arrow.

New Advanced Report Settings pop-up

This is where you can select the exact types of data that can be added at the end of your Subject Events report. You have to select the visits, forms, and questions that should appear in the report. We recommend using the latest study design version for the most recent collected data.

Figure 19-45 Fig. 1-2 New Advanced Report Settings pop-up in the Subject Events report



Already working in a live study?

As soon as the upgrade for this release is complete, you can start running the Subject Events report with customized fields in any mode of the study: Testing, Training, or Production.

Send kit replacement and kit re-dispensation data to Oracle InForm

Integration managers can now send more data about additional kit-related events from Oracle Clinical One Platform to Oracle InForm.

How does this work?

From now on, you can configure your integration to send kit replacement and re-dispensation information from Oracle Clinical One Platform to Oracle InForm. Previously, only the initial kit dispensation was transmitted.

For kit replacement: When a subject loses or damages a kit and the kit is replaced, data related to the new kit is now sent to Oracle InForm and included in a visit form. The new data includes dispensation date, original kit number, and new kit number, amongst others.

For kit re-dispensation: When kits are conserved and re-dispensed, Oracle Clinical One Platform can send the conserved kit number and any other relevant data to Oracle InForm.

Sponsors: How can I send data about additional kit-related events to Oracle InForm?

If you want to transmit data about kit replacement and kit re-dispensation from Oracle Clinical One Platform to Oracle InForm, reach out to your Oracle Project Manager.

Fixed issues

- All users
- Code lists
- Forms, visits, and rules
- Integrations
- Oracle Clinical One Analytics
- Reports, archives, extracts, and notifications
- Sites, labs, depots, settings, and user management
- Site users and subject data
- Fixed issues for integrations
- Fixed issues for reports and notifications

Fixed issues for integrations

Multiple retry jobs are now properly managed on the SFTP server



Note:

This fix impacts integrations between Oracle Clinical One Platform and Catalent Clinical Supply Services and Oracle Clinical One Platform and Fisher Clinical Services.

Integration managers: When two or more retry jobs for the same integration file execute at the same time, the concurrent jobs are now properly managed. Previously, the second retry job failed while attempting to remove the integration file that was already processed and removed by the first retry job, on the SFTP server. (Issue **31005970**)

Fixed issues for reports and notifications

Kit numbers are now displayed correctly in reports

Study team members: When you run certain reports in a CSV format, kit numbers are now displayed correctly. For example, in the Kit Number or Dispensation Kit Number columns you now see numbers displayed as "47 | 683 | 313 | 107 | 015". Previously, kit numbers were displayed incorrectly in the Subject Visit Schedule (Blinded) and Subject Events reports.

Retracted workaround: If you must run these two types of reports in a CSV format you no longer have to run them in a PDF or HTML format, as a workaround. (Issue **31036715**)

Oracle Clinical One Platform 20.1.0.1 (April 2020)

- Randomization and kit stability improvements

Randomization and kit stability improvements

Randomization allowed only for visits with valid forms

Site users: This release corrects a behavior introduced in the previous release that allowed you to randomize a subject even after a validation error occurred. The **Randomize** button is now disabled when a validation error occurs. Previously, if a validation error occurred and you clicked **Save & Close** for the forms in that visit, the **Randomize** button remained enabled and you were allowed to randomize the subject. Because the validation errors indicate incorrect answers in a form, the **Randomize** button should have been disabled until the errors were corrected. (Issue 31115021)

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.1 (March 2020)

- [What's new](#)
- [Stability improvements](#)
- [Retracted Known Issues](#)

What's new

- [User impact of each feature in 20.1](#)
If you need to have an overview of what user role is impacted by each feature, check the table below.
- [Collect valuable data with new types of questions and forms](#)
Study designers can now create new types of questions and forms with these new features:
- [Create and manage rules on the user interface](#)
Study designers can now create, test, and publish rules from the product's user interface.
- [Set a subject's blinded dose level for kits](#)
Study designers can now specify the dose level for blinded kit type titrations, so site users know whether a subject is on a low, medium or high dose during the study, for example.
- [Use barcodes for creating kit lists and confirming dispensation](#)
Clinical supply managers can set a study to use barcodes and let site users confirm dispensation.
- [Create resupply strategies with "0" values](#)
Clinical supply managers can now use values of "0" to set their resupply strategies.
- [Use data flags to label unanswered questions](#)
You can now use data flags to mark questions that have a missing answer and complete your forms and visits without disruption or delays.
- [New reports and enhancements](#)
From now on, the Subject Visit Schedule report and Titration Summary report keep you informed about your subject's visits schedules and titrations. With all this new data available, you can easily schedule and predict future visits, forecast supply

needs, and better understand dosing for subjects. Additionally, five existing reports are now available in a PDF format.

- [New subject and shipment notifications](#)

Subject and shipment monitoring play a crucial role in the outcome of any clinical study. With the right roles and permissions, users in a study can now receive notifications every time a randomization or dispensation visit is complete or not, as well as when a shipment is cancelled.

User impact of each feature in 20.1

If you need to have an overview of what user role is impacted by each feature, check the table below.

Table 19-6 Feature impact matrix for each user

Feature or enhancement	Impacted user
Question groups	Study designers
Dynamic questions	Study designers
Dynamic forms	Study designers
Drop-down questions with a single answer	Study designers
Create and manage rules on the user interface	Study designers
Use barcodes for creating kit lists and confirming dispensation	User administrators, clinical supply managers and site users
Set a subject's blinded dose level for kits	Study designers and site users
Use data flags to label unanswered questions	Site users
Create resupply strategies with "0" values	Clinical supply managers
New reports and enhancements	Clinical research associates (CRAs), clinical supply managers, study managers, site users
New subject and shipment notifications	User administrators, clinical supply managers, randomization list managers, site users and any other users want to receive these new notifications

Collect valuable data with new types of questions and forms

Study designers can now create new types of questions and forms with these new features:

- [Drop-down questions with a single answer](#)
Study designers can now create and save drop-down questions that only have one option for an answer.
- [Dynamic forms](#)
Study designers can now create dynamic forms to display forms only when relevant for specific subjects.
- [Dynamic questions](#)
Study designers can now create dynamic questions that let them display certain questions based on specific answers.
- [Question groups](#)
Study designers can now create question groups and site users can use them to collect more detailed and intuitive data.

Drop-down questions with a single answer

Study designers can now create and save drop-down questions that only have one option for an answer.

What are the benefits?

For example, drop-down questions with singular answers are particularly useful in clinical studies where subjects are only female. For such studies, there's no need to differentiate between the male and female gender when screening a subject.

Details for study designers

When you create a new drop-down question, now the question only has one option for an answer.

To update a drop-down question so it contains only one option for an answer, click the trash can icon next to the second option to delete it.

Figure 19-46 How study designers update an existing drop-down question to contain only one option for an answer



Already working in a live study?

As a study designer, you can either edit an existing drop-down question or create a new one, with a single option for an answer, as soon as the system upgrade is complete. The changes will be effective after the updated study is approved and live.

Dynamic forms

Study designers can now create dynamic forms to display forms only when relevant for specific subjects.

What are the benefits?

Dynamic forms let you display certain forms for a subject only if a specific answer is given to a question on another form, during the same visit. For instance, the Surgery form appears only if the subject answers **Yes** to the question "Has the Subject had any surgery?". If the answer is **No**, the Surgery form doesn't appear.

Details for study designers

When you create a form, you can now add a **Show form** rule to a question in the form to enable another form to appear. The form that is enabled by the **Show form** rule is dynamic and displays only when a specific answer is given to the parent question, the one containing the rule.

 **Note:**

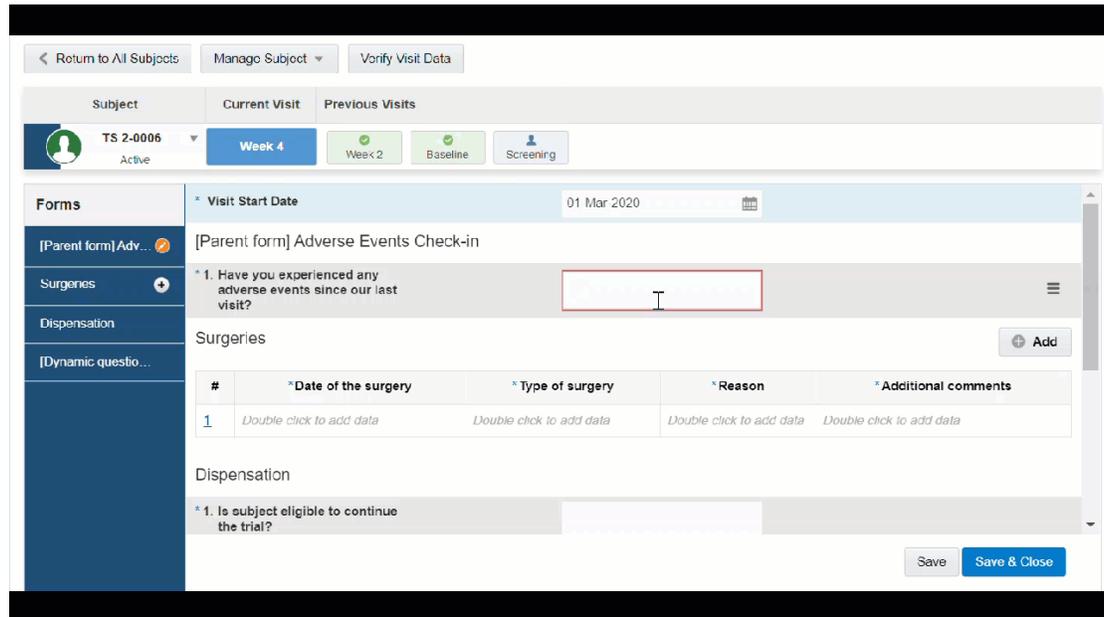
The question containing the **Show Form** rule can set off one or more dynamic forms.

When adding forms to a visit, you must ensure that both the form containing the parent question and any dynamic forms enabled by the question are present in the same visit.

Details for site users

There are no workflow changes for you. Just remember that dynamic forms only appear if you enter a specific answer to a question containing a **Show Form** rule. For example, a Pregnancy form only appears if you enter **Yes** for a question assessing a female subject's child bearing potential.

Figure 19-47 How dynamic forms appear for site users



The screenshot shows the Oracle Clinical One interface for a subject named TS 2-0006, currently in Week 4. The interface includes a navigation bar with 'Return to All Subjects', 'Manage Subject', and 'Verify Visit Data'. Below this, there are tabs for 'Subject', 'Current Visit', and 'Previous Visits'. The 'Current Visit' tab is active, showing 'Week 4' and 'Active' status. There are also buttons for 'Week 2', 'Baseline', and 'Screening'. The main content area is titled 'Forms' and contains a question: '* 1. Have you experienced any adverse events since our last visit?'. Below the question is a table for 'Surgeries' with columns for '#', 'Date of the surgery', 'Type of surgery', 'Reason', and 'Additional comments'. The table has one row with the number '1' and placeholder text 'Double click to add data'. There are also buttons for 'Add', 'Save', and 'Save & Close'.

Already working in a live study?

As a study designer, you can start designing dynamic forms in Draft mode, as soon as the system upgrade is complete. As a site user, you will see these new types of forms as soon as the updated study is approved and live.

Dynamic questions

Study designers can now create dynamic questions that let them display certain questions based on specific answers.

What are the benefits?

Dynamic questions let you control other questions that are displayed in a form. For instance, the question assessing the child bearing potential for a subject only appears if a site user

chooses the **Female** option for the **Gender** field. If a site user selects **Male** as the answer, the question doesn't appear. Dynamic questions help you keep your form clear and clean by displaying only the relevant questions for each subject.

Details for study designers

When you create a question, you can now add a **Show Question** rule to it. This allows you to display one or multiple questions only if a certain answer is given to the parent question (the one containing the rule) on the same form.

 **Note:**

Dynamic questions are displayed only when the question containing the **Show question** rule and the dynamic question are on the same form.

Details for site users

There are no workflow changes for you. Just remember that a dynamic question only appears if you enter a specific answer to a question containing a **Show Question** rule.

 **Note:**

If the dynamic question is required and shown, you must answer it for the visit to be considered complete.

Already working in a live study?

As a study designer, you can start designing dynamic questions in Draft mode, as soon as the system upgrade is complete. As a site user, you will see these new types of questions in forms as soon as the updated study is approved and live.

Question groups

Study designers can now create question groups and site users can use them to collect more detailed and intuitive data.

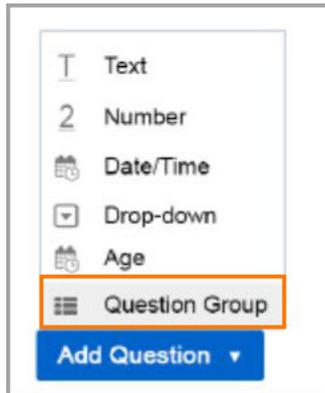
What are the benefits?

Question groups allow study designers to display multiple related questions on the same line, in a form. For example, study designers can now group two related questions for values such as systolic and diastolic blood pressure. This grouping makes data entry easier and more intuitive for site users, and improves the overall data collection process in a study.

Details for study designers

On the Forms tab, when you click **Add Question**, there's a new option for adding a **Question Group**.

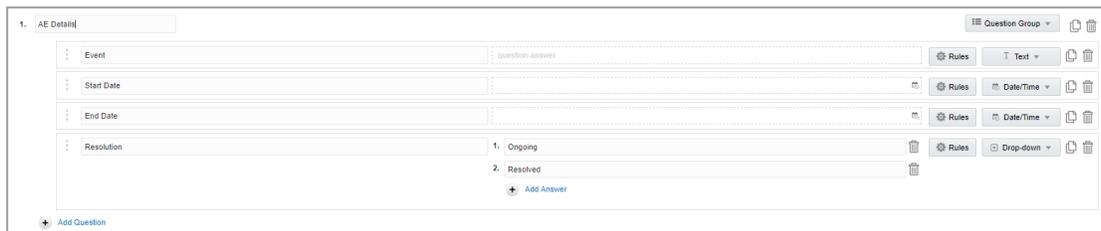
Figure 19-48 How study designers see the Question Group option in the Add Question drop-down



The system automatically creates a group with two questions by default. Before adding questions, provide a name for the **Question Group**. You can add as many questions as needed to the group. Each question within the group has its own rules, labels, and question type. You can specify the same details for questions within the question group, as you can for any other question in a form.

For example, if you want to perform a routine eye examination, and need to collect data about the axis and cylinder of a subject's eye, you can include two or three number questions in a question group.

Figure 19-49 How study designers see question groups in a form



What type of questions can I include in a question group?

A question group can include any type of questions: text, number, date/time, drop-down, age, or coding questions, as well as read-only items.

Details for site users

There are no workflow changes for you. Just remember that forms can now include question groups with multiple questions displayed on the same line.

If all questions in a question group are required, make sure you answer all of them when completing your forms, so you can screen or randomize a subject or dispense kits.

Figure 19-50 How site users see non-required question groups in a form

The screenshot displays a clinical trial form with the following sections and data:

- Visit Start Date:** 20-Feb-2020
- Dosing Section:**
 - Enter the dose level for this visit: 0.5
 - Subject's weight today: 10.0 kg
- Adverse Events Section:**
 - AE Details:** A table with columns for Event, Start Date, End Date, and Resolution. One entry is highlighted with an orange border: Event: Severe headache, Start Date: 02-Mar-2020, End Date: 04-Mar-2020, Resolution: Ongoing X.
- Dosing Bands Section:**
 - Weight: 10.0
 - Kits to dispense: 1
 - Confirm the kit to dispense (enter number from above): 1

Already working in a live study?

As a study designer, you can start designing question groups in Draft mode, as soon as the system upgrade is complete. As a site user, you will see these new types of questions in forms as soon as the updated study is approved and live.

Create and manage rules on the user interface

Study designers can now create, test, and publish rules from the product's user interface.

Last year, in December, we announced that more details about your rules and automated queries workflow will be coming soon. At the end of this month, you will get a complete workflow on how to create, modify, test and publish rules, and generate automated queries. In the meantime, here's what's new and changed in your workflow, if you're a user manager or study designer.

Details for user administrators

Your workflow hasn't changed, but there are some new roles that you need to be aware of. Study designers must have these roles assigned to them in order to create, test, approve and publish rules.

Table 19-7 Roles for working with rules

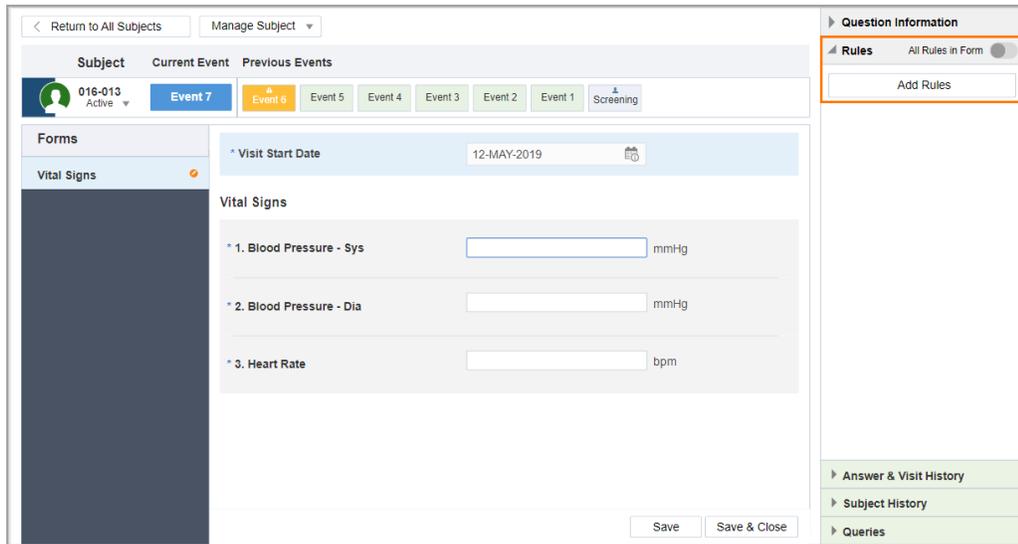
Role	Available tasks include
Rule Designer	<ul style="list-style-type: none"> • Create a rule • Edit a rule with a status of Draft • Update a rule's status from Draft to UAT • Update a rule's status from UAT to Draft • Enable or disable a rule with a status of Draft, UAT or Approved while the rule is running in Testing mode • View a rule with a status of Draft, UAT, Approved or Published • Edit a rule with a status of Published in Testing mode • Edit a rule that's published in a live study • Delete a rule with a status of Draft, UAT or Approved
Rule Tester	<ul style="list-style-type: none"> • View a rule with a status of Draft, UAT, Approved or Published • Update a rule's status from UAT to Approved • Update a rule's status from Approved to UAT • Update a rule's status from Published to Draft • Enable or disable rules with a status of Draft, UAT, Approved or Published
Rule Publisher	<ul style="list-style-type: none"> • View a rule with a status of Draft, UAT, Approved or Published • Enable or disable a rule with a status of Published while they're running in a live study • Update a rule's status from Approved to Published • Update a rule's status from Published to Draft • Move the study from the Testing to the Production container to publish multiple rules in Production

Details for study designers

New pane for adding rules in Testing mode

When you view a visit, on the right, there's a new Rules pane that you can expand. On this pane, you can add rules, show all rules in a form, or change a rule's status.

Figure 19-51 How rule designers see the Rules pane on a visit



Rule editor where you can define rules

This is your very own rule editor where you can create a rule from scratch, from its variables to its expressions. Additionally, you can also set a rule's action, whether it should calculate a value or create an automated query.

Update a rule's status

Depending on your role, you can update a rule's status to:

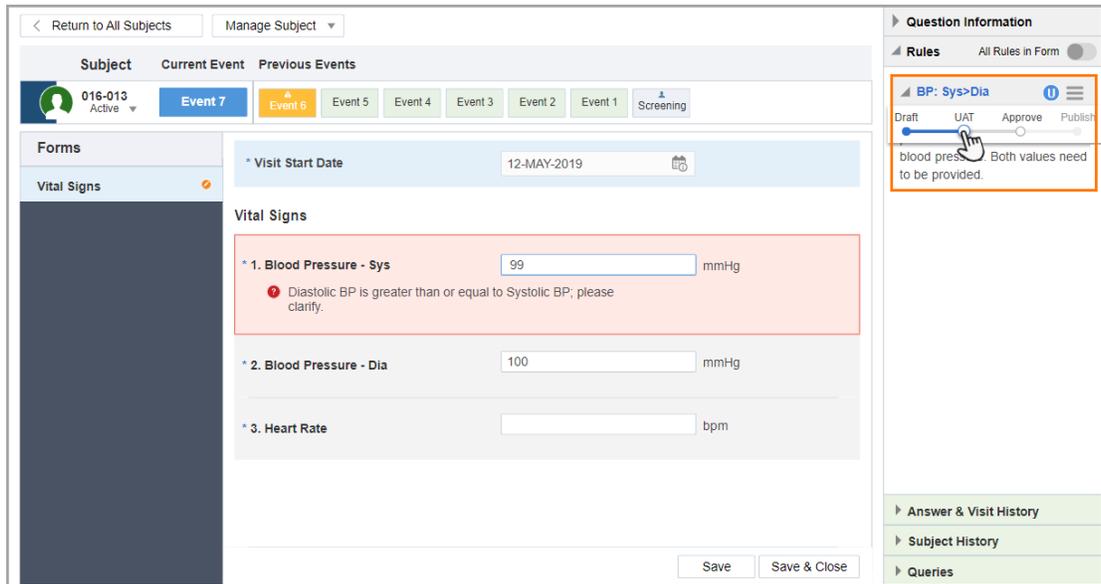
- **Draft:** this is the initial status a rule has right after it's created. Additionally, a published rule in Production also gets a status of **Draft** when it is updated in Testing.
- **UAT:** if the rule is ready to be tested
- **Approved:** if a rule passed testing and is ready to be published
- **Published:** if a rule is published in Production

Here's a diagram of a rule's lifecycle, so you can better understand your workflow, whether you're a Rule Designer, Rule Tester or Rule Publisher.

Figure 19-52 A rule's lifecycle in the system



Figure 19-53 How a rule's status is updated



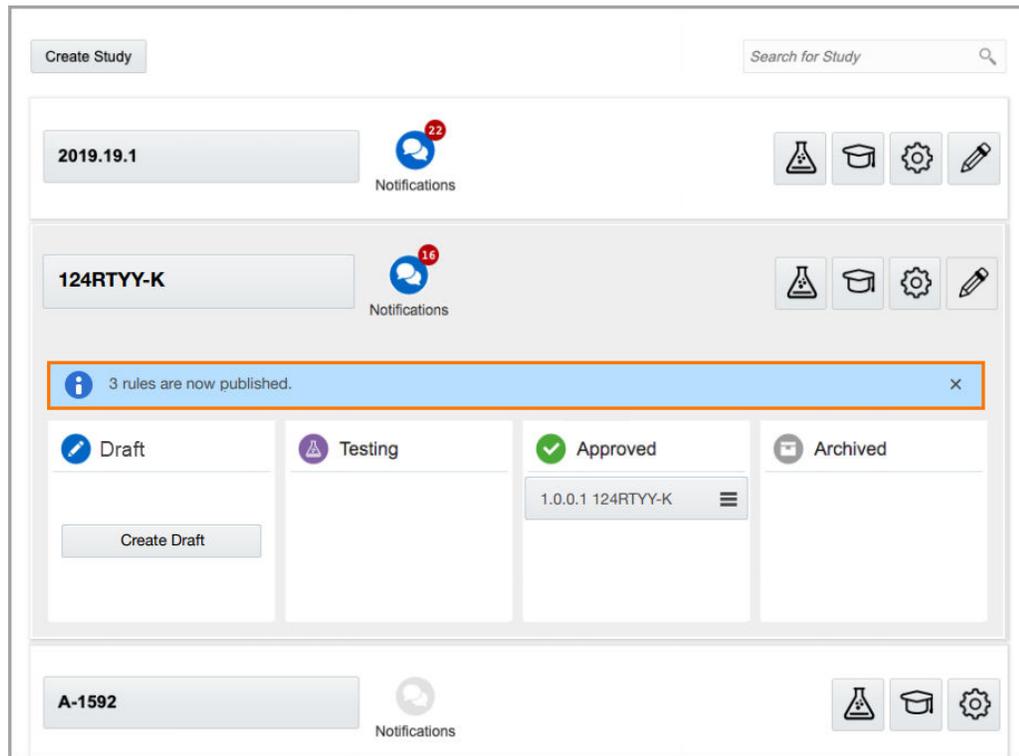
Publish, modify, and re-publish a rule

You can:

- Publish a single rule on a form by updating its status to Published.
- Publish multiple rules in a form by clicking **View all Rules in the Form** and **Publish All Approved Rules**.
- Publish one or multiple rules in Production by moving a study from the Testing to the Approved container.

You can also re-publish one or multiple rules in Production.

Figure 19-54 Message received when multiple rules are published in Production



Already working in a live study?

As soon as you're provisioned as a rule designer, rule tester or rule publisher, you can start creating, testing, and publishing rules after the system upgrade is complete. Rules will be running as soon as the study is moved from Testing to Approved.

Set a subject's blinded dose level for kits

Study designers can now specify the dose level for blinded kit type titrations, so site users know whether a subject is on a low, medium or high dose during the study, for example.

Details for study designers

To add labels for a subject's dose level, go to the first column in the Create Kit Type Titration pop-up. Use general terms to describe a subject's dose level without offering unblinding information, so site users know a subject's dose and perform the right dose changes during visits.

Details for site users

Every time you want to perform a dose change for a subject, a label appears on the Dispense Kits wizard. For example, this label can indicate whether the subject is on a low, medium or high dose of the investigational product without unblinding the kits.

After you decide whether to maintain, decrease or increase a subject's dose, the dose label changes in the Dispense Kits wizard.

Reporting changes

Data about blinded dose levels can be seen in the Titration Summary report, Subject Dispensation report, and the Study Design report.

Already working in a live study?

As a study designer, you can start adding dose level titles for blinded kits in a kit type titration as soon as the system upgrade is complete. As a site user, you will see these changes as soon as the updated study is approved and live.

Use barcodes for creating kit lists and confirming dispensation

Clinical supply managers can set a study to use barcodes and let site users confirm dispensation.

What are the benefits?

First of all, including barcodes in your kit lists helps you improve the quality of data related to supplies and dispensation. Additionally, enabling confirmation of kit dispensation ensures subjects' safety with the validation of kits during the dispensation process.

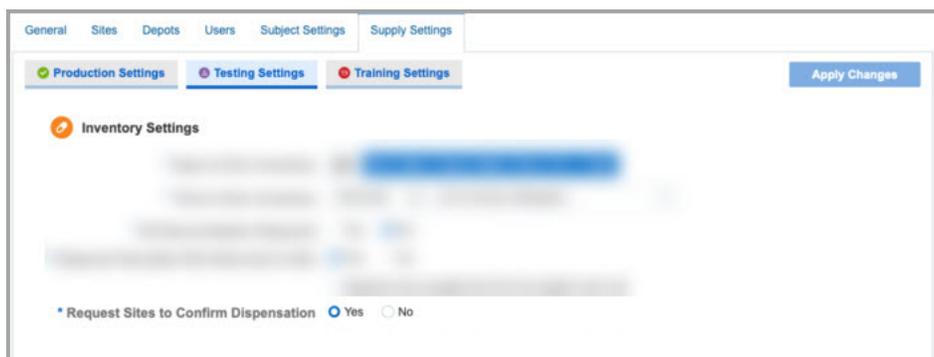
Details for clinical supply managers

If your study protocol allows barcodes to be included in kit lists, then you may be able to either upload or create kit lists that contain 1D or 2D barcodes (such as QR codes). Moreover, you can now configure your study in order for site users to confirm the dispensation of kits to subjects.

Enable site users to confirm dispensation of kits to subjects

There's a new setting on the Supply Settings tab that lets you enable site users to confirm the dispensation of kits to subjects. By default, this setting is set to **No**.

Figure 19-55 New setting for clinical supply managers



Barcodes can be included in uploaded or generated kit lists in the system

- When you upload a kit list that contains barcodes, you can map headers for both 1D barcodes and 2D barcodes (such as QR codes). A 1D bar code is a regular string of numbers that can be created based on kit numbers . A 2D barcode can be a QR code and it typically appears as a much longer string of numbers in the system.

- When you generate a kit list in the system, you can choose to generate 1D barcodes, as well. Additionally, you can choose whether bar codes can use kit numbers or the system should generate new numbers for barcodes.

Figure 19-56 How a clinical supply manager uploads or generates a kit list with bar codes

You now get a better view of kits for both the entire study and at a site level

On the Supplies tab, you can now access two separate inventories for a study and a site.

The **Site Inventory** tab is where you're able to see kits at a site from a blinded site user's perspective, regardless of whether kit reconciliation is required or not in the study. This gives you a more granular view of a site's inventory. On this tab you can:

- Search kits by their number.
- See which kits are verified or not by the CRA in the new CRA verified column. For each kit, you can also click the check mark in this column, if the kit is verified by the CRA
- See which of the kits' dispensation is confirmed in the new Dispensation Confirmed column.
- Update a blinded kit's status

Figure 19-57 Site Inventory tab

Kit Number	Kit Description	Dispensation Confirmed	CRA Verified	Status	Last Modified	Units per Kit	Returned Units	Missing Units
1276	ORS-123 5 mg			Temporarily Unavailable	13-Aug-2019	16		
1562	ORS-123 5 mg			Available	12-Aug-2019	16		
1705	Blinded			Available	12-Aug-2019	16		
1753	Blinded			Available	12-Aug-2019	16		
2098	ORS-123 5 mg			Not in Use	26-Aug-2019	16		
2231	Blinded			Available	12-Aug-2019	16		
2647	Blinded			Available	12-Aug-2019	16		
2682	Blinded			Available	12-Aug-2019	16		
2850	Blinded			Available	12-Aug-2019	16		
2952	Blinded			Available	12-Aug-2019	16		
3119	Blinded			Available	12-Aug-2019	16		

On the **Study Inventory** tab you can:

- See the generated kit lists
- View or edit a kit's barcode, on the new Barcode pane
- Make updates to both blinded and unblinded kits in a study

Details for site users

If dispensation confirmation is enabled in your study, you can either confirm the dispensation of multiple kits at once or confirm the dispensation of one single kit at a time:

- **On the Dispense Kits wizard:** You can confirm the dispensation of multiple kits right after you've dispensed them to a subject in the system.

Figure 19-58 How site users confirm dispensation on the Dispense Kits wizard

Dispense Kits

Dispense the following kits to subject **site1-16** and confirm you've dispensed them.
You can either scan or manually type a kit's barcode, then click **Confirm**. [Learn more about Barcodes](#)

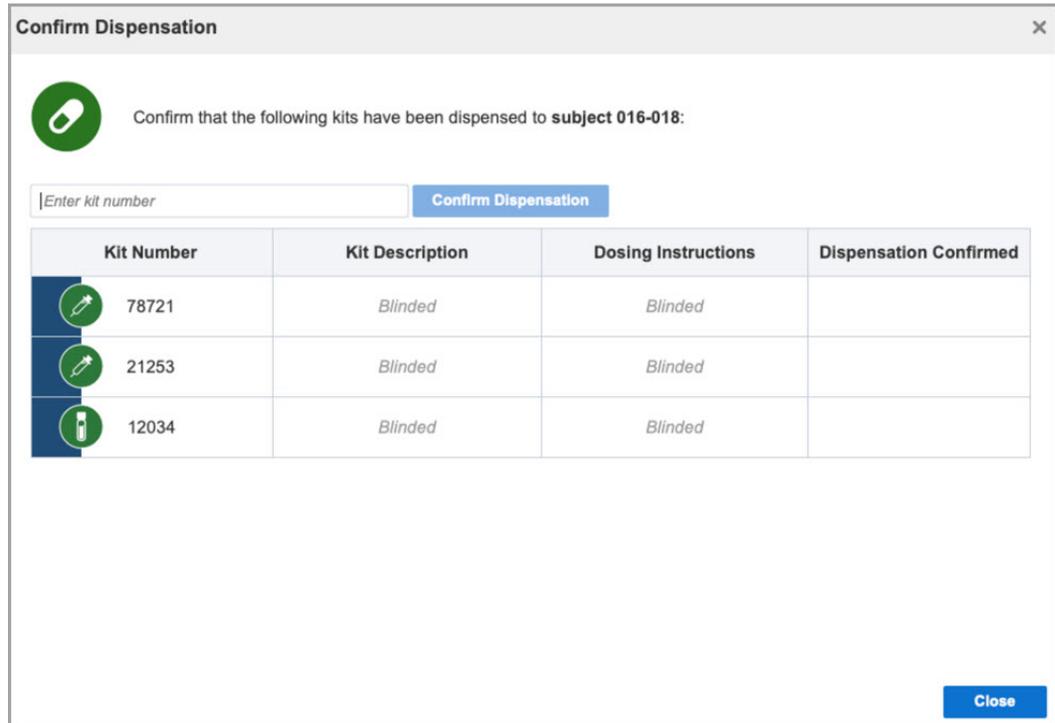
Confirm Dispensation

Kit Number	Kit Description	Dosing Instructions	Dispensation Confirmed
1213	<i>Blinded</i>	N/A	
Total Kits: 1			

Tip: To see the kit numbers again, open **Subject History** on the right.

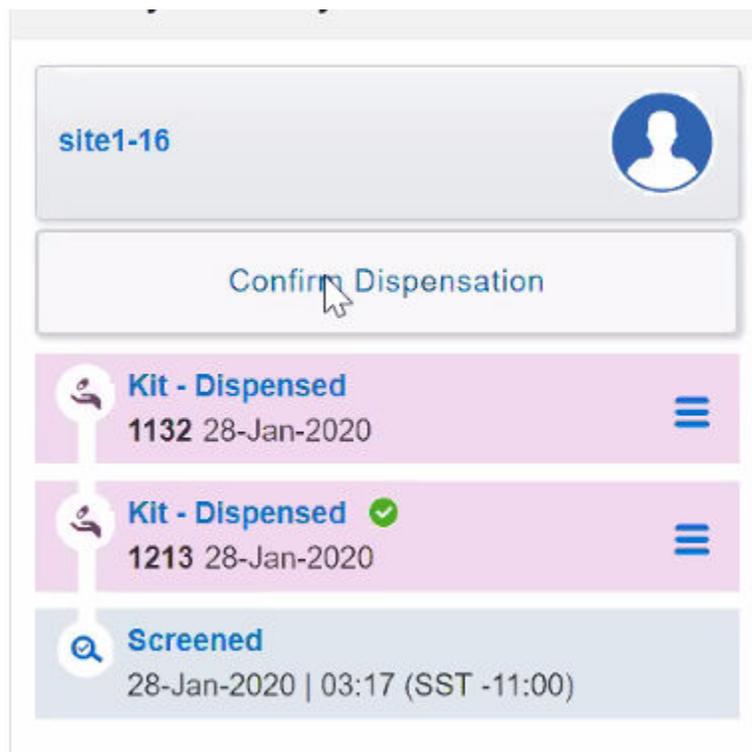
- **On the Confirm Dispensation window:** You can confirm the dispensation of kits later, too. You can select a subject and either confirm the dispensation of all kits at once or confirm the dispensation of kits individually. In both cases, the Confirm Dispensation pop-up appears where you can confirm the dispensation of your kits by either scanning their bar codes or manually typing them.

Figure 19-59 How site users confirm dispensation on the Confirm Dispensation pop-up



Additionally, you can now replace, reconcile or confirm a subject's kit from the same place, with the new menu icon displayed on the right next to each kit. A green check mark appears next to each dispensed and confirmed kit, in the Subject History.

Figure 19-60 How site users see kits that need to be confirmed on the Subject History



Reporting changes

Data on the new setting for dispensation confirmation can be found in the Study Design report.

Already working in a live study?

As a clinical supply manager, you can enable kit dispensation confirmation and include barcodes in your study as soon as the system upgrade is complete. As a site user, you can start confirming the dispensation of kits as soon as the updated study is approved and live.

Create resupply strategies with "0" values

Clinical supply managers can now use values of "0" to set their resupply strategies.

What are the benefits?

Being able to set 0 values for certain kit types or weeks in a resupply strategy is particularly beneficial for:

- **Single ascending dose studies** where not all kit types are shipped at site initiation.
- **Ancillary supply orders** where you may need to supply non-drug packages, equipment or study-related documents from another location other than the depots configured in your study.

Details for clinical supply managers

Here's what can change in your workflow, if you decide to use "0" values:

- When it comes to **Min/Max Resupply Groups**, you can now use "0" values in the **Kits in First Shipment** and **Kits in Manual Shipment** columns, for each kit type.
- When it comes to **Predictive Resupply Groups**, you can now use "0" values in the **Trigger Weeks**, **Resupply Weeks**, **First Shipment** and **Manual Shipment** columns, for each kit type.

Details for site users and depot users

There are no changes in your workflow.

Already working in a live study?

As a clinical supply manager, you can update your resupply strategy using values of "0" as soon as the system upgrade is complete. The changes will be effective when the updated study is approved and live.

Use data flags to label unanswered questions

You can now use data flags to mark questions that have a missing answer and complete your forms and visits without disruption or delays.

What are the benefits?

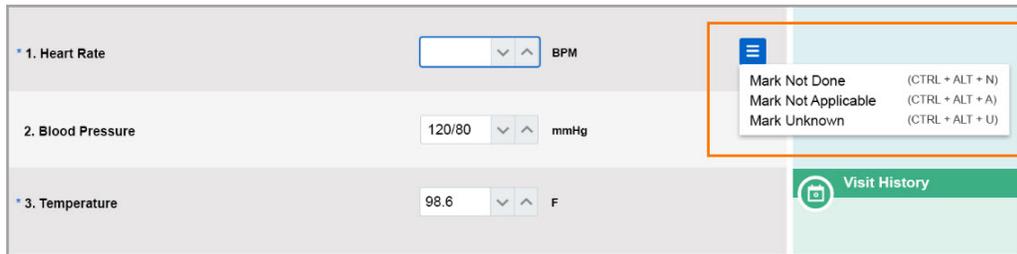
Data flags are labels in the user interface that let site users mark questions with a certain status, so they can leave these questions unanswered. Data flags are particularly useful for site users who can't provide an answer to certain questions. To avoid delays in the process of data collection or to not disrupt their work, data flags can be used to label questions and complete visits. For example, if a subject can't be weighed during a regular visit, the weight question remains unanswered. This leaves the site user unable to properly monitor the subject and complete their visit. Labeling that question about weight allows site users to move forward with their work, all the while having better control over their data.

Details for site users

If you ever need to use data flags, all you have to do is hover over a question in a form and a menu icon appears. If you click that menu icon, a drop-down appears with three options for data flags:

- **Mark Not Done:** Use this flag if the answer to a question can't be provided. For example, a subject can't be weighed during a visit, so a required question about their weight can be marked as Not Done to proceed with form completion.
- **Mark Not Applicable:** Use this flag if the answer to a question isn't applicable at the moment. For example, a subject doesn't need its heart rate measured during this visit, so the answer to a BPM question isn't applicable during this visit.
- **Mark Unknown:** Use this flag if the answer to a question is unknown. For example, a subject doesn't know their blood type and there's no way to determine that on the spot.

Figure 19-61 How site users apply a data flag to a question



Other things that you need to know about data flags for now include:

- You can't add data flags to required questions during a screening, randomization or dispensation visit.
- Data flags can always be updated, but you always have to provide a reason for this change for audit trail purposes.
- Information about data flags is included in the Subject Data and Subject Events report.

Already working in a live study?

As a site user, you can start flagging questions as soon as the system upgrade is complete.

New reports and enhancements

From now on, the Subject Visit Schedule report and Titration Summary report keep you informed about your subject's visits schedules and titrations. With all this new data available, you can easily schedule and predict future visits, forecast supply needs, and better understand dosing for subjects. Additionally, five existing reports are now available in a PDF format.

Subject Visit Schedule report

This report helps you get an overview of your subjects' visit schedule so you can predict future visits and better organize their next appointments. Additionally, this report allows the clinical supply team to easily forecast supply needs.

Who can run this report?

Typically, study team members who are assigned the role of a Clinical Research Associate (CRA), clinical supply manager or study manager can run this report.

What data does this report show?

The Subject Visit Schedule report is available in all 3 modes, for both blinded and unblinded studies. The report contains details about each subject's visit, including:

- Completed and projected visits
- Subject ID and a subject's status
- Kit information (displayed depending on the type of study - blinded or unblinded)
- Kit description (displayed depending on the type of study - blinded or unblinded)
- Quantity (displayed depending on the type of study - blinded or unblinded)

- Country and Site ID

Titration Summary report

With this report, you view at a glance all visits for each subject, along with titration details.

Who can run this report?

Typically, a site user or study team member with the role of a Clinical Research Associate (CRA), clinical supply manager or study manager can run this report.

What data does it contain?

The Titration Summary report is available in all 3 modes, for blinded and unblinded studies. The report contains details about each subject's treatment including:

- Visit name
- Type of titration
- Dose level
- Kit number
- Duration from the last dose change
- Dispensation date and many more

Enhanced reports for better data access

You can now save the following reports in a PDF format:

- **Subject Data** report
- **Subject Events** report
- **Randomization List** report
- **Kit Chain of Custody** report
- **User Assignment** report

Already working in a live study?

As a site or sponsor user, you can run these new reports as soon as the system upgrade is complete.

New subject and shipment notifications

Subject and shipment monitoring play a crucial role in the outcome of any clinical study. With the right roles and permissions, users in a study can now receive notifications every time a randomization or dispensation visit is complete or not, as well as when a shipment is cancelled.

What are the benefits?

The Subject randomization and **Subject dispensation** notifications inform you whether a dispensation or randomization visit was successfully completed or failed to complete. Additionally, you receive data such as the subject ID, as well as the site where the visit took place, the date, and visit name. Depending on the roles you are assigned in the study, you can also receive details about the treatment arms, kit descriptions and dosing instructions. This way you can effectively react to any change concerning your subjects.

The Shipment cancellation notification keeps you updated on the shipment status and alerts you every time a shipment is cancelled. This notification includes details such as the shipment number, the date the shipment was cancelled, as well as the study name and the site name.

Details for user administrators

Your workflow hasn't changed, but there are some new rights that you need to be aware of. Users must have these rights associated with their assigned roles in order to receive these notifications.

If a user who should receive these notifications already has the role that includes these rights, there's no need to make any changes. The user will be able to receive these notifications immediately after the system update.

Type of notification	Created when...	Roles & permissions	Details
Subject randomization (unblinded)	An unblinded randomization visit is completed at a site you are assigned to.	Following roles should include the Receive the Unblinded Randomization notification permission: <ul style="list-style-type: none"> Clinical supply manager Randomization list manager 	Includes treatment details.
Subject randomization (blinded)	A blinded randomization visit is completed at a site you are assigned to.	Following roles should include the Receive Randomization notification permission: <ul style="list-style-type: none"> Subject notifications 	Doesn't include treatment details. However, if current randomization is unblinded, users with this right also receive details about treatment arms.
Randomization failure	Randomization of a subject failed to complete at a site you are assigned to.	Following roles should include the Receive the Randomization Failure notification permission: <ul style="list-style-type: none"> Randomization list manager 	N/A
Subject dispensation (unblinded)	An unblinded dispensation visit is completed at a site you are assigned to.	Following roles should include the Receive the Unblinded Dispensation notification permission: <ul style="list-style-type: none"> Clinical supply manager 	Includes a kit description for each kit number.
Subject dispensation (blinded)	A blinded dispensation visit is completed at a site you are assigned to.	Following roles should include the Receive Dispensation notification permission: <ul style="list-style-type: none"> Subject notifications 	Includes the kit description only if the dispensed kits are of unblinded distribution type. If they're not, kit description isn't disclosed in this notification.
Subject dispensation with dosing instructions	A dispensation visit with kits including calculated doses is completed at a site you are assigned to.	Following roles should include the Receive the Dispensation with dosing instructions notification permission: <ul style="list-style-type: none"> Site user with detailed dosing view 	N/A

Type of notification	Created when...	Roles & permissions	Details
Dispensation failure	A dispensation visit failed to complete at a site you are assigned to.	Following roles should include the Receive the Dispensation Failure notification permission: <ul style="list-style-type: none"> • Site user with detailed dosing view • Subject notifications • Clinical supply manager 	N/A
Shipment cancellation	A shipment is cancelled.	Following roles should receive this notification: <ul style="list-style-type: none"> • Clinical supply manager • Unblinded Depot User • Shipment notification 	Includes the shipment number, the date the shipment was cancelled, and the site name.

Details for sponsor and site users

Once you have the appropriate roles and permissions, you receive these notifications over email and see them when you click the notifications button, on the Home page, next to your study ID.

Already working in a live study? As a site or sponsor user, you can get provisioned with the correct roles and permissions to receive these notifications as soon as the system upgrade is complete.

Need help accessing the notifications? See View notifications.

Stability improvements

- [Form and visit stability improvements](#)
- [Randomization and kit stability improvements](#)
- [Stability improvements affecting all users](#)
- [Stability improvements for integrations](#)

Form and visit stability improvements

Deleted forms no longer appear in live studies

Study designers: Deleted forms while the study is in Draft mode no longer appear when the study is placed in the Approved container. Previously, forms that you removed in Draft mode appeared in the live study.

Retracted workaround: None. (Issue [30660525](#))

Date/time question and Age field are numbered correctly

Study designers: When you now design an age type of question, the date/time age fields are numbered correctly in a form. Previously, these two fields skipped a number in their order.

Retracted workaround: None. (Issue [30770217](#))

Action buttons now work for forms with dynamic questions and repeating forms

Site users: From now on, whenever a repeating form containing a dynamic question is associated with a visit, the action button for that visit works. Previously, when you answered a dynamic question in a repeating form, the data wasn't properly saved and you couldn't either screen, randomize or dispense kits to a subject. (Issue **30976490**)

Randomization and kit stability improvements

Additional shipments no longer created when site has Pre-Quarantined kits

Clinical supply managers: When kits are marked as **Pre-Quarantined** at a site (such as if kits need to be evaluated after a temperature excursion), unnecessary shipments are no longer created. Instead, **Pre-Quarantined** kits are now counted as part of a site's inventory when the resupply process runs.

Retracted workaround: Previously, we advised clinical supply managers to temporarily remove the resupply strategy associated with a site until they evaluated **Pre-Quarantined** kits. And select it again once they're done evaluating kits. That workaround is no longer required. (Issue **30732926**)

Proper error message appears when moving study without stratum groups to the Testing container

Study designers: When you attempt to move a study from the Draft to the Testing container, you now see the right error message indicating that your randomization design doesn't contain stratum groups.

Retracted workaround: Previously, we advised study designers to run the Study Design report and check the data related to randomization design to make sure it contains stratum groups. That step is no longer mandatory since the error message will indicate the cause of the error. (Issue **30659798**)

Resupply strategies now work as expected

Clinical supply managers: Resupply strategies now work as expected for sites who reach the minimum buffer of kits, so they can be supplied with the right amount of kit types. Previously, resupply strategies didn't work as expected potentially leaving sites without the required number of kit types to be dispensed to subjects.

This stability improvement impacts both min/max resupply groups and predictive resupply groups. (Issue **30756880**)

Stability improvements affecting all users

Cache issues no longer affect product behavior

From now on, you no longer have to clear your web browser's cache to avoid any errors in the system. Previously, after an upgrade, some elements such as buttons or fields in the user interface didn't work properly due to cache issues.

While this issue is less likely to happen in the future, keep in mind that your web browser will cache some elements in the system so it doesn't affect performance. Should you run into any issues, reach out to Health Sciences Support. (Issue **30689467**)

You can no longer fast forward through mandatory video training

If there is any product training assigned to you in the system, you can no longer fast forward through the video. Previously, you could do that, even though product training is mandatory and important for you in order to perform required tasks in the system. (Issue **30631478**)

Stability improvements for integrations

Oracle Clinical One Platform to Catalent Clinical Supply Services: Shipment Receipt and Shipment Dispatch files validation

Integration managers: An error message now appears if names of the Shipment Receipt and Shipment Dispatch files don't match the content in these files. This alerts you to any inconsistencies within the files so you can reach out to Catalent Clinical Supply Services to have them resolved. Oracle Clinical One Integration Hub will not process the files unless values are consistent. The error message contains information about the issue and a solution for it: "Error: One or more files could not be processed due to file name and contents mismatch. If the job detected any other files which were accurate, those will be retained internally but not processed until such time the corrupted file(s) are corrected. Remediation: Correct the corrupted file(s). Oracle Clinical One Integration Hub will then ensure that all files are correctly processed, including any retained files no longer visible on sFTP."

Previously, the job didn't validate that the values present in the file name and file contents matched, since it's not expected that Catalent Clinical Supply Services would ever send corrupted files. Oracle Clinical One Integration Hub now explicitly validates and fails the job if the <Protocol>, <PerformCode>, <RequestorCode> or <ShipmentID> used in a file name don't match the same tags used within a file. (Issue **30781401**)

Oracle Clinical One Platform to Oracle Siebel CTMS: Reports failing due to missing data

When you now remove data from a form, jobs in Oracle Clinical One Integration Hub are no longer failing. The Subject Data for CTMS report is also successfully generated without showing the data you removed. Previously, whenever you removed data from a form, jobs were failing and the report couldn't be generated. (Issue **30893883**)

Retracted Known Issues

- [Forms can't be created in Internet Explorer 11](#)
- [Randomization design remains deleted after you click Cancel](#)
- [Search by Country filter available even when no sites exist for a country](#)

Forms can't be created in Internet Explorer 11

Study designers: Previously, we reported the Known Issue that you couldn't click the **Add Form** button to create forms using Microsoft Internet Explorer 11 browser.

However, the issue couldn't be fully reproduced and the button now works in all compatible browser versions for Oracle Clinical one Platform.

Retracted workaround

Previously, we recommended that study designers use Google Chrome to access the system and create forms. While the Known Issue associated with this workaround is no longer

available, we still recommend you use Google Chrome for the best user experience and performance. (Issue **30527381**)

Randomization design remains deleted after you click Cancel

Study designers: Previously, we reported the Known Issue that a randomization design was permanently removed from a visit despite study designers clicking **Cancel** in the process.

However, the issue couldn't be fully reproduced and the feature now works as expected. When study designers remove a randomization visit from a visit and click **Cancel**, the randomization design isn't removed from the visit.

Retracted workaround for study designers: None. (Issue **30578927**)

Search by Country filter available even when no sites exist for a country

Site managers: Previously, we reported the Known Issue that you could filter your search for sites by country, even when no sites existed for that country.

However, this behavior is as designed, so this issue is no longer a Known Issue. The option for filtering sites by country appears even though no sites in a study are associated with a country.

Retracted workaround for site managers: None. (Issue **30732366**)

Oracle Clinical One Platform 20.0.2 (February 2020)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Prevent site users from manually adding subjects](#)
As a study manager, you can now choose to enable or prevent site users from manually adding subjects in a rollover study.

Prevent site users from manually adding subjects

As a study manager, you can now choose to enable or prevent site users from manually adding subjects in a rollover study.

What are the benefits?

Subjects in a rollover study are typically enrolled from a previous study, where they have already been screened. Preventing site users from manually adding subjects to this type of study helps you avoid protocol errors or incorrect data in subject reports.

How do I perform this task?

This setting is available on the Subjects Settings tab in both Testing and Production mode. For details, see Specify subject, visit, limit, and cohort settings [Testing mode].

Already working in a live study?

By default, this setting is set to **Yes** which allows site users to add subjects manually. To prevent site users from manually adding subjects, you must change the setting to **No**.

Figure 19-62 New setting for manually adding site users

The screenshot shows the 'Subject Settings' tab in the Oracle Clinical One Platform. The 'Allow Subjects to be Manually Added' setting is currently set to 'Yes'. A tooltip is displayed over the 'No' radio button, stating: 'Click Yes to let site users manually add subjects to this study. Click No if site users shouldn't manually add any subjects to this study.' Other settings include 'Include Hyphen in Subject Numbers' (Yes), 'Leading Zeros in Subject Number' (2), 'First Subject Number' (empty), and 'Subject Numbering' (Sequential at Sites). The 'Apply Changes' button is visible in the top right corner.

Stability improvements

Notifications are now sent to the assigned site users

Site users and site managers: You will now receive notifications only for the sites that you're assigned to. Previously, you may have received notifications for sites you weren't assigned to, due to an issue with site assignments for those notifications.

This fix is related to the following notifications:

- New shipment
- Cancel shipment
- Insufficient kits
- Code break
- Cohort limits reached

(Issues **30805166** and **30205839**)

Visit status is correctly updated when you complete a visit in a different study version

Site users: When you start a visit in one study version and complete that visit in another study version, the visit is completed and its status is properly updated. Previously, when you started a visit in one study version and completed it in another, the visit appeared as incomplete. And site users couldn't start the next visit for a subject. (Issue **30805680**)

Longer URLs now allowed for shipments

Clinical supply managers and depot users: On the Supplies tab, you can now enter longer URLs in the **Tracking Link** field when you edit or add a tracking number for a shipment.

Previously, you could only enter short URLs (such as https://www.site.com) in the **Tracking Link** field. (Issue **30867797**)

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 20.0.1 (January 2020)

- [What's new](#)

What's new

- [Automate and distribute shipments using Catalent Clinical Supply Services](#)
Oracle Clinical One Platform now integrates with Catalent Clinical Supply Services.
- [Enhanced Subject Data for CTMS report](#)
When a visit ID contains both numbers and letters, data about the visit now appears in the Subject Data for CTMS report.

Automate and distribute shipments using Catalent Clinical Supply Services

Oracle Clinical One Platform now integrates with Catalent Clinical Supply Services.

What are the benefits?

This new integration lets you effectively manage shipments and forecast your clinical supplies inventory. This way, you make sure you have the right amount of supplies available at a site at all times.

Sponsors: How can I connect my Oracle Clinical One Platform study with Catalent Clinical Supply Services?

Reach out to your Oracle Project Manager if you're interested in setting up this shipment workflow. The Oracle Services team will define the integration between your Oracle Clinical One Platform study and Catalent Clinical Supply Services.

Clinical supply managers and depot users: What is the workflow for this integration?

You will see these changes in Oracle Clinical One Platform only after the Oracle Services team sets up a study so that it's connected with the Catalent Clinical Supply Services.

More details about prerequisites and the workflow of this integration will be coming soon in the Oracle Clinical One Integration Hub User Guide.

Activity in the study	Activity that can be automated in Oracle Clinical One Platform
A shipment request is made.	The status of the shipment changes to Pending either manually or automatically, based on how the resupply strategy is set in the study.
The depot acknowledges the shipment request.	The status of the shipment changes to Confirmed .
The depot fulfills a shipment.	The ship date and tracking number are set. The status of the shipment changes to In Transit .

Activity in the study	Activity that can be automated in Oracle Clinical One Platform
The site receives the shipment.	<ul style="list-style-type: none"> • If the integration is configured to support this, the courier provides the information and Catalent Clinical Supply Services receives delivery information from the courier: The shipment's status changes to Received. The status of all the kits in the shipment automatically changes to Available. • If the integration isn't configured to interpret the delivery as a receipt: No updates take place in Oracle Clinical One Platform. A site user must mark the shipment as Received in Oracle Clinical One Platform.

 **Note:**

If you need to update (add or remove kits from a shipment) or cancel a shipment after the shipment request has been sent to the depot, you must contact Catalent Clinical Supply Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot. When the shipment is marked as **Received**, this status update applies to the entire shipment, and not to individual kits. Therefore, all the kits in the shipment, including kits added after the original request, are updated once the shipment is received.

If a shipment request is sent in error, the clinical supply manager must contact Catalent Clinical Supply Services and request the shipment's cancellation. Once Catalent Clinical Supply Services cancels the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform. To allow the resupply process create a new shipment the next time inventory runs, the clinical supply manager must also explicitly cancel the shipment in Oracle Clinical One Platform.

Enhanced Subject Data for CTMS report

When a visit ID contains both numbers and letters, data about the visit now appears in the Subject Data for CTMS report.

Details for study designers

Visits that should appear in the Subject Data for CTMS report can now have visit IDs that contain both numbers and letters, so you can keep that in mind when designing visits in your study.

Details for data managers or production admins

Nothing is changing in your workflow. All you need to know is that visit IDs containing both numbers and letters will show up in the Subject Data for CTMS report whenever you run the report in your study.

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Releases in 2019

Browse the content of all Oracle Clinical One Platform and Oracle Clinical One Digital Gateway releases in 2019.

- [Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 19.6 \(December 2019\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.5 \(October 2019\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.4](#)
- [Oracle Clinical One Platform & Oracle Clinical One Integration Hub 19.3 \(September 2019\)](#)
- [Oracle Clinical One Platform 19.2.0.3 \(August 2019\)](#)
- [Oracle Clinical One Platform 19.2.0.2 \(August 2019\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.2.0.1 \(July 2019\)](#)
- [Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.2 \(June 2019\)](#)
- [Oracle Clinical One Platform 19.1.0.2 \(May 2019\)](#)
- [Oracle Clinical One Digital Gateway 1.3 \(May 2019\)](#)
- [Oracle Clinical One Platform 19.1.0.1 \(April 2019\)](#)
- [Oracle Clinical One Platform 19.1 \(March 2019\)](#)
- [Oracle Clinical One Digital Gateway 1.2.1 \(March 2019\)](#)
- [Oracle Clinical One Digital Gateway 1.2 \(February 2019\)](#)
- [Oracle Clinical One Platform 1.3 \(January 2019\)](#)

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway 19.6 (December 2019)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Automatic recovery and no more downtime for integrations](#)
Good news for Oracle Clinical One Integration Hub users! Starting with this release, product updates are deployed without any downtime for your integrations. From now on, your use of the product will be uninterrupted during upgrades.

- [Collect data in a better and more efficient way](#)
We've enhanced the data collection process in a study with new options for study designers to create forms and questions, and site users to collect better data.
- [Conserve and dispense reusable kits](#)
Want to reduce waste? If they're not expired or damaged, some of the kits returned to the site by a subject can be conserved, and re-dispensed to the same subject.
- [Create your own rules and take control over your study data](#)
Study designers can now create, test, and execute rules to ensure a seamless data collection process. Rules also provide site users better support for collecting accurate data.
- [Secure the quality of your study data with auto-queries](#)
It's time to say goodbye to data errors! Starting now, you can use auto-queries to foolproof data against mistakes.
- [Easily maintain doses for subjects](#)
If you manage a study that allows subjects to titrate, you now have even more options for titration.
- [Run better reports](#)
The Kit Dispensation, Study Enrollment, and Subject Queries reports now include additional details that allow you to better manage your study processes.
- [Transform your data with coding questions](#)
Study designers can now design coding questions for adverse events, concomitant medications, and subjects' medical history. And site users can now collect data about them by answering these coding questions in forms.

Automatic recovery and no more downtime for integrations

Good news for Oracle Clinical One Integration Hub users! Starting with this release, product updates are deployed without any downtime for your integrations. From now on, your use of the product will be uninterrupted during upgrades.

Moreover, Oracle Clinical One Integration Hub will also recover when integration target systems (such as sFTP) become available again after planned or emergency maintenance downtime, and automatically resubmit failed jobs.

Collect data in a better and more efficient way

We've enhanced the data collection process in a study with new options for study designers to create forms and questions, and site users to collect better data.

As a study designer, you'll be able to use these enhancements after the system update. As a site user, you will start seeing these changes as soon as they're configured in the study you're working in. Other than that, existing studies won't be affected in any way by these new capabilities.

Read more about these new features...

- [Read-only items](#)
Study designers can now create forms that include read-only items. These items show up as fields that are automatically populated without site users editing them.

- **Repeating forms**
Study designers can now create repeating forms that allow site users to collect multiple instances of the same data.

Read-only items

Study designers can now create forms that include read-only items. These items show up as fields that are automatically populated without site users editing them.

What are the benefits?

Read-only items optimize the data collection process because they work like a security mechanism protecting sensitive data against any errors and inaccuracies. For instance, lab data or information gathered from an integrated third-party app is automatically entered in a read-only field. Also, values such as age can be calculated automatically using a subject's date of birth entered by the site user.

Details for study designers

You can now mark a form item as read-only if the value for that item can be automatically generated by the system.

What do I need to do?

When you add a question in a form, click the new **Read Only** toggle button on the right, on the **Details** pane.



Note:

You can only mark a form item as read-only while the study is in the Draft container.

What form items can I mark as read-only?

You can mark any item as read-only. Just make sure the value for that item is automatically generated by the system, since site users can't manually enter data in a read-only field.

Figure 20-1 A read-only item and a read-only toggle button for study designers

The screenshot displays a user interface for configuring a form. On the left, a list of items is shown under the heading "Demographics". Item 4, "BMI", is highlighted with a red box and labeled "(Read Only)". The BMI value is displayed as "1" in a grayed-out field. To the right, a "Details" panel is visible, also with a red box around the "Read Only" toggle switch, which is currently turned on. Other settings in the details panel include "Reference Code" (DEMOG_CAL_NUM), "Question Hint" (Enter hint), "Required" (off), "Include Unit of Measure" (off), and "Format" (1). At the bottom of the form, there are buttons for "Add Question", "Cancel", and "Save".

Details for site users

Values in read-only fields are populated based on other information you add to the form. For example, Body Mass Index (BMI) can be calculated based on a subject's height and weight.

How do I recognize a read-only item?

In a form, read-only values are grayed out and can't be edited.

What do I need to do?

Read-only fields are updated automatically. You must enter data for any other fields used to calculate the read-only item.

Figure 20-2 A read-only item in a form for site users

The screenshot displays a clinical trial form interface. At the top, there are three tabs: 'Subject', 'Current Visit', and 'Previous Visits'. The 'Subject' tab shows a profile icon and the ID '016-014'. The 'Current Visit' tab is active, showing a 'Check 9' button. The 'Previous Visits' tab shows buttons for 'Check 8' through 'Check 1' and a 'Screening' button. Below the tabs is a 'Forms & Data' sidebar with a list of items: 'Date of Dosing' (checked), 'Adverse Event' (checked), and 'Demography' (checked). The main content area is titled 'Demographics' and contains four items: '1. Demographics collected' (Yes), '2. Height' (63 cm), '3. Weight' (61 kg), and '4. BMI' (33). The '4. BMI' item is highlighted with an orange border, indicating it is read-only. At the bottom right, there are three buttons: 'Save', 'Save & Close', and 'Dispense'.

Repeating forms

Study designers can now create repeating forms that allow site users to collect multiple instances of the same data.

What are the benefits?

Repeating forms also ensure a more efficient data collection process, by allowing site users to easily collect the same type of data on multiple rows. Each row represents a form that they can add and fill in with data. For instance, if the subject experienced multiple surgeries, the site user can now add new instances of the Surgeries form to collect data for each event. Each new instance appears on a new row so all data is displayed together. This workflow makes data analysis easier for site users.

Details for study designers

To create a repeating form, click the **Repeating Form** toggle button on the right, on the Details pane.

Keep in mind that a form can only be made repeating while the study is in the Draft container. Once the study is moved to the Testing container, the **Repeating Form** toggle button becomes read-only.

Note:

You can add as many repeating forms to as many visits as you need and you can also add the same repeating form to one or more visits.

Figure 20-3 Repeating Form toggle button



Details for site users

Within each visit, you can create as many versions of a repeating form as you need. For instance, if a subject experienced multiple adverse events, you can capture all of the AEs with a single Adverse Event Log form. All you have to do is create a new empty version of the form for each AE. To create a new empty version of the form, click the **Add** button that appears in the upper right corner of the form, or you can click the plus sign (+) that appears next to the form name, on the left.

Repeating forms are displayed in a table view with each new instance of the form on a different row. To add or edit data in a repeating form double-click anywhere in the row.

If the subject reports an adverse event during their next visit, you should capture that information in the Adverse Event Log form for the next visit.

Figure 20-4 A repeating form for a site user

The screenshot shows a user interface for a clinical trial. At the top, there are tabs for 'Subject', 'Current Visit', and 'Previous Visits'. Under 'Current Visit', there is a 'Check 10' button and a series of 'Check 1' through 'Check 9' buttons. Below this is a 'Forms & Data' sidebar with a list of forms: 'Did Subject Have Any A...', 'Adverse Event Log', 'Cornea Image', 'Weight Scale', and 'Blood Glucose'. The 'Adverse Event Log' form is selected and highlighted with an orange border. The main content area shows a question: '1. Did the subject have any adverse events?' with a 'Yes' button. Below this is a table titled 'Adverse Event Log' with columns: '#', 'Adverse Event Date', 'Adverse Event Name', 'Reason', and 'Additional Comments'. The table contains one row with a green checkmark, the number '1', the date '22-Apr-2019', the name 'Headpain', the reason 'Subject experiencing headpain ...', and 'N/A'. An 'Add' button is in the top right corner of the table.

#	Adverse Event Date	Adverse Event Name	Reason	Additional Comments
1	22-Apr-2019	Headpain	Subject experiencing headpain ...	N/A

Figure 20-5 Add data in a repeating form

Conserve and dispense reusable kits

Want to reduce waste? If they're not expired or damaged, some of the kits returned to the site by a subject can be conserved, and re-dispensed to the same subject.

Clinical supply managers can now set their studies to conserve reusable kits that were brought back to the site by subjects. And site users can now dispense these conserved kits to the same subjects during the next visit in the study.

A reusable kit is a kit that can be safely re-dispensed to a subject because it is still sufficient to meet the needs of the subject and the study. For example, a subject might have unexpired medication left from a previous dispensation that can be used in place of dispensing a new kit. Sometimes, that product can be conserved by the system, and you can re-dispense it to the same subject during the next visit.

Already working in a live study?

The setting for allowing kits to be re-used and re-dispensed by site users is set to **No**, by default.

As a clinical supply manager, you can specify the right supply settings for your study as soon as the upgrade is complete. As a site user, you can start conserving reusable kits and re-dispensing them as soon as your study is configured for that feature. Other than that, existing studies won't be affected in any way by this new feature.

Read more about how this change affects...

- [Clinical supply managers](#)
 Clinical supply managers can now configure supply settings to allow site users conserve and re-dispense reusable kits that were previously dispensed to the same subject.

- **Site users**
Site users can now determine if a kit from a previous visit can be conserved and re-dispensed during the current visit. This workflow is available for scheduled, unscheduled, and titration visits.

Clinical supply managers

Clinical supply managers can now configure supply settings to allow site users conserve and re-dispense reusable kits that were previously dispensed to the same subject.

New setting: Dispense Reusable Kits

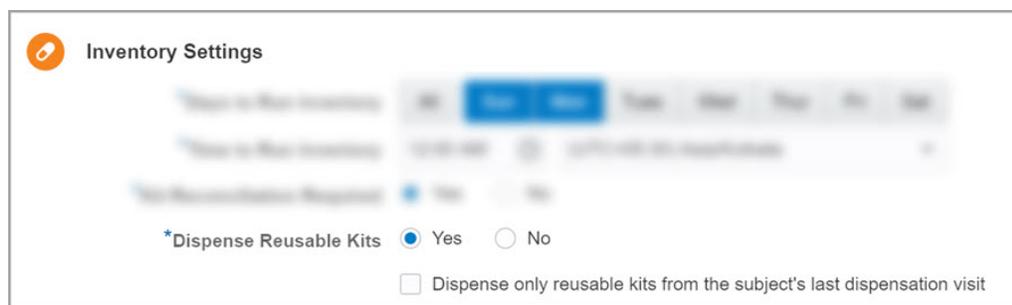
For this new setting, you have the following options:

- Choose **Yes** if you want to let site users conserve reusable kits and re-dispense them to the same subject.
- Choose **No** if you don't want site users to conserve and re-dispense any reusable kits.

New checkbox: Dispense only reusable kits from a subject's last visit

Click this checkbox to allow site users to conserve and re-dispense any reusable kits that were dispensed during the last dispensation visit.

Figure 20-6 New settings for clinical supply managers



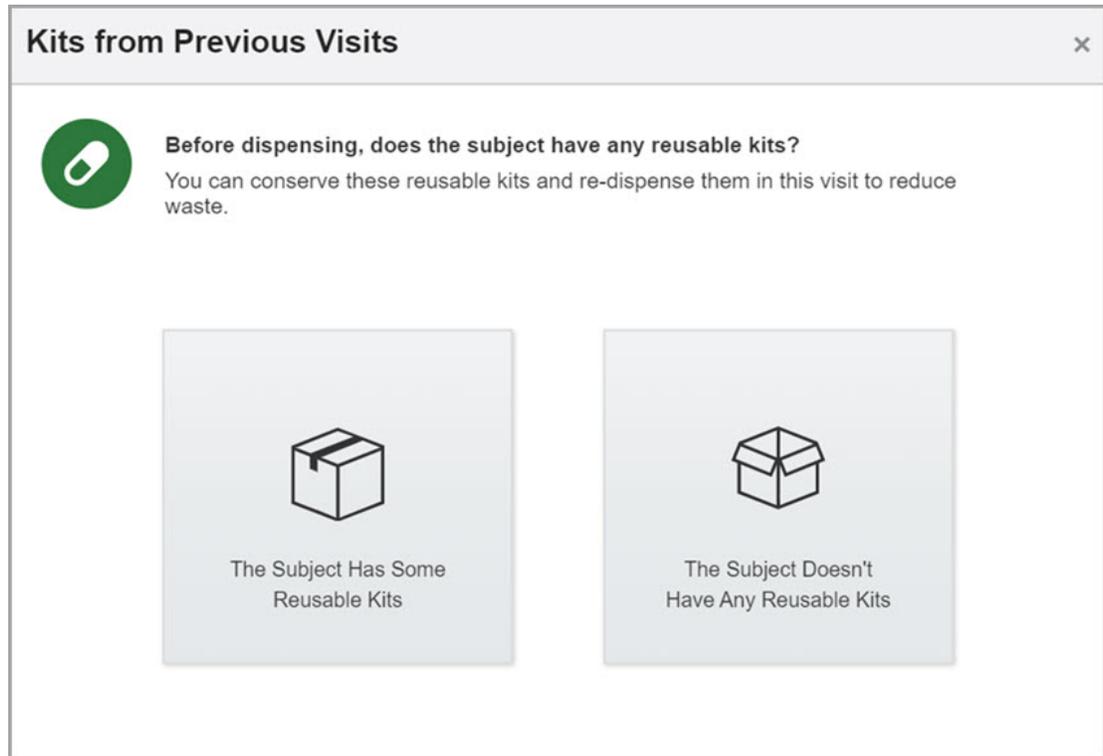
Site users

Site users can now determine if a kit from a previous visit can be conserved and re-dispensed during the current visit. This workflow is available for scheduled, unscheduled, and titration visits.

New pop-up: Kits from Previous Visits

After you complete a form and click **Dispense** during a visit, a new pop-up might appear asking you to specify whether the subject has any reusable kits or not. Remember that you can only dispense conserved kits to the same subject that initially had those kits.

Figure 20-7 Kits from Previous Visits pop-up

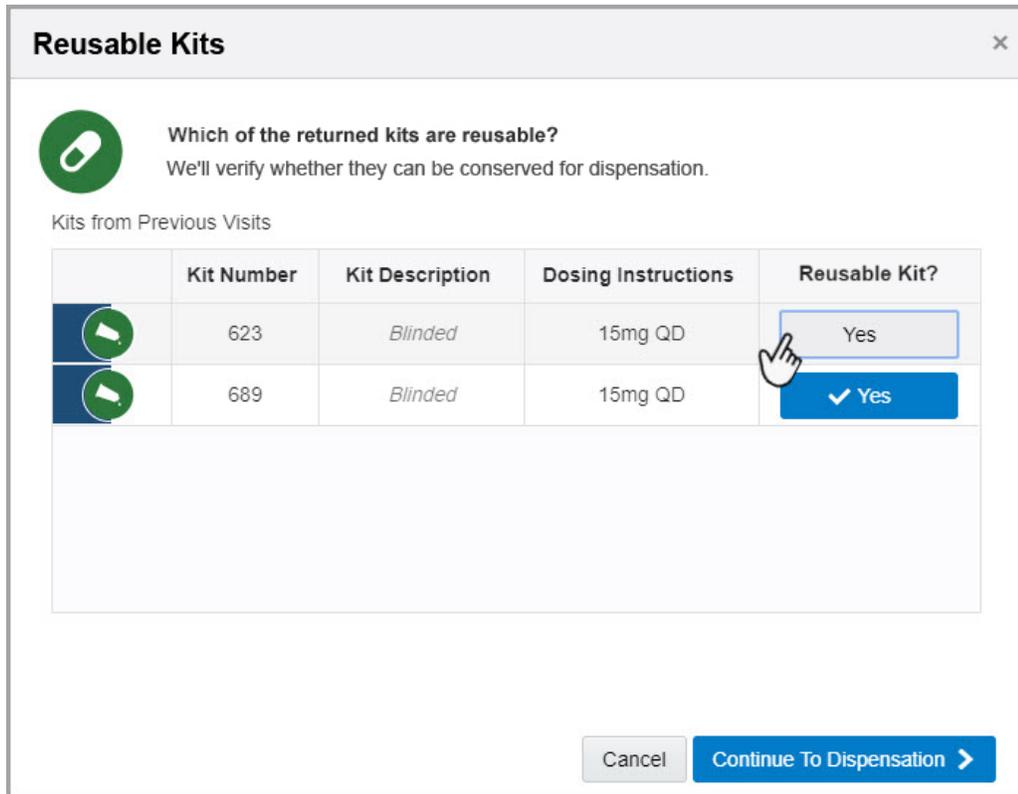


New pop-up: Reusable Kits

If you specify that a subject has any reusable kits, the Reusable Kits pop-up appears. In here, you can mark kits as reusable, so the system can determine whether they can be conserved for a further dispensation. If a reusable kit can be conserved, you see it in the Dispense Kits wizard along with the new kits that are about to be dispensed to the subject.

If you don't see a reusable kit on the list, it means that kit can't be conserved. In that case, don't forget to reconcile kits that can't be conserved in the system. For example, if you use Oracle Clinical One Platform for kit reconciliation, as soon as a reusable kit is considered ineligible for conservation, mark that kit as **Returned to Site** in the inventory.

Figure 20-8 Reusable Kits pop-up



The image shows a 'Reusable Kits' pop-up dialog box. At the top, there is a title bar with the text 'Reusable Kits' and a close button (X). Below the title bar, there is a green pill icon and the text: 'Which of the returned kits are reusable? We'll verify whether they can be conserved for dispensation.' Underneath, it says 'Kits from Previous Visits'. A table with four columns is displayed: 'Kit Number', 'Kit Description', 'Dosing Instructions', and 'Reusable Kit?'. The first row has a green pill icon, '623', 'Blinded', '15mg QD', and a 'Yes' button. The second row has a green pill icon, '689', 'Blinded', '15mg QD', and a blue '✓ Yes' button. At the bottom of the dialog, there are two buttons: 'Cancel' and 'Continue To Dispensation >'. A mouse cursor is pointing at the 'Yes' button in the first row.

	Kit Number	Kit Description	Dosing Instructions	Reusable Kit?
	623	Blinded	15mg QD	Yes
	689	Blinded	15mg QD	✓ Yes

Conserved kits eligible for dispensation are shown in the Dispense Kits wizard

When kits can be conserved, they appear in the Dispense Kits wizard in a separate table.

Figure 20-9 New kits and conserved kits from previous visits

Dispense Kits [Close]

Dispense the following kits to subject **IN29**:

Kits from Previous Visit

Kit Number	Kit Description	Dosing Instructions
689	<i>Blinded</i>	15mg QD

New Kits

Kit Number	Kit Description	Dosing Instructions
582	<i>Blinded</i>	15mg QD
Total Kits: 2		

Tip: To see the kit numbers again, open **Subject History** on the right. [Close]

[Close] [Print Dispensation Information] [Return to All Subjects]

Create your own rules and take control over your study data

Study designers can now create, test, and execute rules to ensure a seamless data collection process. Rules also provide site users better support for collecting accurate data.

What are rules and their benefits?

Think of rules as the director of a movie. They steer the course of action and define how the system behaves throughout the study in response to various events or parameters.

For study designers: Rules allow you to better control the data collection process and ensure the system reacts whenever things go off-track.

For site users: Rules check your data and let you know when something looks inaccurate or is inconsistent with the study protocol.

What's new for users when it comes to rules?

For study designers: You can now create rules to help site users only enter certain values when collecting data in forms. For instance, you can set up a rule that allows only a specific range of values for blood pressure. Anytime the data entered in a form is outside the range specified by that rule, the system generates a query letting site users know they should verify their findings and correct any errors. Also, you can set up a rule to automatically calculate a specific value using data entered by a site user and populate a read-only item with that

calculated value. For example, the Body Mass Index (BMI) can be automatically calculated based on a subject's height and weight.

For site users: You now have an automatic data checker that triggers a message each time the data you enter in a form is not consistent with the study rules. For instance, if the data you enter in the Weight field is outside of the range established by a study rule, you see a query containing a reason for why the data isn't valid and a request for clarification.

Already working in a live study?

Study designers with the appropriate roles and rights can start creating, testing and publishing rules as soon as the feature is available in the system. Site users only see changes if rules are implemented in a study they're working on.

Secure the quality of your study data with auto-queries

It's time to say goodbye to data errors! Starting now, you can use auto-queries to foolproof data against mistakes.

An auto-query is a text that is generated automatically whenever the criteria of a rule is met.

What are the benefits?

For sponsor users: Auto-queries represent a guarantee that every time data entered into a form isn't compliant with the study rules, site users are notified to solve the issue. This way you can ensure that the data collected in a study is accurate and reliable.

For site users: You now have a fact-checker available every time you complete a form. If a typing error occurs or the info you entered is inconsistent you are prompted with a query informing you of any inaccuracy or error, so you can quickly respond and solve the problem.

What's new for users when it comes to auto-queries?

For study designers: You can now create rules to deter site users from entering the wrong information in a form. For example, you can create an age rule stating that the subject must be between the ages of 18 and 60 years. If during a screening visit a site user enters 17 in the age field, when the form is saved the system automatically generates a query informing the site user that the age value is outside of the expected range. Or, you can create a rule that asserts the mandatory blood pressure parameters a subject is allowed to have. Based on that rule, a query is automatically triggered every time the site user enters a value that is outside of that mandatory range. The query remains open until the site user corrects the error.

For site users: If you ever enter data that is outside the expected range, a query appears next to the field that contains incorrect data. That query tells you what's wrong and asks you to review data, and correct the error. After you solve the issue, no other manual update for the query is required, since it automatically updates when it's resolved.

Already working in a live study?

As a study designer, you can start creating auto-queries at any time after the system update. As a site user, you start seeing auto-queries as soon as they're configured in the study you're working in, and you add any data that isn't following your study's

rules. Other than that, existing studies won't be affected in any way by this new functionality.

Easily maintain doses for subjects

If you manage a study that allows subjects to titrate, you now have even more options for titration.

You can now specify a Maintain Kit type for each kit type titration that you create. Additionally, whenever you create a kit type titration for a study's open label phase, remember to specify both the blinded kits that were used in previous kit type titrations, as well as the unblinded kit types that should be dispensed to subjects.

Already working in a live study?

If you're already working in a live study that uses kit type titrations, you can keep using the current titration design. You can always change your study design to adjust when and how subjects should titrate after this new enhancement is in place, but keep in mind that can only be done while the study is in the Draft container.

Read more about how this change affects...

- [Study designers](#)
Study designers can now create kit type titrations that also include kits for maintaining doses.
- [Site users](#)
Site users can now easily maintain the same dose of the investigational product during multiple visits.

Study designers

Study designers can now create kit type titrations that also include kits for maintaining doses.

Previously, for each kit in a kit type titration, you had to specify an Up Titrate kit type and a Down Titrate kit type. Now, for any new kit type titrations that you create, you must also specify a Maintain kit type. The Maintain kit type is dispensed when subjects need to remain on a specific dose for multiple visits.

New Maintain Kit column for creating kit type titrations

On the Create Kit Type Titration pop-up, you can now add kits in the Maintain Kit column to make sure site users have enough kits to keep a subject on the same dose level throughout multiple visits. Lastly, the Distribution Type drop-down is removed.

Kit type titrations used in maintaining the same dose now show up in the user interface

For example, every time you hover over your kit type titration or want to add a kit type titration to a visit, you also see the kits designed for maintaining the same dose for subjects.

Site users

Site users can now easily maintain the same dose of the investigational product during multiple visits.

To keep the subject on the same dose, all you have to do is click the **Maintain Dose** button.

Figure 20-10 Maintain Dose option for site users

Dispense Kits [X]

 Subject **HHM-02071992** is eligible for titration.

Choose whether to change the subject's dose:

I understand that the titration can't be changed after dispensation occurs.

Run better reports

The Kit Dispensation, Study Enrollment, and Subject Queries reports now include additional details that allow you to better manage your study processes.

Kit Dispensation report

Study managers now have access to new details related to subjects, sites, and visits in the Kit Dispensation report. These changes allow you to better manage your kit inventory and build the base for a seamless dispensation process.

In this report, you will now see details such as the Principal Investigator's Full Name and the subject's current state. Additionally, you'll also see:

- **Projected Dispensation Date:** This column shows the date of the next dispensation that should take place in the study.
- **The country where a site is located:** When a site manager creates a site, the country is now included.

Study Enrollment report

The Study Enrollment report now includes more information about subjects. To monitor enrollment events more efficiently, you now have a broader view of the number of subjects included in a study as well as the state of the subjects.

You can now view the number of subjects in the Screen failed, Withdrawn and Complete states. There is also a new column for subjects that were enrolled from another study.

In addition, we have updated the Randomized subjects column to contain the total number of subjects that have ever been randomized in a study, including those subjects with a status of Withdrawn or Complete.

Subject Queries report

With the right user role, you can now review queries associated with unscheduled visits in the Subject Queries report. Seeing this information in the report helps you correctly identify data associated with any unscheduled visit in a study.

Transform your data with coding questions

Study designers can now design coding questions for adverse events, concomitant medications, and subjects' medical history. And site users can now collect data about them by answering these coding questions in forms.

What exactly is a coding question and how does it work?

In a nutshell, a coding question is simply a Text question with a coding-related property specified for it. You use coding questions to collect and map different types of data such as adverse events or concomitant medications, according to the terminology listed in dictionaries in Oracle Central Coding.

Coding questions facilitate medical coding in Oracle Clinical One Platform and improve the way data is collected during a clinical study. For example, a site user might list "splitting headache" as an adverse event that a subject experienced after consuming the investigational product during the study. Using the coding question feature, a term such as "splitting headache" can be encoded as "severe headache" based on Medical Dictionary for Regulatory Activities (MedDRA). This ensures data consistency and ultimately helps you better analyze the data that is collected in a study.

Note:

One thing to keep in mind is that this feature will be further developed in a future release when the configuration between Oracle Clinical One Platform and Oracle Central Coding is ready. For now, the only task that can be performed in Oracle Clinical One Platform is specifying details for a coding question by study designers.

Already working in a live study?

As a study designer, you can start specifying details for coding questions as soon as the upgrade is complete.

Read more about how this change affects...

- [Study designers](#)
Coding question is a property that study designers can apply to a text question in a form within the study. Applying that coding question property to a question lets them select other details for the question, such as the Dictionary Type (MedDRA or WHODrug), Coding Item Type, and Tag for Central Coding.
- [Site users](#)
When the configuration of this feature is ready, site users can start collecting data from subjects on their adverse events, concomitant medications, or medical history.

Study designers

Coding question is a property that study designers can apply to a text question in a form within the study. Applying that coding question property to a question lets them select other details for the question, such as the Dictionary Type (MedDRA or WHODrug), Coding Item Type, and Tag for Central Coding.

New Coding Question property

Figure 20-11 Coding Question property for study designers

The screenshot shows a user interface for configuring a 'Coding Question' property. At the top, there is a section titled 'Advanced' with a dropdown arrow. Below it is a button labeled 'Add Property' with a small downward arrow. The main configuration area is titled 'Coding Question' and includes a trash icon in the top right corner. It contains three required fields, each marked with an asterisk (*):

- Dictionary:** A dropdown menu with the text 'Select Dictionary' and a downward arrow. A mouse cursor is pointing at the arrow.
- Coding Item Type:** A dropdown menu with the text 'Select Item Type' and a downward arrow.
- Tag for Central Coding:** A dropdown menu with the text 'Select Tag for Central Coding' and a downward arrow.

To include a coding question in your forms, and to make sure the data collected is properly translated, you need to:

- Create a text question, specify its details, and then apply the **Coding Question** property to it.
- Create one or more read-only items in the same form to make sure these items are automatically populated with values based on the answer to the coding question.
- Always specify details for a coding question while the study is in the Draft container.

New selections for Dictionary, Coding Item Type and Tag for Central Coding

After you apply the **Coding Question** property, on the right, you need to specify the details of the coding question so the answer that a site user fills in for this item is properly encoded.

Dictionary

From this drop-down, you select the dictionary that is used by Oracle Central Coding to search for the term that you want to convert. For example:

- **World Health Organization Drug Dictionary (WHODrug)** is the dictionary used for concomitant medications that subject take during a study.
- **Medical Dictionary for Regulatory Activities (MedDRA)** is the dictionary used for adverse events and medical history of subjects.

Coding Item Type

The Coding Item Type identifies a question for coding mapping. The options you see in this drop-down depend on the selection you make for the Dictionary field above. For example, if you choose WHODrug as the Dictionary, your list of options for the Coding Item Type might contain the following:

- **Verbatim Term:** Translates the collected answer into a universal term. For example, a verbatim term for "aspirin child" can be "aspirin children".
- **Indication:** Translates a symptom for which a certain medication is prescribed.
- **Route of Administration:** Translates the way in which a drug is administered to a subject. For example, "intravenous" is a term used for the route of administration.

Tag for Central Coding

From this drop-down, you select a tag that categorizes your data in Central Coding. Options in this drop-down include:

- **AE:** Identifies the verbatim term as an adverse event.
- **MH or NT:** Identifies the verbatim term as medical history.
- **CM:** Identifies the verbatim term as concomitant medication.
- **LB:** Identifies the verbatim term as lab data.



Note:

The Coding Item Type is unique for every question in the study. Also, each combination of the Coding Item Type and Dictionary Type should be unique within the study.

Site users

When the configuration of this feature is ready, site users can start collecting data from subjects on their adverse events, concomitant medications, or medical history.

Coding questions allow you to capture really specific and sensitive data more easily. For instance, a subject's medication history requires a highly particular, even unique, language and specific additional indicators. Coding questions support you in collecting all this important data by providing a more intuitive and reliable process.

Good news! There are no changes in your workflow. All you have to do is make sure you complete all fields in a form before screening, randomizing or dispensing kits to a subject.

Figure 20-12 How coding questions show up for a site user

Subject	Current Visit	Previous Visits
016-014	Check 9	Check 8, Check 7, Check 6, Check 5, Check 4, Check 3, Check 2, Check 1, Screening

Forms & Data	Con-Med
Date of Dosing ✓	* 1. Medication Taken: Lanaxolone
Adverse Event ✓	* 2. Indication: Ocular History
Con-Med ⚠	3. OH #: 15
	4. OH Condition/Diagnosis: Normal

Save Save & Close Dispense

Stability improvements

- [Randomization and kit stability improvements](#)
- [Site, depot, setting, and user management stability improvements](#)
- [Stability improvements for integrations](#)

Randomization and kit stability improvements

You can now remove a kit from all visits (former known issue)

Study designers: On the Kits tab, in the Add Kit to Schedule dialog box, when you deselect all visits associated with a kit type, and click **Save**, the kit type is removed from all visits. Previously, whenever you deselected all visits associated with a kit type, the kit wasn't removed from all visits. (Issue **30372988**)

Retracted workaround: You no longer have to remove each kit type individually from each visit in the schedule. However, we still recommend you run the Study Design report to make sure the kit type was in fact removed from all visits.

Site, depot, setting, and user management stability improvements

Error message no longer appears for valid Production URL

Study designers: On the Device Service tab, when you update the Production URL field with a valid URL path, the error message no longer appears. Previously, if you entered an incorrect URL in the Production URL field, and then corrected that URL, the error message still appeared.

Retracted workaround: None. (Issue **30231190**)

Stability improvements for integrations

General: New Oracle branding for the Oracle Clinical One Integration Hub UI

The blue top banner now shows the official Oracle logo. Previously, the banner simply included the word "Oracle" in clear text. (Issue: **30493315**)

General: Integration templates are now properly formatted

Integration managers: In Oracle Clinical One Integration Hub, existing integration templates are now downloaded with the correct XML formatting. Previously, starting with the 19.2 release, the formatting was no longer followed by Oracle Clinical One Integration Hub and you had to manually format the text to make it easier to read. (Issue **30275026**)

 **Note:**

This stability improvement impacts all integrations.

General: You can now enable or disable integrations at a group level

Integration managers: Integrations within an integration group can now be enabled or disabled at the same time, at a group level. Previously, if you attempted to enable or disable a group of integrations, you received an error message stating you couldn't enable or disable certain integrations from the group. (Issue **30245962**)

Oracle InForm to Oracle Argus Safety: Line breaks and tabs now appear correctly in the narrative field

Integration managers: Line breaks and tab characters now appear as expected in narrative fields sent from Oracle InForm Publisher to Oracle Argus Safety. Previously, the formatting was not followed by Oracle Clinical One Integration Hub and you had to manually format the text to make it easier to read. (Issue **30440507**)

 **Note:**

This stability improvement only impacts integration managers working with integrations between Oracle InForm and Oracle Argus Safety.

Oracle Clinical One Platform to Veeva Vault CTMS: Invalid value for subject state corrected in the template

Integration managers: Integrations between Oracle Clinical One Platform and Veeva Vault CTMS no longer fail due to the "Invalid value [Active]" error. Previously, the integration template was incorrectly configured so the integration also sent information for subjects in an Active state in Oracle Clinical One Platform. This resulted in job failures since Veeva Vault CTMS doesn't accept that subject state. (Issue **30303588**)

Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.5 (October 2019)

- [What's new in 19.5](#)
- [Stability improvements](#)

What's new in 19.5

- [Enroll subjects in a rollover study](#)
Study designers can now create rollover questions and design rollover studies, and site users can enroll subjects in rollover studies.
- [New options for blocked fixed randomization lists](#)
Randomization list managers can now assign blocks of randomization numbers to sites, countries and regions faster and more efficiently.

Enroll subjects in a rollover study

Study designers can now create rollover questions and design rollover studies, and site users can enroll subjects in rollover studies.

What are the benefits of this new feature?

- **For study designers:** You can now create a rollover question in the original study for site users to answer in the study completion form. Additionally, you can also design a rollover study so the sponsor organization can further test their investigational product and assure a continuous treatment for subjects.
- **For site users:** You can now enroll subjects in a rollover study and dispense kits to them once they are enrolled.

Ready to learn more? Keep reading for all the details about this new feature.

- [Details for study designers](#)
Here's what's new in your workflow when it comes to this new feature: to make sure subjects can be enrolled from the original study to a rollover study, you can now create rollover questions in the original study. Additionally, you can also design a rollover study.
- [Details for site users](#)
Here's what's new in your workflow when it comes to subjects: you can now answer the rollover question typically found in a study completion form, in the original study, and automatically enroll subjects in a rollover study. Additionally, you can also dispense kits to subjects in a rollover study.
- [Reporting changes](#)
The following reports include data about rollover questions and enrolled subjects.

Details for study designers

Here's what's new in your workflow when it comes to this new feature: to make sure subjects can be enrolled from the original study to a rollover study, you can now create rollover questions in the original study. Additionally, you can also design a rollover study.

 **Note:**

Before doing any of your study design tasks, work with your user administrator to make sure you're provisioned as a study designer for both the original and the rollover study that you need to design.

New rollover property for drop-down question in the original study

To let site users in the original study enroll subjects in a rollover study, include a specific question in a form, and associate that form with a visit in the schedule of the original study. Typically, a rollover question is included in a study completion form. Here's how you can do this:

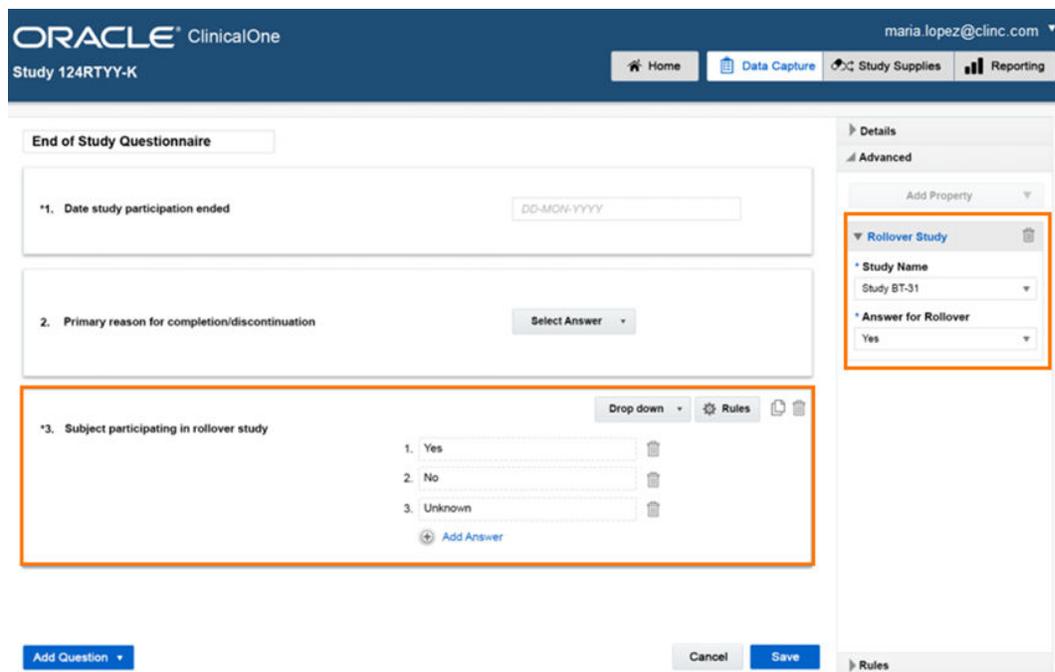
1. For the original study, on the Data Capture tab, create the study completion form, and add a drop-down question for site users to enroll subjects in a rollover study.

 **Note:**

This question should have at least two options for an answer: Yes and No.

2. On the right, click the **Advanced** pane, and select the **Rollover Question** property.
3. Still on the right, in the Rollover Study box:
 - a. Click the **Study Name** field and from the drop-down, select the name of the rollover study where you want subjects to be enrolled in.
 - b. Click the **Answer for Rollover** field and from the drop-down, select **Yes** as the mandatory answer. When a site user selects **Yes** as an answer the subject is automatically enrolled in the rollover study.

Figure 20-13 Rollover drop down question



The screenshot shows the Oracle ClinicalOne interface for 'Study 124RTYY-K'. The main area displays an 'End of Study Questionnaire' with three questions. The third question, '*3. Subject participating in rollover study', is a drop-down question with three options: '1. Yes', '2. No', and '3. Unknown'. The 'Yes' option is selected. The right sidebar shows the 'Advanced' pane with a 'Rollover Study' section containing 'Study Name' (Study BT-31) and 'Answer for Rollover' (Yes).

New icon for rollover studies

On the Data Capture tab, to identify forms that contain a rollover question or to see

which question in a form is a rollover, look for the new green icon () next to each form or question.

Design a rollover study without a screening visit

Lastly, if you're familiar with designing a regular study, your workflow for designing a rollover study is almost the same. Just keep in mind that a rollover study shouldn't contain a screening visit. Subjects are already screened in the original study, so they don't need to go through that visit again in the rollover study.

Details for site users

Here's what's new in your workflow when it comes to subjects: you can now answer the rollover question typically found in a study completion form, in the original study, and automatically enroll subjects in a rollover study. Additionally, you can also dispense kits to subjects in a rollover study.

New rollover question

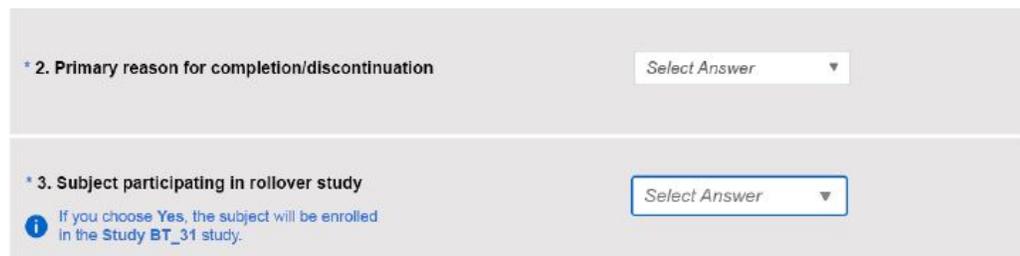
For subjects that should be enrolled in a rollover study, you now see a rollover question typically in a study completion form in the original study. Selecting **Yes** from the **Select Answer** drop-down automatically enrolls the subject in the rollover study.



Note:

Subjects enrolled in a rollover study keep their subject number from the original study.

Figure 20-14 Rollover question in form



* 2. Primary reason for completion/discontinuation

* 3. Subject participating in rollover study

 If you choose Yes, the subject will be enrolled in the Study BT_31 study.

New state for subjects enrolled in a rollover study

Subjects who were just enrolled in a rollover study show up in a state of **Enrolled**. Moreover, you can see the details of their enrollment on the right, in the **Subject History** pane: the original study they're coming from and the date, and time of their enrollment.

According to the rollover study's design, you can always dispense kits or withdraw subjects from a rollover study.



Note:

In a rollover study, you shouldn't screen a subject because they've already been screened in the original study.

Figure 20-15 Enrolled state in Subject History



Reporting changes

The following reports include data about rollover questions and enrolled subjects.

- In the original study, the **Study Design report** now shows which form contains the rollover question. Moreover, there's a new **Advanced** column that shows details of the rollover question.
- In the rollover study, the **Subject Events report** now shows the **Enrolled** event for subjects enrolled in the rollover study.

New options for blocked fixed randomization lists

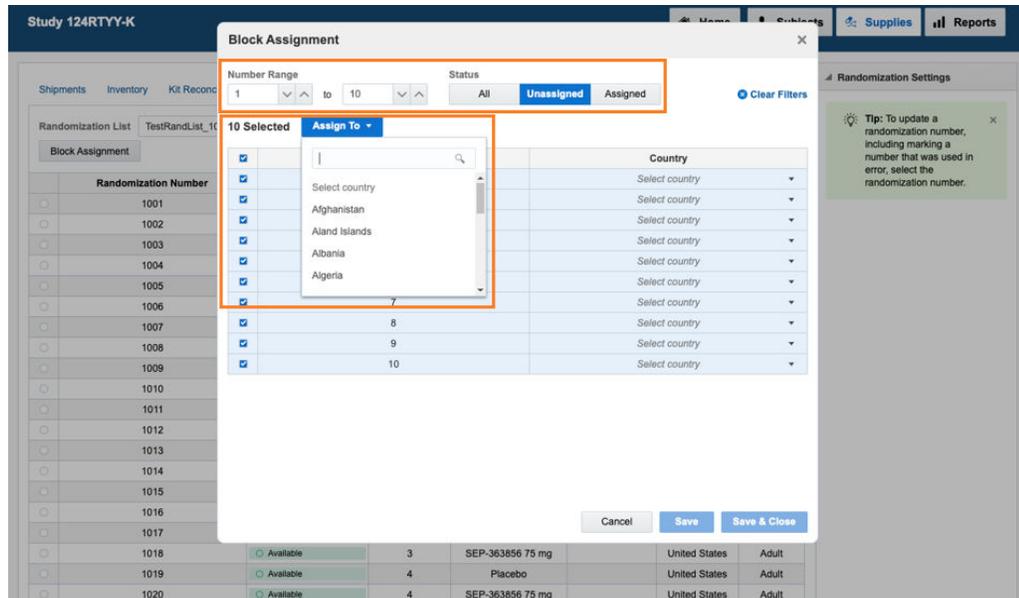
Randomization list managers can now assign blocks of randomization numbers to sites, countries and regions faster and more efficiently.

We've added new filters for assigning blocks of randomization numbers to sites, countries and regions so you can benefit from the best allocation of participants to treatment arms. This way you can ensure that your study generates relevant and reliable results.

Details for randomization list managers

When you assign blocks of randomization numbers now you can:

- Search for block numbers based on a specific status. For instance, you can filter for unassigned blocks, so that you don't reassign a block that has been partially used.
- Search for a specific range of block numbers.
- Manually select a range of blocks and assign them to a site, country or region.



Reporting changes

The Randomization List report now contains new details for the assignment of blocks.

Stability improvements

- [Randomization and kit stability improvements](#)
- [Integrations stability improvements](#)

Randomization and kit stability improvements

Kit type titrations can now be assigned to visits using Internet Explorer

Study designers: From now on, when you work in Oracle Clinical One Platform using Internet Explorer, you can assign kit type titrations to visits in the study. Previously, you couldn't do that in Internet Explorer due to a code issue.

Note:

We recommend using Google Chrome for working in Oracle Clinical One Platform to make sure your browser is compatible with all features within the product.

Integrations stability improvements

Freezing data items is now optional

Integration managers: For the integration between Oracle Clinical One Platform and ODM 1.3 - RWS, you now can choose whether a data item must be frozen before being modified. If you require data items to be frozen, keep in mind that the integration account will require freezing privileges. (Issue **30385595**)

The following template tag allows you to configure this requirement:

- This enables the freezing of a data item as a requirement for the integration. This is the default setting in the template.

```
<FreezeDataItem>true</FreezeDataItem>
```

- This disables the freezing of a data item as a requirement for the integration.

```
<FreezeDataItem>>false</FreezeDataItem>
```

Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.4

- [What's new](#)
- [Stability improvements](#)

What's new

- [Dispense IoT-enabled devices managed with Oracle Health Sciences mHealth Connector Cloud Service](#)
Oracle Clinical One Platform and Oracle mHealth Connector now work together to enable new and better features for our users!
- [New type of event: unscheduled visit](#)
As a study designer, you can now add unscheduled visits to your study as needed. As a site user, you can dispense kits and perform dose changes at unscheduled visits when they are available in your study.
- [Send subject information to Oracle Siebel Clinical Trial Management System](#)
Great news for integration managers! Oracle Clinical One Platform now integrates with Oracle Siebel Clinical Trial Management System (CTMS).
- [New email notification for Almac Global Depot Network](#)
A new notification is now available for the integration between Oracle Clinical One Platform and the Almac Global Depot Network.

Dispense IoT-enabled devices managed with Oracle Health Sciences mHealth Connector Cloud Service

Oracle Clinical One Platform and Oracle mHealth Connector now work together to enable new and better features for our users!

Here's what this implementation is all about:

You can now design a study that allows site users to dispense device kit types to subjects during their visits. For example, if a subject needs a heart monitor device during one of their visits, study designers are now able to design a device kit type containing such a device, and site users can dispense it to the subject. Additionally, site users can also replace or retire the device, in case something happens with the device, or the subject no longer needs it.

Creating and dispensing device kit types is optional. If the study that you're working on doesn't dispense device kit types, your workflows don't change, though you may see some interface changes. For example:

- If you're a study designer, you'll see a new option for devices in the drop-down for creating kit types. In the Create Device Kit Type dialog box, you'll see two new options for designing devices enabled through Oracle mHealth Connector: Device to Cloud and Cloud to Cloud. Moreover, you'll also see small changes in the dispensation schedule.
- If you review certain reports, you'll see new fields related to device kit types.

 **Note:**

Configuration of the Oracle mHealth Connector implementation is done by the Oracle Services team. As an Oracle Clinical One Platform user, you don't have to do any work outside of the product that you're working with.

Want to learn more about this exciting new feature? Use the links below to see what it means for each type of user.

- [Details for user administrators](#)
Your workflow hasn't changed, but there are some new roles and rights that you need to be aware of. Study designers and site users must have these roles and rights assigned to them in order to work with IoT-enabled devices configured through Oracle mHealth Connector.
- [Details for study designers](#)
If you're familiar with creating kit types for investigational products, you can apply that knowledge to creating kits for devices. The workflows for drugs and devices are very similar with just a few new steps at the beginning for setting up the connection to Oracle mHealth Connector.
- [Details for the study team](#)
Your workflow hasn't changed, but many of the tasks that you previously performed for investigational product kit types and individual kits are also applicable to device kit types and individual devices.
- [Details for site users](#)
If your study allows dispensing devices, there are some changes in your workflow such as activating devices before dispensing them, and a new drop-down menu that you can use to refresh a device's access code or replace a device, among other things.
- [Reporting changes](#)
Read more about the new data on devices that shows up in existing reports. Data about IoT-enabled devices is included only if IoT-enabled devices managed with Oracle mHealth Connector are part of your study's design.

Details for user administrators

Your workflow hasn't changed, but there are some new roles and rights that you need to be aware of. Study designers and site users must have these roles and rights assigned to them in order to work with IoT-enabled devices configured through Oracle mHealth Connector.

The following new rights allow you to manage and dispense IoT-enabled devices managed with Oracle mHealth Connector. All users working with devices must have the required roles.

New right	Tasks that users with this right can perform	Roles that include the right
Update Settings for Connected Device Configuration	Set up the connection to Oracle mHealth Connector on the new Device Service tab in Study Settings.	<ul style="list-style-type: none"> Production Admin You must have this role in all three modes to update the URL fields on the Device Settings tab.
	<p> Note:</p> <p>You must have a role with this right in every mode to be able to specify URL settings for every mode.</p>	<p> Note:</p> <p>Not all designers have this role. You may need to update a designer's access if they are responsible for setting up the connection to Oracle mHealth Connector.</p>
View Settings for Connected Device Configuration	This right doesn't grant any access in the user interface. Instead, this right allows site users to connect to Oracle mHealth Connector using the credentials entered on the Device Settings tab. This connection is required for users who dispense devices to subjects.	<ul style="list-style-type: none"> Lead Site User Site User Site User with detailed dosing view
Take Action on Connected Devices	Take action on a dispensed device, including registering it, deactivating it, refreshing its access code, and replacing it.	<ul style="list-style-type: none"> Lead Site User Site User Site User with detailed dosing view

If a user who will be working with devices already has the role that includes the rights...

No need to make any changes. The user will be able to start working with devices immediately after the system update.

Details for study designers

If you're familiar with creating kit types for investigational products, you can apply that knowledge to creating kits for devices. The workflows for drugs and devices are very similar with just a few new steps at the beginning for setting up the connection to Oracle mHealth Connector.

Already dispensing devices in a live study?

In previous releases, you could select Device as the Type for a kit type. This option hasn't gone away, and you can continue dispensing devices in your studies without making any changes. The changes that are introduced in this release are applicable only if you want to dispense IoT-enabled devices that are managed with Oracle mHealth Connector.

Prerequisites: Set up the connection to Oracle mHealth Connector

Before you can set up the connection to Oracle mHealth Connector, you need a user account and some details about the Oracle mHealth Connector study.

1. Work with a delegated administrator to provision an Oracle mHealth Connector user in Oracle Health Sciences Identity and Access Management Service. The user account is typically a service or integration account and isn't used by a user to sign in to Oracle mHealth Connector. You'll need both the user name and password for this account.
2. Reach out to your Oracle project manager to obtain the following information:
 - The value in the Study Name field for the Oracle mHealth Connector study.
 - The URLs for the Production, Training, and Testing instances (three URLs in total).

Note:

Having a study available in Training mode isn't mandatory for setting up the connection to Oracle mHealth Connector, so having a URL for the Training field is optional.

How to: Set up the connection to Oracle mHealth Connector

After getting a user account and the name of the Oracle mHealth Connector study, you're ready to set up the connection between the Oracle Clinical One Platform and Oracle mHealth Connector studies.

Perform these steps in Oracle Clinical One Platform. To work on this tab, you need the required rights (see [Details for user administrators](#)).

1. Open Study Settings  for the study, select the General tab, and check the Study ID field. The Study ID must be identical to the Study Name field that you obtained in the steps above.

General Sites Depots Users Subject Settings Supply Settings

* Study Title ORS-123

* Study ID ORS-123

Study Phase IV

Therapeutic Area Vaccines

Open Label / Blinded Open Label

Contract Code PA# 12345

Apply Changes

2. Open Study Settings  for the study, select the Device Service tab, and fill in the fields:
 - Enter the credentials for the user account you obtained in the steps above.
 - Enter the URLs that you obtained in the prerequisites above.

General Sites Depots Users Subject Settings Supply Settings Device Service

Username tenantabc.jsmith

Password

Production URL https://mhealth.us.oracle.com/dth-ext-api/dth/service/studies/87E22E699BBBFD27E0534A16C40AC518

Testing URL https://mhealth-test.us.oracle.com/dth-ext-api/dth/service/studies/87E22E699BBBFD27E0534A16C40AC518

Training URL https://mhealth-train.us.oracle.com/dth-ext-api/dth/service/studies/87E22E699BBBFD27E0534A16C40AC518

Apply Changes

3. Save your changes.

How to: Create a device kit type

You create device kit types in the same place you create drug kit types, on the Kits tab. The Create Kit Type button is now a drop-down with two options:

- **Investigational Product:** Choose this option for all drug kit types. The name of the pop-up that appears is now Create Investigational Product Kit Type, but there aren't any other changes in the pop-up.
- **Device:** Choose this option for all device kit types.

Complete the fields in the pop-up.

New icon for device kit types

When a device kit type is dispensed during a visit, a new icon now appears on the visit in Visits & Events. Here is a visit that dispenses both drugs and devices:

Additional tasks for dispensing devices

As you might know, after you create kit types for investigational products, you have to perform a few steps to create the kits in Oracle Clinical One Platform. Tasks that are required for investigational product kits are also required for device kit types. Tasks that are optional for investigational product kits are also available for device kit types.

1. Create kit lists

You must create (by either generating or uploading) kit lists for the device kit types in all three modes.

You can skip this step for Training mode if your users don't use Training mode.

You can create multiple kit lists if needed, such as one kit list for all devices and another for all investigational products.

2. Add device kit types to manufacturing lots

After creating the kit list for devices, you must add all the device kit types to manufacturing lots.

Kits can't be dispensed without expiration dates. Manufacturing lots are how you specify expiration dates. You can add kits to one or more manufacturing lots, but every kit must be in a manufacturing lot, even if the devices never expire.

3. If required, add device kit types to blinded lots

If you want to monitor batches of kits while protecting the study blind, or if you want to organize the devices in multiple groupings, add your manufacturing lots to one or more blinded lots.

4. If required, add device kit types to blinded groups

If the devices are blinded, the study doesn't allow single-kit ordering of devices, and the kits in the study use different packaging, add the device kit types to blinded groups.



Note:

This list includes only the tasks that the study designer performs. A few other tasks are required to dispense devices. For more information, see [Details for the study team](#).

Details for the study team

Your workflow hasn't changed, but many of the tasks that you previously performed for investigational product kit types and individual kits are also applicable to device kit types and individual devices.

The following tasks are required when you're preparing a study for dispensing devices or are working in a study that dispenses devices:

- **Include device kit types in resupply strategies**

You now must include device kit types in resupply strategies on the Subject Settings tab.

- **Associate kit types with depots**
When you set up your depots, you now must choose the device kit types that each depot ships.
You must associate each device kit type with at least one depot.
- **If required, reconcile devices**
If the study requires it, you can perform kit reconciliation for devices on the Kit Reconciliation tab.
- **View devices in a subject's unblinding results**
This one is not mandatory, but if you ever need to perform a code break or code view on a subject, just know that you also see dispensed devices in their unblinding results.

When a study dispenses devices, you can view details about the device kits in the same places where you view details about investigational product kits, including the Shipments tab (for unblinded users only) and the Inventory tab.

Details for site users

If your study allows dispensing devices, there are some changes in your workflow such as activating devices before dispensing them, and a new drop-down menu that you can use to refresh a device's access code or replace a device, among other things.

How to: Dispense devices

When it comes to dispensing devices, there are a couple of new steps added to your workflow. If dispensing devices is allowed for the study that you're working in, these devices show up in the Dispense Kits wizard when you're about to dispense them to subjects. In the Dispense Kits wizard, click the **Next** button to activate each device before dispensing them.

To activate a device, you must use one of the following codes:

- **Vendor code:** This field is required for devices with a Cloud-to-Cloud connection. Every device comes with a unique vendor code that you can use to activate devices.
- **Access Code and Password:** These fields are required for devices with a device-to-cloud connection. Every device comes with an initial access code and password that you can refresh if they expire.
- For devices that aren't configured through an Oracle mHealth Connector implementation, just follow your regular workflow.

If there are multiple devices that you need to activate and dispense to subjects, click **Next** to activate all of them.

Finally, in the final Dispense kits wizard, you see all of your dispensed kits just like you used to, including devices.

New menu icon for managing devices

First off, there's a new menu icon for each dispensed device that appears in Subject History, on the right. When you click that icon, a new drop-down appears with multiple options such as Deactivate (or Activate), Refresh Access Code, Replace, and Go to Inventory.

 **Note:**

Depending on your permissions or the configuration of the devices, some of these options may not appear in the drop-down. For example, for devices with a Cloud-to-Cloud connection, you don't see the **Refresh Access Code** option.

How to: Activate or deactivate a device

You can activate a device that was dispensed to a subject, as well as deactivate it if the subject is no longer using it or something happened with it. The options for activating or deactivating devices are available in the drop-down menu for devices configured through a Cloud-to-Cloud connection and for devices that aren't configured using Oracle mHealth Connector.

 **Note:**

Activation or deactivation of devices can only be done by site users.

How to: Refresh access codes

Devices with a device-to-cloud connection come with a one-time access code and password that expire within 24 hours from registering the device to Oracle mHealth Connector. If the original access code doesn't work, you can refresh it by selecting **Refresh Access Code** from the drop-down.

 **Note:**

For devices with a Cloud-to-Cloud connection and for devices not configured through Oracle mHealth Connector, you don't see the option for refreshing access codes.

How to: Replace devices

If something happened to a device that was already dispensed to a subject, you can always replace it by clicking **Replace** in the drop-down menu.

 **Note:**

You can replace only one kit at a time.

How to: See your dispensed devices in the inventory

To locate the dispensed devices in your inventory, click **Go to Inventory** in the drop-down menu.

Reporting changes

Read more about the new data on devices that shows up in existing reports. Data about IoT-enabled devices is included only if IoT-enabled devices managed with Oracle mHealth Connector are part of your study's design.

Changes to the Study Design report

You'll see these changes in the Study Design report only for studies that dispense devices. Existing studies without this new feature don't see any changes in the Study Design report. Failed device activations do not appear in this report.

- The Study Design Summary section now includes information about devices that were dispensed to subjects.
- There's a new column called Device Connection in the Kits section of the report.
- The Kit Dispensation section includes a new row that shows devices dispensed to subjects.
- The Generated Kit List will also include device names.

Changes to the Kit Dispensation report

The Kit Dispensation report now displays new status changes for devices such as **Activated**, **Deactivated**, or **Refreshed**. Moreover, a new **Replacement** status is used in the Event column for both investigational products and devices.

New type of event: unscheduled visit

As a study designer, you can now add unscheduled visits to your study as needed. As a site user, you can dispense kits and perform dose changes at unscheduled visits when they are available in your study.

Unscheduled visits are an optional feature and must be enabled as part of the study design.

Ready to learn more? Keep reading for all the details about this new feature.

- [Details for study designers](#)
If you're familiar with creating scheduled visits and defining the dispensation scheduled for them, you can apply that knowledge to creating unscheduled visits. The workflow for designing unscheduled visits is very similar with just a couple of new steps.
- [Details for site users](#)
If unscheduled visits are part of your study's design, there are only a few changes in your workflows that you should know about such as a new option in the Manage Subjects drop down and a new visit card for unscheduled visits on the Subjects tab.
- [Reporting changes](#)
Read more about the data on unscheduled visits that shows up in existing reports. Data about unscheduled visits is included only if unscheduled visits are part of your study's design.

Details for study designers

If you're familiar with creating scheduled visits and defining the dispensation scheduled for them, you can apply that knowledge to creating unscheduled visits. The workflow for designing unscheduled visits is very similar with just a couple of new steps.

New option for creating unscheduled visits

Create an unscheduled visit using the Create Visit or Event dialog. In the dialog box, you'll see a new option in the Type drop-down.



Note:

You can only create one unscheduled visit in a study.

Figure 20-16 Create an unscheduled visit

The screenshot shows a dialog box titled "Create Visit or Event" with a close button (X) in the top right corner. The dialog contains the following fields and options:

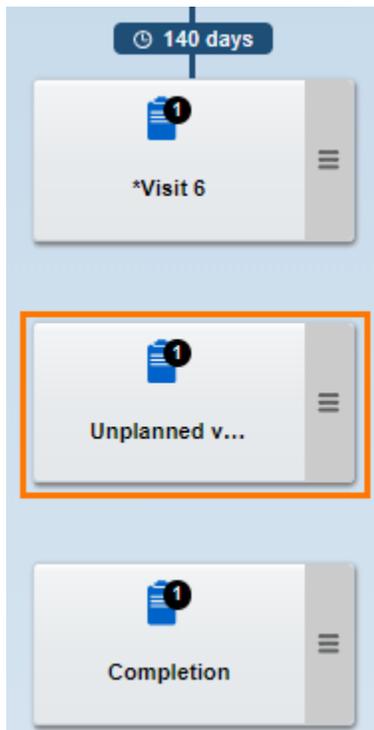
- * Title: Text input field.
- * ID: Text input field.
- * Type: Dropdown menu with "Scheduled Visit" selected. The dropdown is open, showing "Scheduled Visit" and "Unscheduled Visit". The "Unscheduled Visit" option is highlighted with an orange border.
- * Required: Text input field.

At the bottom of the dialog, there are three buttons: "Cancel", "Save & Add Another", and "Save".

Unscheduled visits appear in the Visits & Events pane

Unscheduled visits now appear on the right after the scheduled visits, and before the study completion visit.

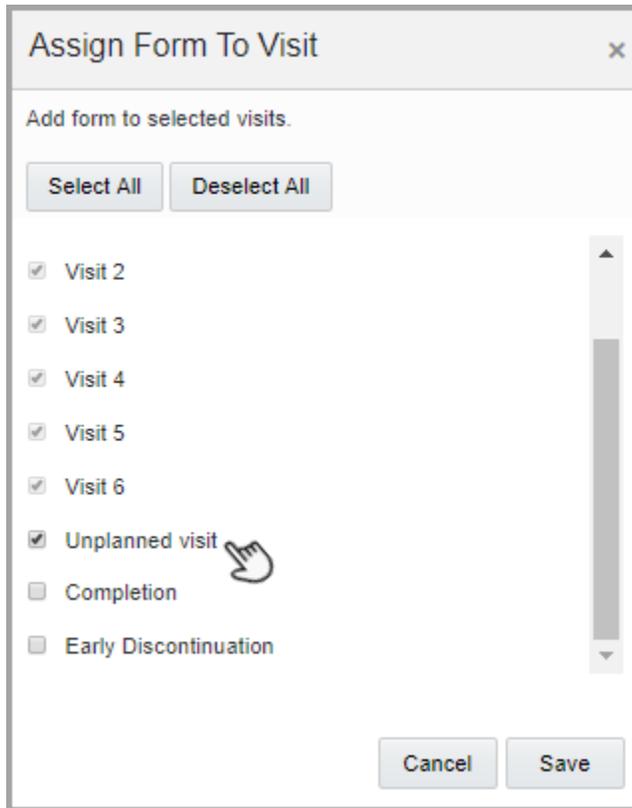
Figure 20-17 Unscheduled visit in the Visits and Events pane



You can assign forms to an unscheduled visit

A new option for unscheduled visits appears in the Assign Form to Visit dialog.

Figure 20-18 Assign forms to an unscheduled visit



New visit flyout for unscheduled visits

Clicking an unscheduled visit in the Visits & Events pane on the right opens a visit flyout where you can:

- Select a kit from the drop down for each treatment arm or all subjects. After a kit type is added, that kit is removed from the drop down for the treatment arm. Additionally, you can also drag and drop a kit on an unscheduled visit to define the dispensation for it.
- As with regular scheduled visits, you must add at least one form to an unscheduled visit.
- Change the visit type or visit ID.

Figure 20-19 Visit flyout for an unscheduled visit

Small changes in how you define the dispensation for unscheduled visits

- In the Add Kit to Visit Schedule dialog box you can now associate a kit type with an unscheduled visit, choose the treatment arm to associate with the kit type, and the options are the same as when you associate a kit type with a scheduled visit. That is, you can associate the kit type with one or more treatment arms, all treatment arms, or all subjects.
- You no longer see the **Dispense Outside Window** checkbox for unscheduled visits, because unscheduled visits don't have visit windows.
- Depending on how you defined the kits, the **Calculated Dose** column may or may not appear in this dialog box.

Figure 20-20 Changes for dispensing kits during an unscheduled visit

Visits	Quantity	DND (Days)
<input type="checkbox"/>		
<input checked="" type="checkbox"/> Unplanned visit		

New options for dispensing kit type titrations during unscheduled visits

In the Create Kit Type Titration dialog box, you'll see a new column for unscheduled dose changes. The content of that column may change depending on the selection that you make for the Maximum Dose Changes option. For example:

- If you select **Total**, the **Unscheduled Dose Changes** column displays a drop down for the total number of dose changes that can occur during unscheduled visits.
- If you select **Up and Down**, the **Unscheduled Dose Changes** column displays two fields: one for the Up Titration Limit and one for the Down Titration Limit.

Additionally, you'll also see the Add Titration to Visit Schedule wizard where you can choose how to associate kit type titrations with treatment arms and subjects, and specify the DND (Days) value for each kit type titration that can be dispensed during an unscheduled visit.

Details for site users

If unscheduled visits are part of your study's design, there are only a few changes in your workflows that you should know about such as a new option in the Manage Subjects drop down and a new visit card for unscheduled visits on the Subjects tab.

New option in the Manage Subjects drop down

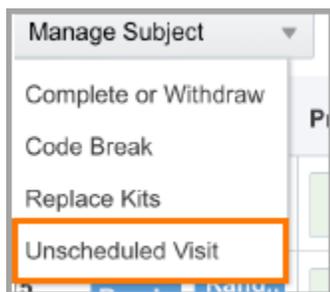
If there's an unscheduled visit during which you need to dispense kits to subjects, you'll see a new option in the **Manage Subject** drop down when you select the checkbox to the left of a subject. Clicking **Unscheduled Visit** opens up the Dispense Kits wizard where you can review and dispense kits to a subject during an unscheduled visit.



Note:

A study can contain multiple unscheduled visits during which you can dispense both kits containing an investigational product and perform dose changes.

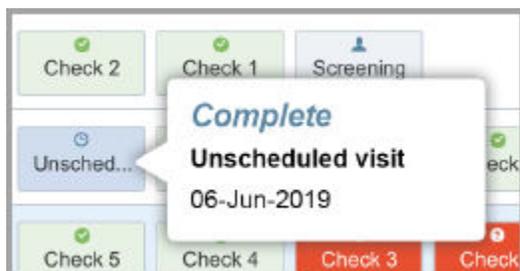
Figure 20-21 Unscheduled visit option in the Manage subjects drop down



New visit card for unscheduled visits

If a subject attends and completes an unscheduled visit during the study, it will show up in the Subjects table, on the Subjects tab. Additionally, the visit card changes every time a subject didn't complete the visit or forms for the unscheduled visit contain errors.

Figure 20-22 New visit card for an unscheduled visit



New column in the Subject Dispensation report

In the Dispense Kits wizard, after you dispense kits to a subject during an unscheduled visit, click **Print Dispensation Information**. The Subject Dispensation report that shows up now contains a column called **Unscheduled Visit Number**.

Reporting changes

Read more about the data on unscheduled visits that shows up in existing reports. Data about unscheduled visits is included only if unscheduled visits are part of your study's design.

Changes to the Study Design report

- The Study Design Summary section now includes information about unscheduled visits
- The Visits section also includes information about unscheduled visits. Look for the new visit type showing up in the Visit Type column for unscheduled visits
- The Kit Dispensation section now shows a separate heading row for unscheduled visits

Changes to other reports in Oracle Clinical One Platform

The following reports now display a new column for Unscheduled Visit Number:

- The Subject Data report
- The Subject Events report
- The Kit Dispensation report
- Additionally, the Kit Chain of Custody report will show kits that are dispensed during unscheduled visits

Send subject information to Oracle Siebel Clinical Trial Management System

Great news for integration managers! Oracle Clinical One Platform now integrates with Oracle Siebel Clinical Trial Management System (CTMS).

What does this mean for you?

From now on, you can send information about all of your subjects in Oracle Clinical One Platform to Oracle Siebel CTMS. All subject data is included in a report that was designed to give you an accurate overview of your subjects' activity in the study.

Sponsors: How can I connect my study with Oracle Siebel CTMS?

If you want to transmit subject information from Oracle Clinical One Platform to Oracle Siebel CTMS, reach out to your Oracle Project Manager.

New email notification for Almac Global Depot Network

A new notification is now available for the integration between Oracle Clinical One Platform and the Almac Global Depot Network.

From now on, for each electronic order, Oracle Clinical One Integration Hub will send Almac an additional human-readable order form via email. The new email notification will allow Almac to further inform its third-party facilities about the pending shipment requests and ensure that clinical supplies are delivered quickly and efficiently to your sites and depots.

Sponsor users: How does this work?

Every time there's a pending shipment request, Almac depot users at an Almac-managed depot facility receive an email containing a depot order.

Sponsor users: What are the prerequisites for this email notification to work?

To make sure depot users at an Almac-managed depot facility get this email notification in their inbox, in Oracle Clinical One Platform, on the Depots tab, check that the Almac-managed depots are correctly defined and their Depot IDs match the exact names of the depot facilities.

Stability improvements

- [Randomization and kit stability improvements](#)
- [Integrations stability improvements](#)

Randomization and kit stability improvements

Misallocated kits can now be assigned to subjects (former known issue)

In Oracle Clinical One Platform you can now dispense kits with a **Misallocated** status to subjects that aren't randomized yet and who are not in an **Active** state. Previously, you couldn't dispense misallocated kits to subjects that weren't randomized, resulting in issues with your randomization process. (Issue **30222368**)

Integrations stability improvements

Integration files are now uploaded as expected

Integration managers: In Oracle Clinical One Digital Gateway, uploading integration files now works as expected. Previously, whenever you deleted an integration file and then re-uploaded it, you received an error message saying an integration file with the same name already exists. (Issue **29779756**)

Oracle Clinical One Platform & Oracle Clinical One Integration Hub 19.3 (September 2019)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Track kit status and location in SmartSupplies PMD](#)
We rolled out yet another integration for our sponsor users working with kits!
- [Send subject enrollment information to Veeva Vault CTMS](#)
You can now send subject enrollment information from Oracle Clinical One Platform to Veeva Vault CTMS using a new integration.
- [New report: Subject Data for CTMS](#)
We've created the Subject Data for CTMS report, which allows you to keep track of - you guessed it! - subject information.
- [Randomize subjects using the Country Blocked Fixed Stratified algorithm](#)
Good news for study designers! There's a new randomization algorithm available for designing your study and it's called Country Blocked Fixed Stratified.

Track kit status and location in SmartSupplies PMD

We rolled out yet another integration for our sponsor users working with kits!

The integration between Oracle Clinical One Platform and SmartSupplies PMD lets you automatically track the status and location of kits from your clinical inventory, making sure you always have the right amount of supplies available at your sites at all times.

What type of information can Oracle Clinical One Platform share with SmartSupplies PMD?

This integration automatically sends updates to SmartSupplies PMD whenever one of these changes occurs in Oracle Clinical One Platform:

- A kit's status is updated
- A kit's location is updated (including kits whose location is updated from one depot to another)

Sponsors: How can I connect my Oracle Clinical One Platform study with SmartSupplies PMD?

If you're interested in setting up this kit status and location workflow, reach out to your Oracle Project Manager.

Send subject enrollment information to Veeva Vault CTMS

You can now send subject enrollment information from Oracle Clinical One Platform to Veeva Vault CTMS using a new integration.

If you choose to implement this integration, you can get:

- Faster and better data monitoring when it comes to subject enrollment information.
- A unified clinical experience for all Oracle Clinical One Platform users working with subjects' enrollment information.

What type of information can Oracle Clinical One Platform share with Veeva Vault CTMS?

For example, whenever a subject is screened, screen failed, or randomized in Oracle Clinical One Platform, this status update is sent to Veeva Vault CTMS.

Sponsors: How can I connect my Oracle Clinical One Platform study with Veeva Vault CTMS?

If you want to transmit subject enrollment information from Oracle Clinical One Platform to Veeva Vault CTMS, reach out to your Oracle Project Manager.

New report: Subject Data for CTMS

We've created the Subject Data for CTMS report, which allows you to keep track of - you guessed it! - subject information.

You can run this report in Testing, Training, and Production mode to get an accurate overview of your sites and their subject related activity at all times, and send the data to your clinical trial management system in no time.

Who can run this report?

This report is typically run by a study team member. In Oracle Clinical One Platform the user who runs this report should have the the appropriate roles and rights assigned to them.

How can I get this report for my Oracle Clinical One Platform study?

Read below to learn more about what study designers and other study team members need to do before generating this report.

- [Details for study designers](#)
- [Details for study team members](#)

Details for study designers

The Subject Data for CTMS report is a little different than your regular Oracle Clinical One Platform report. There are a couple of things that you need to keep in mind before designing a study that contains this report.

Visit IDs should always be numeric

Typically, you'd use both numbers and letters to update a visit's ID. But to make sure visit IDs are correctly mapped to subjects' data for this report, visit IDs must always be written using numbers only.

Demography forms should be standard

The demography form is very important for you to map subjects' data with visit and dispensation details.

- A demography form should always be associated with the first visit (the Screening visit) in a study.
- There should be only one demography form in the study.
- Name of the form should always be "FORM_DEMOGRAPHICS" written in capital letters with an underscore character.
- A demography form should always include the following elements:
 - Subject's initials
 - Their date of birth
 - Subject's gender
 - Date of their informed consent

Want more details about how to design visits and forms? Check out this topic on how to create visits

and this topic on how to create forms.

Details for study team members

First things first, you need the right user roles and rights to run this report. Before doing anything, make sure you have one of these roles assigned to you:

- Data Manager
- Production Admin
- View Only - Support

Typically, you'd run this report in Oracle Clinical One Platform on a daily basis and download it in a TXT file format.

Since this report will be used to send subject data to another platform, there is a naming convention that must be followed. Always make sure your downloaded reports are named like this: *<the protocol number>_<your product environment>_<the vendor's name>_<date of the generated report>.txt*. For example, here's how a valid file name for the report would look like: CR-0207_UAT_ORACLE_08262019.txt.

Lastly, keep in mind these details about the way data is shown in the Subject Data for CTMS report:

- The latest reason for an action is shown in the report. For example, if a subject is screen failed, their screen failure is undone, they're withdrawn, and their withdrawal is undone - in that order - the report shows the latest reason provided for undoing their withdrawal, and enrolling them back into the study
- The Subject Data for CTMS report doesn't include data for unscheduled and repeating visits or kit replacements
- If a subject is re-randomized and has multiple randomization numbers associated with them, all randomization numbers are listed in the report
- Demographic details (such as gender or date of birth) are shown for every visit in a study
- The Subject Data for CTMS report only captures subject information at a glance for all sites within a study

Randomize subjects using the Country Blocked Fixed Stratified algorithm

Good news for study designers! There's a new randomization algorithm available for designing your study and it's called Country Blocked Fixed Stratified.

How does the Country Blocked Fixed Stratified algorithm work?

When a subject is randomized using this algorithm, Oracle Clinical One Platform selects the next treatment arm from the block assigned to the country based on strata. When a block is exhausted by a stratum group at the country, Oracle Clinical One Platform selects the next treatment arm in the next block that is allocated to the site's country. In a nutshell, this new type of randomization helps you balance treatment arms within a country.

Details for study designers

This change doesn't significantly affect your workflow, but it's worth mentioning anyway.

In the Create Randomization pop-up, there's a new option in the drop-down for the **Randomization** field. If you choose **Country Blocked Fixed Stratified**, you will have to create cohort groups, and define treatment arms next.

Stability improvements

- [Randomization and kit stability improvements](#)
Learn more about product improvements or fixed Known Issues in this section.
- [Integrations stability improvements](#)

Randomization and kit stability improvements

Learn more about product improvements or fixed Known Issues in this section.

Kit type titration can now be associated with re-randomization visit (former known issue)

Study designers: You can now associate a kit type titration with a re-randomization visit from the Assign Titration to Visit Schedule pop-up. Previously, an error sometimes occurred when you tried to associate a kit type titration with a re-randomization visit and that same kit type titration was also associated with a randomization visit on another treatment arm. (Issue: **29948880**)

Integrations stability improvements

Correct error message showing up when creating credential keys

Integration managers: In this release, when you attempt to create a credential key and its name contains a space, you will see an error message informing you that spaces are not allowed. Previously, when the names of credential keys contained a space, the error message incorrectly stated that spaces were allowed. (Issue: **29892583**)



Note:

This stability improvement applies to all integrations.

Retriever and Transporter sections in the configuration file shouldn't contain any values

Integration managers: Configuration template for the Oracle Clinical One Platform to Fisher Clinical Services integration now shows no values in the Retriever and Transporter sections, for <StudyId>, <Mode>, and <UserName>. This change applies to both the Shipment Request and Shipment Response integration configuration files. (Issue: **29803382**)

Credential key is now updated correctly for Oracle InForm

In Oracle Clinical One Digital Gateway, when you now edit an existing credential key for Oracle InForm, and click **Save**, the credential key is updated as expected. Previously, when you edited an existing credential and clicked **Save** in quick succession, an identical credential key for the same product was created. Moreover, you couldn't delete or edit any of the two credential keys afterward. (Issue **29521983**)

Investigational product names can now be written using uppercase letters

Integration managers: Now when you use different capitalization for product names in Oracle InForm or Oracle InForm Publisher, only a single product tab is created in Oracle Argus

Safety. Previously, product names with different capitalization resulted in the creation of multiple product tabs in Oracle Argus Safety.

By default, the integration applies an all-capitals rule to all product names. For instance, both product and Product are sent to Oracle Argus Safety as PRODUCT. However, you also have the option of converting the value to all lower-case letters, so product and Product are sent to Oracle Argus Safety as product.

The template for setting up Oracle InForm to Oracle Argus Safety integrations contains a default uppercase converter. If needed, you can also opt for a lowercase converter, or remove the case converter entirely.



Note:

This enhancement only applies to Oracle InForm to Oracle Argus Safety integrations.

To learn more about the case converter, check Step 5.1: Create the test integration file from the Oracle Clinical One Integration Hub User Guide. (Issue **29902781**)

Oracle Clinical One Platform 19.2.0.3 (August 2019)

- [Study Design report generates as expected](#)

Study Design report generates as expected

Study designers: The Study Design report now generates as expected when a study includes dozens of stratum groups and hundreds of questions. Previously, the report wasn't being created for such studies when you included details about the randomization design in the report. (Issue: 30215178)

Oracle Clinical One Platform 19.2.0.2 (August 2019)

- [Stability improvements](#)

Stability improvements

- [Study Design report complete for Health Sciences Support](#)
- [Study Design report only shows new names for renamed kits](#)

Study Design report complete for Health Sciences Support

Health Sciences Support team: The Study Design report now contains all expected sections. Previously, some sections about kits weren't included for users with the View Only – Support role (Issue: 30036619).

Study Design report only shows new names for renamed kits

The Visit Summary section of the Study Design report now shows only the new names for renamed kits. Previously, the report showed both old and new names for renamed kits (Issue: 30091706).

Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.2.0.1 (July 2019)

- [Integration stability improvements](#)

Integration stability improvements

Failed jobs for Almac integrations

Integration managers: Jobs related to Almac integrations now run as expected, and shipments are created correctly. Previously, the jobs for Almac integrations failed, and new shipments weren't saved to the database. (Issue 30042470)

Oracle Clinical One Platform and Oracle Clinical One Integration Hub 19.2 (June 2019)

- [What's new](#)
- [Stability improvements](#)

What's new

Check out the newest video for this release!

Want to get a quick overview of what's new in this release before diving into the details of the *Release Notes*? Watch the video below.  [Video](#)

- [Two great products - a unified experience](#)
- [Allow subjects to titrate up and down](#)
- [New notifications for your study](#)
- [Subject Queries report requires new role](#)
- [Improving the Oracle Clinical One Platform home page](#)
- [Longer subject numbers are now visible](#)
- [New rule for demographic cohort randomization designs](#)

Two great products - a unified experience

Oracle Clinical One Platform and Oracle Clinical One Digital Gateway will be released together from now on, and you can read about all the changes in a single *Release Notes*

book. This change doesn't affect any product functionality or your use of Oracle Clinical One Platform or Oracle Clinical One Digital Gateway.

The benefits?

- Oracle Clinical One Digital Gateway customers can now validate and test new releases of Oracle Clinical One Platform and Oracle Clinical One Digital Gateway at once, making the entire validation process easier and less time-consuming.
- For Oracle Clinical One Digital Gateway, there will be downtime for this release, but going forward downtime for upgrades will be minimized.

Allow subjects to titrate up and down

You can now design a study that allows subjects to titrate up or down - that is, increase or decrease their dose levels - based on input from a clinician at a site. Starting with this release, when subjects titrate, they must switch to a different kit type for the same investigational product, such as moving from a 5 mg kit type to a 7.5 mg or 2.5 mg kit type.

Titration by changing dosing frequency, such as consuming more or fewer pills per day, isn't supported in this release.

Titration is an optional feature. If the study that you're working on doesn't allow subject titration, your workflows won't change, though you might still see small interface changes. For instance:

- If you're a study designer, you'll see the button for creating kit type titration, and there are some small changes to fields when you define the dispensation schedule.
- If you review some reports, you'll see some new fields related to titration.

A couple more things you should know about titration before you keep reading: In this release, when a kit type has calculated doses defined for it, the kit type can't be titrated. And subjects can't titrate during unscheduled visits.

Ready to learn more? Keep reading for all the details about this great new feature.

- [Details for study designers](#)
- [Details for unblinded users](#)
- [Details for site users](#)
- [Details for clinical research associates](#)
- [Reporting changes](#)

Details for study designers

If you need to design a study in which subjects choose whether to titrate, you'll have a few new tasks that weren't previously part of your workflow.

Overview: Your new workflow for a study that allows titration

1. Create kit types like you do right now.
You can combine kit types for an up titration or down titration, but only if they're different kit types. In other words, you can't dispense two or more kits of the same type when subjects titrate up or down. Here's an example: Let's say a subject starts at 10 mg and can titrate up to 15 mg.

- This is not allowed: Create one kit type, 5 mg, and dispense two 5 mg kits for the 10 mg dose and three 5 mg kits for the 15 mg dose.
 - Instead, do this: Create two kit types, 10 mg and 15 mg, and dispense each for the appropriate dose.
 - Or this: Create two kits types, 5 mg and 10 mg, and dispense the 10 mg kit type for the 10 mg dose, and the 5 mg and 10 mg kit types for the 15 mg dose.
2. **New step:** Create one or more kit type titrations. In each kit type titration, you specify the lowest dose, the highest dose, and everything in between, including how subjects can change from one dose to another.
Remember that a treatment arm can only have one kit type titration. And the same kit type titration can be used for multiple treatment arms.
3. Define the dispensation schedule by dragging the starting kit type for each treatment arm to the first dispensation visit.
This step has a new workflow for studies that allow titration:
- First off, the only kit types that you should associate with visits are the kit types that subjects start on before titrating, plus any kit types that need to be dispensed and aren't included in the kit type titration.
 - Additionally, after dragging a starting kit type to a visit, you should choose to dispense the kit type **only in the first dispensation visit**, and not in any other dispensation visits. Here's why: You'll associate the kit type titration with all other dispensation visits, and the kits are dispensed based on the kit type titration. We recommend using this workflow, even if the study doesn't allow titration until later in the study, because this workflow simplifies any future protocol amendments that allow titration on additional visits.
- In addition to the workflow change we just described, there is **one small change** in the Add Kit to Visit Schedule pop-up: **Doses** was renamed to **Quantity**. The new label is the only change. You still enter the number of kits to dispense in the visit.
4. **New step:** Drag each kit type titration to the second dispensation visit (even if subjects can't titrate until a later dispensation visit). Keep reading for more details about this step.

How to: Create a kit type titration

To specify how subjects titrate up and down, you create kit type titrations. You perform this task after creating all your kit types.

Each treatment arm can have only one kit type titration, and you can use the same kit type titration for multiple treatment arms. All kit types in the kit type titration must dispense the same product.

1. On the Kits tab, click Create **Kit Type Titration**.
2. On the first page of the wizard, choose whether you're dispensing blinded or open label kits, and then specify how subjects can titrate up and down from each kit type. Delete rows for any kit types that aren't used in the kit type titration. For instance, if subjects start at 5 mg and can titrate up to 10 mg and then 10 mg, 20 mg, and 30 mg, the page might look like this:
This page includes the following titration rules:
 - a. Subject starts at the 5 mg dose and can remain on 5 mg (there is no lower dose than 5 mg, but you need to specify a kit type for every cell in the table) or titrate up to 10 mg.
 - b. Subjects on the 10 mg dose can titrate down to 5 mg or titrate up to 20 mg.

- c. Subjects on the 20 mg dose can titrate up to 30 mg or remain on 20 mg.
 - d. Subjects on the 30 mg dose can titrate down to 20 mg or remain on 30 mg (there is no higher dose than 30 mg, but you need to specify one a kit type for every cell in the table).
3. On the second page of the wizard, specify additional settings, including the allowed number of dose titrations, the minimum time between dose titrations, and what to do if a subject is on the lowest (or highest) dose and wants to go lower (or higher).

How to: Specify the visits when subjects can titrate

You choose when dose titrations are allowed while defining the dispensation schedule.

1. Drag a kit type titration to the second dispensation visit (even if subjects can't titrate until later). Keep in mind the following rules for associating a kit type titration with a visit:
 - You must associate the starting kit type for each treatment arm with the first dispensation visit before you associate the kit type titration with the visits.
 - Subjects can never titrate during the following visits:
 - Randomization
 - Study completion
 - Withdrawal
 - A scheduled visit for which the visit schedule hasn't been defined yet
2. Complete the fields on the first page of the wizard.

Tip:

We recommend selecting the **Dispense** checkbox in the leftmost column for every visit, regardless of whether they allow titration. And then for any visits don't allow titration, deselect the **Allow Titration** checkbox. That way, if a protocol amendment allows titration on other visits in the future, all you have to do is select **Allow Titration** for the visit and then follow the standard workflow for updating the study version that's assigned to each site.

3. Complete the remaining pages in the wizard. The wizard has one page for each kit type in the kit type titration.

How to: View details about titrations

- To view details about allowed titrations for each kit type, point to the titration icons to the right of the kit type.
- To see whether subjects can titrate during a visit, look for the titration icon on the visit.
Keep in mind that a few settings determine whether each subject can change doses in any given visit. If, for example, the subject has already reached the maximum number of dose changes in the study, the subject won't be able to change doses, even if the dispensation schedule allows for dose changes in a given visit.

- To see details about the kit type titrations associated with each treatment arm, click a visit with the titration icon on it.
 - To edit the dispensation schedule for individual kit types, click the plus sign for the treatment arm.
 - To edit the dispensation schedule for kit type titrations, click the pencil button on the treatment arm.

Details for unblinded users

Your changes for titrations consist of a single warning message that you'll probably never see.

You'll see the message only if you try to manually assign a randomization number to a subject when all of the following circumstances are true:

- The study allows titrations.
- The new randomization number that you assign to the subject is for a different treatment arm than the subject is currently on.
- The subject has already been dispensed at least one kit.

You probably won't manually change a subject's treatment arm mid-study, but if you do, you need to know that the subject won't be able to receive any more kits during the study. And that's exactly what the warning message tells you.

Details for site users

When a study allows or requires a subject to titrate, you'll see some new pop-ups and might be called upon to make a decision. Additionally, there's a new rule to be aware of if you destroy kits on site. Keep reading for more details.

New process for dispensing kits

When dose titrations are allowed for a study, visit, and subject, you'll be asked during dispensation whether to titrate. For an open label study or dispensation event, the kits the subject received last also appear.

When the subject maintains their dose levels

The Dispense Kits pop-up shows you the kits to dispense, just like before.

When the subject titrates, and the study allows the change

The Dispense Kits pop-up shows you the kits to dispense, just like before.

When the subject tries to titrate, but the study doesn't allow the change

You might be told that the choice isn't allowed, and you might be allowed to dispense on the subject's current dose. Talk to your CRA to get details about what you should expect for each study you're working on.

New rule if you destroy kits onsite

When a study allows titrations and requires kit reconciliation, don't mark the last kits that were dispensed as destroyed until a subject receives their next kits. You would probably never do this, but if you did, Oracle Clinical One Platform wouldn't be able to dispense kits at the subject's next visit.

Reporting changes

When you dispense kits for a subject and click Print Dispensation Information from the Dispense Kits pop-up, the report Subject Kit Dispensation report now contains two new fields:

- At the top of the report, the new **Visit Title** field displays the name of the visit.
- In a new column, **Titration**, one of the following values appears for each kit: N/A, Up, Down, or Maintain.

Details for clinical research associates

There's just one new rule that you need to know about, and it's applicable only when a study allows titrations and requires kit reconciliation. Here is the rule: Don't mark the last kits that were dispensed as destroyed until a subject receives their next kits. It's unlikely that you'd ever mark kits as destroyed before subjects receive their next kits, but if you do, Oracle Clinical One Platform won't be able to dispense kits at the subject's next visit.

Reporting changes

Changes to the Study Design report

You'll see these changes in the Study Design report only for studies that allow titrations. Existing studies without titrations won't see any changes to the Study Design report.

- The Study Design Summary section now includes information about kits that were dispensed as a result of titration.
- The fields that you specify when you create a kit type titration now appear in the new Kit Type Titrations section.
The report contains two tables of information for each kit type titration. One table contains titration rules (how subjects can titrate up and down), and the other contains titration settings.
- In the Kit Dispensation section, there is now one table for each visit so that you can see any titration activities for a given visit.
Both the kit types and the kit type titrations that are assigned to a given visit appear.

Changes to the Kit Dispensation report

The Kit Dispensation report, which is available to site users from the Dispense Kits pop-up and to various users from the Reports page, now contains a new column, **Titration**. One of the following values appears for each visit: N/A, Up, Down, or Maintain.

New notifications for your study

Being aware of what's going on with subjects during their visits is crucial. Sometimes, problems may arise in the screening process or during visits. To improve the way subjects are monitored, a new set of notifications is available. For more details, check the table below.

Notification	Created when...	Available for this role
Subject screening	A subject is successfully screened at a site that you're assigned to.	Subject Notifications
Subject screening failed	A subject's screening fails at a site that you're assigned to.	Subject Notifications
Subject visit completed	A subject successfully completed a non-dispensation or optional visit at a site that you're assigned to.	Subject Notifications
Subject visit completed with errors	A subject completed a non-dispensation or optional visit at a site that you're assigned to, but one or more questions have errors.	Subject Notifications

- [Details for study managers](#)
- [Details for site users](#)

Details for study managers

The change is fairly easy to cover for study managers. In all three modes (Testing, Training, and Production), there's a new column for Visit Settings that allows you to set notifications for certain visits that subjects complete (or not).

Here's how it goes:

1. On the Home page, click the study settings button on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Subject Settings** tab.
3. Along the top, select **Testing Settings**, **Training Settings** or **Production Settings**, depending on the mode where you want work.
4. Scroll down to Visit Settings, and see the new column **Send Visit Notification**.
5. Select an option to allow study team members and site users to receive notifications for subjects completing their screening, non-dispensation, and optional visits.

If you have the appropriate roles, according to your study's settings, you will be able to receive notifications every time a subject was screened or completed a non-dispensation or optional visit, including any errors that might have occurred.



Note:

Failure notifications also include a reason for failure, so you can find the right solution on time. And more information on the subject notification settings can be found in the Study Design report, under the Subject Settings section.

Details for site users

The change here is simple. If you have the appropriate roles, according to your study's settings, you will be able to see these notifications for the study that you're assigned to.

1. On the Home page, click the notification button on a study.
2. Filter your view as needed.
3. Click one of the new notifications to view its details.

 **Note:**

A blue circle appears to the left of an unread notification.

- **Subject screening:** when a subject has been screened or has failed screening.
- **Subject visit complete:** when a subject has completed a non-dispensation or optional visit (with errors or not).

Subject Queries report requires new role

This change only affects CRAs, data managers, and study managers. From now on, you can run the Subject Queries report only if you have the Sponsor Query Manager user role.

Improving the Oracle Clinical One Platform home page

An efficient home page is a better home page.

We've made some changes to the Oracle Clinical One Platform home page that we're sure will make your life easier.

We fixed some performance issues so the Home page loads faster. Additionally, a new search bar lets you type a study's name and find it quickly. This new search field helps you find a study in a couple of seconds, without having to scroll to find the study that you want.

Longer subject numbers are now visible

This may be a small change, but we thought it might matter to you.

The width of the Subject column is now increased throughout the product to make sure longer subject numbers (containing 10 digits, for example) can fit in.

New rule for demographic cohort randomization designs

It's true, there's a new rule in place for study designers. From now on, you must have at least one treatment arm defined for each cohort group before you define randomization. If cohort groups don't have at least one treatment arm defined for each group, you won't be able to assign demographic cohort randomization designs to your visits.

Stability improvements

- [Site users and subject data stability improvements](#)
- [Form and visit stability improvements](#)

- [Report and notification stability improvements](#)
- [Oracle Clinical One Platform integrations stability improvements](#)

Site users and subject data stability improvements

Submit button no longer grayed out for creating a query (former known issue)

The Submit button is no longer grayed out when you create a query. Previously, the button was sometimes grayed out when you created a query but didn't enter a comment, and the button remained grayed out even after you entered a comment. (Issue: 29016019)

Form and visit stability improvements

Default Reference Code can be edited for an Age question (former known issue)

Study designers: You can now edit the default Reference Code for Age questions. (Issue: 28679613)

Report and notification stability improvements

Last Query State filter works fine for Subject Queries report (former known issue)

In a previous release, we reported a known issue because some sponsor users couldn't run the Subject Queries report. The workaround that we recommended is in fact the new requirement: Sponsor users must have the Sponsor Query Manager role to run the report. (Issue: 29496241)

Subject Queries report now showing data (former known issue)

Users who run the Subject Queries report: When you now run a report containing more than 5000 records the HTML and PDF outputs show all of the columns in that reports. (Issue: 29310619)

Oracle Clinical One Platform integrations stability improvements

Scheduled jobs now run according to your settings (former known issue)

Integration managers: Scheduled jobs now run correctly, according to your selected weekdays. Previously, scheduled jobs ran one day late instead of following the selected weekdays in Oracle Clinical One Digital Gateway.

Retracted workaround: You no longer have to schedule jobs one day early to make sure the integration is running during the right days. (Issue: 29553544)



Note:

This change does not affect the Oracle InForm to Oracle Argus Safety integration.

First and last name displayed as sign-in details

Integration managers: This fix is part of the bigger change for releasing Oracle Clinical One Digital Gateway at the same time with Oracle Clinical One Platform. We want to make sure users have a unified experience and that also impacts the user interface. So from now on,

when you sign in Oracle Clinical One Digital Gateway, you see the same sign-in details as in Oracle Clinical One Platform: your last and first name. Previously, you could see your email address. (Issue: 29425676)

Scheduled jobs are no longer blocked by simultaneous job executions (former known issue)

Integration managers: From now on, when multiple job executions happen within the same integration, at the same time, scheduled jobs after that will no longer be blocked. Previously, when that happened, scheduled jobs ended up being blocked.

Retracted workaround: You no longer have to contact Oracle Support to make sure all jobs within an integration are successfully executed. (Issue: 29758518)



Note:

This change does not affect the Oracle InForm to Oracle Argus Safety integration.

Screening failure time now appears in a third-party EDC system (former known issue)

Site users: From now on, when a subject fails the screening process in Oracle Clinical One Platform, the time is populated as expected, along with the date of the screening failure. (Issue: 29273716)

Hourly scheduled jobs now run correctly (former known issue)

Integration managers: From now on, if you schedule jobs to run once every one hour, the schedule is working as expected. Previously, hourly scheduled jobs ran once every 5 minutes, instead.

Additionally, if you want to schedule a job to run once every 5 minutes, for example, you can do that, as well. There's a new drop-down list with predefined values shown in either minutes or hours, ranging from 5 minutes to 12 hours.

Retracted workaround: You no longer have to contact Oracle Support to make sure all jobs run as scheduled. (Issue: 29778314)



Note:

This change does not affect the Oracle InForm to Oracle Argus Safety integration.

Protocol names with underscores now allowed

Integration managers: When setting up a Fisher to Clinical One integration (using the Shipment Response integration file) you can now use the underscore character ("_") for protocol names.

Previously, study names containing underscores didn't work in Oracle Clinical One Digital Gateway. (Issue: 29867764)

Integrations with two depot IDs in the same country now work properly

Integration managers: For Clinical One to Fisher integrations, the Request Shipment integration file now supports two different Depot IDs for Fisher depot facilities in the same country.

Previously, this functionality worked but you had to manually edit the original integration file to remove single quotes that were incorrectly added around depot IDs. (Issue: 29777313)

Oracle Clinical One Platform 19.1.0.2 (May 2019)

- [What's new](#)

What's new

Study Design report contains correct kit descriptions

The Study Design report now contains the correct descriptions for all kit types. Previously, the older description of a kit type sometimes appeared in the report, even after you saved your changes to the kit type.

To see the correct kit descriptions in the report, just run the Study Design report after the system update.

Email notifications sent only one time

Email notifications are now sent only one time. Previously, multiple instances of email notifications were sometimes sent.

Oracle Clinical One Digital Gateway 1.3 (May 2019)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Oracle Clinical One Platform now integrates with Fisher Clinical Services](#)

Oracle Clinical One Platform now integrates with Fisher Clinical Services

Last year, we automated some steps in the life cycle of a shipment in Oracle Clinical One Platform for users who distributed investigational products using Almac. This year, we're rolling out the same integration for Fisher Clinical Services, another global depot network. As for the benefits, this is yet another time-saving feature for clinical supply managers and depot users.

Remember that this integration can be used for all types of shipments: the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Sponsors: How can I connect my Oracle Clinical One Platform study with Fisher Clinical Services?

Reach out to your Oracle Project Manager if you're interested in setting up this shipment workflow. The Oracle Services team will define the integration between your Oracle Clinical One Platform study and Fisher Clinical Services.

Clinical supply managers and depot users: How can automation help me?

You'll see these changes in Oracle Clinical One Platform only after the Oracle Services team sets up a study so that it's connected with the Fisher Clinical Services network. These changes don't affect site users.

Want to know more about how this workflow affects your studies? See the table below.

Activity in the study	Activity that is now automated in Oracle Clinical One Platform
A new shipment is raised.	The status of the shipment changes to Pending .
The depot fulfills a shipment.	The ship date is set, and the status of the shipment changes to In Transit .



Note:

If you need to update a shipment after the shipment request has been sent to the depot, you must contact Fisher Clinical Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot.

Stability improvements

- [Oracle Clinical One Platform to Oracle InForm integration stability improvements](#)
- [Oracle InForm to Oracle Argus Safety integration stability improvements](#)
- [Interface stability improvements](#)

Oracle Clinical One Platform to Oracle InForm integration stability improvements

Jobs now fail immediately when the time is incorrectly set (29513814)

Integration managers: Jobs with correct time intervals are now validated and allowed to run in Oracle Clinical One Digital Gateway, while jobs with invalid start times fail immediately, letting you know early on that there are problems with server clocks.

Previously, server clocks weren't synchronized so jobs would run during incorrect time intervals.

Jobs can be manually resent without triggering already sent jobs (29480218)

Integration managers: You can now resend jobs for a Oracle Clinical One Platform to Oracle InForm integration without causing already processed data to be resent to Oracle InForm.

Previously, when you manually resent jobs with null correlation IDs, Oracle Clinical One Digital Gateway set an incorrect time interval for the next scheduled integration. In other words, jobs that were already submitted had to run again, although they shouldn't have.

Data is now sent to Oracle InForm as expected (29480283)

Integration managers: When OnlyRandomized is selected for your integration, data is now sent to Oracle InForm as expected, preventing jobs from being resent before randomization.

Previously, if you tried to resend a blocked job prior to randomization, data for the job was sent, even though it shouldn't have been.

Oracle Clinical One Platform 19.1.0.1 (April 2019)

- [What's new](#)

What's new

Duplicate entries no longer captured in Subject Data report

After the system update, the Subject Data report will have no new duplicate entries, which occurred rarely prior to the system update. You might still see duplicate entries in the Subject Data report if they were created prior to the system update. (29593627)

Oracle Clinical One Platform 19.1 (March 2019)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Randomize into demography cohorts](#)
- [Subjects are now sorted](#)
- [Search for subjects](#)
- [Include an audit trail in your reports on queries](#)
- [Small changes to the user interface](#)
- [Changes related to assigning training](#)
- [New look and feel for documentation](#)

Randomize into demography cohorts

Starting with the previous system update, you could create adaptive cohorts. And now with this system update, you can create demography cohorts.

Adaptive cohorts let you open treatment arms in a gradual manner to measure safety and efficacy as the study progresses. Demography cohorts, on the other hand, are similar to stratum groups: They let you create population groups according to demographic criteria, such as age. One advantage that demography cohorts provide that stratum groups don't is that you can set limits on each population group. Additionally, with demography cohorts, you can open and close each cohort based on the results obtained during the study conduct period. You can also adjust the limits for each population group throughout the study if you need to.

- [Details for study designers](#)
- [Details for study managers](#)
- [Details for clinical supply managers and randomization list managers](#)
- [Details for sites](#)

Details for study designers

The process for building a study with demography cohorts is similar to building a study with adaptive cohorts and creating stratum groups for randomization. If you're familiar with those workflows, you're nearly ready to create demography cohorts.

If you're not familiar with those workflows, keep reading for all the details.

How to: Create questions that will be used to create cohorts

When creating the forms, make sure that the question(s) that you'll use to create your demography cohorts meet one of the following requirements:

- A required Number or Age question with a **Range** validation rule for which **Include Value in Range** is selected.
- A required Drop-down question with a **Select Exactly** validation rule that allows **1** selection.

How to: Create a randomization design that uses demography cohorts

A randomization design that uses demography cohorts has three pages in the wizard:

- On the first page, choose **Demography** from the **Cohort** drop-down.

Create Randomization

1 Randomization Design 2 Cohorts

* **Title** Demography cohort randomization

Description
Description

* **Type** Unblinded

Cohort Demography

* **Randomization** Central Stratified

When you choose **Demography**, the **Randomization** drop-down has fewer options: Only stratified randomization options are available.

- On the second page, create your cohorts by clicking the plus sign in the upper-right. This workflow is similar to creating stratum groups for stratified randomization designs. Enter a name for each cohort, select questions that will be used to create population groups, and specify the ranges or values for each cohort.

Create Randomization

Randomization Design 2 Cohorts 3 Treatment Arms

Demographics

All eligible questions from this form are included in one or more groups.

Male 18-45

Age: 18 to 45

Gender: Male Female Chose not to identify

Female 18-45

Age: 18 to 45

Gender: Male Female Chose not to identify

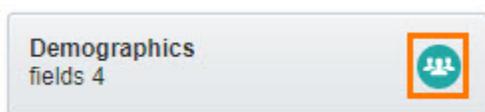
< Back Cancel Next >

- On the third page, specify the appropriate treatment ratio for each cohort you created.

Cohorts	10 mg dose	5 mg dose	Placebo
Male 46-65	1	1	1
Female 46-65	1	1	1
Male 18-45	2	2	1
Female 18-45	2	2	1

How to: Determine whether a question is used in a cohort

You'll see an icon on the form, just like you do when a question is used in an adaptive cohort or stratum group.



How to: Add the randomization design to a visit

Just drag the randomization design to a visit, the same as always. Keep in mind these rules:

- Only one randomization design in the study can randomize into cohorts.
- A randomization design with cohorts must be the first randomization event in the study.

New color coding

A randomization design that uses demography cohorts is labeled as a Demography cohort with a teal icon.

Demography cohort randomizat...

Visit: None (Drag to visit)
Type: **Unblinded**
Cohort: **Demography**
Randomization:
Central Stratified
Cohort Groups: 4
Randomization Factors: 2

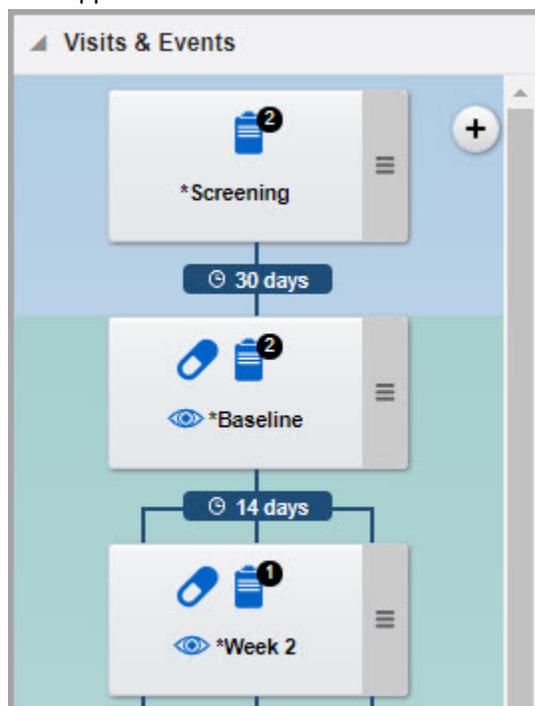
10 mg dose A
ORS-123 10 mg

5 mg dose B
ORS-123 Monad 5 mg

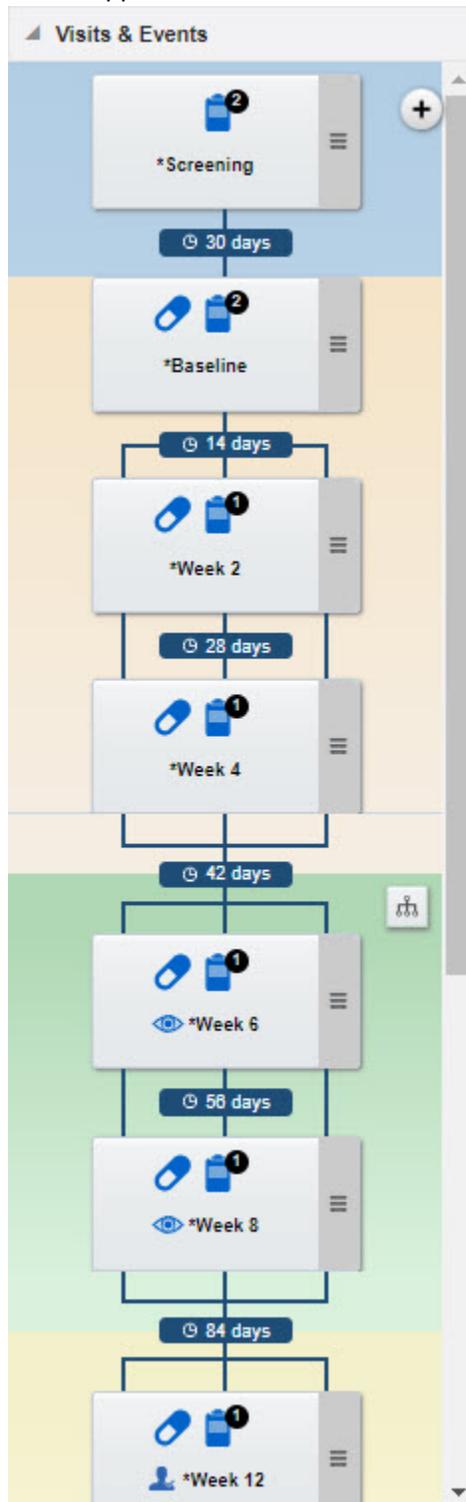
Placebo C
ORS-123 Matching placebo

Additionally, you'll notice new color coding in Visits & Events after you add randomization to visits:

- Blue appears behind unscheduled visits.
- Teal appears behind randomization with demography cohorts.



- Purple appears behind randomization with adaptive cohorts.
- Orange appears behind the first non-cohort randomization.
- Green appears behind the second non-cohort randomization.
- Yellow appears behind the third non-cohort randomization.



Need to add cohorts later?

Just make sure you finalize the cohorts before moving the study version to Approved on the Home page because some fields for a randomization design become read-only after a study design is approved.

However, the following changes are allowed after a study version has been approved:

- Adding cohorts and specifying their treatment ratios.
- Changing the treatment ratios of existing cohorts, but you can set them only to 0 or blank. For example, you can change a value of 1 to 0, but you can't change 1 to 2.

Report updates

You now can view details about any cohorts you create and their treatment ratios in the Study Design report.

Details for study managers

The process for opening and closing demography cohorts is the same as that for adaptive cohorts. If you already know how to open and close adaptive cohorts, you are already prepared for opening and closing demography cohorts.

Your cohort-related tasks are all on the Subject Settings page, below Enrollment Settings. Here, you can:

- Open and close enrollment for cohorts.
- Set limits and notification levels.

You'll see the new options after cohorts have been created in the randomization design and after the study version has been moved to the appropriate mode (for instance, you'll see the cohorts for Testing mode after the study version has been moved to Testing on the Home page).

Enrollment Open/Closed	Screening Limits	Randomized Limits	Notification
<input checked="" type="checkbox"/> Study Total	1350	1000	20%
<input checked="" type="checkbox"/> Site Total			
Cohort			
<input checked="" type="checkbox"/> Female 18-45		25	
<input checked="" type="checkbox"/> Female 46-65		25	
<input type="checkbox"/> Male 18-45			
<input type="checkbox"/> Male 46-65			

Cohort-related notifications

A notification is sent when the specified notification level (for example, 80% of subjects randomized into a cohort) is met.

Managing cohorts

- All cohorts are closed by default. Make sure you open at least one cohort before the study goes live, or **sites won't be able to randomize subjects**.
- After the limit is reached for a cohort, sites won't be able to randomize subjects until you open the next cohort or increase the limit.

Report updates

You now can enrollment limits in the Study Enrollment report.

Details for clinical supply managers and randomization list managers

If you've created a randomization list for an adaptive cohort, you are already prepared for creating a randomization list for a demography cohort. The only new change is a new cohort filter on the Randomizations tab.

If you haven't created a randomization list for an adaptive cohort, keep reading for all the details.

Randomization in a cohort study

During randomization, subjects are assigned the first available randomization number associated with an open cohort. This rule is true whether one, two, or more cohorts are open.

Changes for randomization lists

- **Generating randomization lists**
When you generate a randomization list for a randomization design with cohorts, for the Length field, choose **Number of Blocks per Cohort**, and then specify the number of blocks required for each cohort.

Generate Randomization List

Progress: 1. Select Randomization (checked) | 2. List Settings (active) | 3. Finish

* Title: Randomization List v1

Description: [Empty]

* Mode: Testing

* Multiplier for Blocks: 4

* Starting Number: 1

* Length: Number of Blocks per Cohort (4)

- **Uploading randomization lists**
If you need to upload a randomization list for a cohort study, make sure the list defines the cohort for each randomization number. When you upload the file, you'll be prompted to identify and column with cohort information. Then you'll

map each cohort in the file to the cohorts you created in Oracle Clinical One Platform.

- Viewing the cohort for each randomization number
On the Randomizations tab, the **Cohorts** column appears when a randomization list was created for a randomization design with cohorts. The Cohorts column lists the cohort associated with each randomization number.

There's also a new **Filter by Cohort** option above the table to help you find randomization numbers for a single cohort more quickly.

Reporting changes

In the Randomization List (Unblinded) report, you can view the cohort associated with each randomization number. This information appears in the **Cohort** column.

Details for sites

This enhancement is easy for you: There aren't any changes that affect you.

Subjects are now sorted

Finding a subject is now easier thanks to sorting! Subjects are now grouped by site and sorted on the Subjects page. The subjects who were added most recently appear at the top of the list.

Sites are sorted in alphabetical order (or in numeric order, for sites with numeric names).

Transferred subjects

Even if you have access to only one site, you will still see subjects grouped into multiple sites if any subjects transfer to your site. Transferred subjects are grouped according to their original site, and all subjects who enroll at your site are grouped together.

	Subject	Next Visits	Previous Visits		
	AFP-03 Active	Week 8 (28-Sep - 04-Oct)	Week 6	Week 4	Week 2
	AFP-02 Active	Week 8 (28-Sep - 04-Oct)	Week 6	Week 4	Week 2
	AFP-01 Withdrawn	Withdrawal	Baseline	Screening	
	CD-10 Active	Week 8 (01-Oct - 07-Oct)	Week 6	Week 4	Week 2
	CD-09 Active	Week 8 (08-Oct - 14-Oct)	Week 6	Week 4	Week 2
	CD-08 Active	Week 8 (05-Oct - 11-Oct)	Week 6	Week 4	Week 2

Search for subjects

Finding the subject you're looking for just got easier because you now can search for subjects by subject number.

Just click the Search field above the table of subjects, enter the subject number, and press Enter.

Include an audit trail in your reports on queries

Tracking answers to your questions is now easier with the new audit trail filter included in the **Subject Queries** report.

What does that mean?

It means that, from now on, if you include the audit trail filter in your reports, you will see each query's history, from the time it was first opened up until its last state.

You can run this report if you have one of the following roles:

- CRA
- Data Manager
- Site Manager
- Study Manager
- Sponsor Query Manager
- Site Query User
- View Only - Support

Small changes to the user interface

You might notice a few subtle design changes in the user interface. For example, pages in wizards are now numbered. The changes are minor and don't impact your workflow.

Changes related to assigning training

Previously, changes related to assigning and managing training for Oracle InForm, Oracle IRT, Oracle Central Designer, Oracle Central Coding, and Oracle InForm User Management Tool were included in the *Release Notes* for Oracle Clinical One Platform. Starting with this system update, the changes will be included in the *Release Notes* for HS Learn - Manager.

Reason for the change

If your organization uses Oracle Clinical One Platform only for assigning training (and not for study design and deployment), you'll see **HS Learn - Manager** in the upper left instead of **Clinical One** after this update. The new product name helps you better identify the product you're working in and get any support you might need. More information is in the *Release Notes* for HS Learn - Manager.

If your organization uses Oracle Clinical One Platform both to design and deploy studies and to assign training, you won't see any name changes.

Where to find the *Release Notes* for HS Learn - Manager

You can find the *Release Notes* for HS Learn - Manager on the Oracle Help Center pages for Oracle InForm, Oracle IRT, Oracle Central Designer, Oracle Central Coding, and Oracle InForm User Management Tool starting in late March.

New look and feel for documentation

The next time you click the Help link within Oracle Clinical One Platform, you might notice a few changes on the [Oracle Help Center pages](#), including a new look and feel for the site and many of the guides. It's still the same great content you've come to depend on, just in a new format. And if you like being able to print paper copies, you're in luck: PDFs are now available for most books on the [Books page](#).

All your old bookmarks should still work, but if you run into any issues, feel free to reach out for help at clinical_one_doc_feedback_us_grp@oracle.com.

Stability improvements

- [Randomization and kit stability improvements](#)
- [Shipment and supply stability improvements](#)
- [Site users and subject data stability improvements](#)
- [Report and notification stability improvements](#)

Randomization and kit stability improvements

Re-Randomization field hidden as expected (former known issue)

Randomization designers: The Re-Randomization field is now hidden when it should be in the randomization wizard. Previously, when you created a new Draft version of a study based on an Approved version for a study that randomizes subjects into cohorts, the Re-Randomization field sometimes appeared in the wizard. (Issue: 29024770)

Clearer randomization error

Randomization list managers: An error message has been rewritten for clarity. When a study uses fixed randomization, and you try to assign a subject to a randomization number in a block that hasn't yet been assigned to the subject's location (such as country or site), the message now informs you that you need to first assign the block to the subject's location.

Decimal value allowed for the number of units in a kit

Study designers: Now you can specify a decimal value for the number of units in a kit.

Specify this value when you create a kit type in the Units Per Kit field. You can enter a decimal value with up to 2 places after the decimal (for example, 1.75). Values that are less than 1 are also allowed (for example, .75).

Site users: When you reconcile kits and specify the number of returned and missing units, you now can enter a decimal value with up to 2 places after the decimal.

No more duplicate kits in site inventory

Clinical supply managers: A kit that is added to more than one shipment in Oracle Clinical One Platform now appears only one time in the site's inventory. Previously, when a kit was part of the packing list for a kit but didn't make it into the shipment and you added the kit to the packing list for another shipment, the kit appeared two times in the site's inventory.

Long kit descriptions now show up entirely in a subject's history (former known issue)

Site users: In Subject History, when you now point to a kit with unblinded distribution, the full description appears in the tooltip as expected. Previously, if the kit has a very long kit description, sometimes the first few lines of the kit description were cut off.

Study designers: the workaround for this issue is retracted, so you don't have to do anything from now on. (Issue: 28091949)

No more duplicate kits in site inventory

Clinical supply managers: A kit that is added to more than one shipment in Oracle Clinical One Platform now appears only one time in the site's inventory. Previously, when a kit was part of the packing list for a kit but didn't make it into the shipment and you added the kit to the packing list for another shipment, the kit appeared two times in the site's inventory. (Issue 29284575)

Shipment and supply stability improvements

Initial shipments raised when activating more than one site (former known issue)

Clinical supply managers: Initial shipments are now created as expected when you activate two or more sites at the same time.

Retracted workaround: You no longer need to activate sites one at a time. (Issue: 28672566)

Site users and subject data stability improvements

Returned Units correct in Inventory Management sidebar

Site users: Now when you reconcile more than one kit, the Returned Units that you enter appear as expected in Inventory Management, which is on the right on the Inventory tab.

Started Screening visits can be finished

Site users: If you started a Screening visit for a subject but didn't finish it, and then a new study version with one or more updated forms for the Screening visit was assigned to your site, you now can finish the Screening visit for the subject. Previously, your changes to the Screening visit weren't saved, and you were told to refresh and retry.

Oops error while saving special characters no longer appears (former known issue)

Site users: You can now copy and paste special characters when entering data in a form, and you can also save it. Previously, you could only use allowed characters (typically either numbers, letters, or both), otherwise you couldn't save the change in the form. (Issue: 29021232)

Report and notification stability improvements

Randomization List (Unblinded) report includes stratification details

Statisticians: The Randomization List (Unblinded) report now includes subject stratification data. (Issue 29205790)

Oracle Clinical One Digital Gateway 1.2.1 (March 2019)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Send randomization and dispensation times in UTC or site's time zone](#)
- [More informative job errors](#)

Send randomization and dispensation times in UTC or site's time zone

You can now choose the time zone to use for time and date information that is sent to Oracle InForm or a third-party EDC system. Randomization and dispensation information can use either of the following time zones:

- UTC time
- Each site's time

This option is available for the following integrations:

- Oracle Clinical One Platform to Oracle InForm integration
- Oracle Clinical One Platform to third-party EDC system integration

To choose the time zone that you want Oracle Clinical One Digital Gateway to use, in the configuration file for the integration, configure the `UseSiteTimeZone` setting. By default, `UseSiteTimeZone` is set to `True`. To use UTC time, set `UseSiteTimeZone` to `False`.

More informative job errors

In an Oracle Clinical One Platform to Oracle InForm integration or an Oracle InForm to Oracle Argus Safety integration, the error messages in Oracle Clinical One Digital Gateway for failed jobs now contain more information to better assist you as you troubleshoot. Each error message now includes:

- **Error description:** A clear description of exactly what caused the job to fail. The error description includes as much context as possible to help you identify and locate the problematic data.

- **Remediation suggestion(s):** Whenever possible, each error message includes suggestions for resolving the issue that caused the error.



Note:

Enhanced error messages are only available for jobs that you ran after upgrading to release 1.2.1.

Stability improvements

- [Oracle Clinical One Platform to Oracle InForm integration stability improvements](#)
- [Oracle Clinical One Platform to third-party EDC system integration stability improvements](#)
- [Interface stability improvements](#)

Oracle Clinical One Platform to Oracle InForm integration stability improvements

No more timeout errors when uploading a file for multiple study versions

Integration managers: You now can enable a Oracle Clinical One Platform to Oracle InForm integration with several study versions without encountering a timeout error. (Issue 28989801)

Default setting for SubmitToLockOrFrozenForm in the Data Update template is now False

Integration managers: For the Oracle Clinical One Platform to Oracle InForm integration, the default value of SubmitToLockOrFrozenForm in the Data Update template is now False. This change reduces the likelihood of unintentionally updating a frozen or locked form. (Issue 29019392)

ScreeningPhase1 and ScreeningPhase2 mappings are sent for screening success or failure

Integration managers: For an Oracle Clinical One Platform to Oracle InForm integration, when ProcessScreenFailedEvent and EnrollOnOrsScreenFailure are set to True, Oracle Clinical One Digital Gateway now sends both ScreeningPhase1 and ScreeningPhase2 mapping data. In previous releases, Oracle Clinical One Digital Gateway only sent ScreeningPhase2 data for subjects who were already screened or enrolled in the Oracle InForm study.

A concatenated string of visit names no longer appears for a mapped value on a repeating form

Integration managers: When you map the DispensationKits.Visit field to a question on a repeating form, the visit name now correctly appears in the mapped field in Oracle InForm. In previous releases, a concatenated string of the visits that each form instance existed in was sent to Oracle InForm.

For example, in previous releases, if you mapped the DispensationKits.Visit field to a question on the Concomitant Medications form, which existed in multiple instances of

the Baseline visit, the value that appeared in the item question in Oracle InForm might have been **Baseline,Baseline** instead of the question value. In release 1.2.1, the value that appears in the item question in Oracle InForm is **Baseline**.

Oracle Clinical One Platform to third-party EDC system integration stability improvements

Questions without data no longer receive measurement units (Former Known Issue)

Site users: When a Oracle Clinical One Platform user clears the data for a question with unit information, the unit information is now correctly cleared in the integrated third-party EDC system. (Issue 29285477)

ReasonCodeList mapping values in the Subject Complete template are now correct (Former Known Issue)

Integration managers: The codelist values that appear in the ReasonCodeList mapping in the Subject Complete template are now correct. The values are:

- Subject completed in error
- Other

Retracted workaround for integration managers: For new integrations, you no longer need to modify the ReasonCodeList mapping so that it contains the expected values. (Issue 29314794)

Subject withdrawal visit data now appears as expected

Site users: When you withdraw a subject from your study in Oracle Clinical One Platform, the data from the withdrawal visit now appears as expected in the integrated third-party EDC system. In the previous release, the date and reason for withdrawal appeared, but the withdrawal visit data did not. (Issue 29276492)

Interface stability improvements

Better tip message for monitoring failed jobs

Integration managers: On the Home page, when you click the row of an integration with a failed status, the tip text is now more useful. The text tells you to open a report category rather than a subject category. (Issue 28760639)

Only one inactivity timeout pop-up window appears at a time

Integration managers: When your Oracle Clinical One Digital Gateway session ended due to inactivity, you now see a single pop-up that alerts you that your session is over. In previous releases, an additional pop-up appeared, and incorrectly stated that your session would end in two minutes.

Oracle Clinical One Digital Gateway 1.2 (February 2019)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Oracle Clinical One Platform now integrates with third-party EDC systems](#)

Oracle Clinical One Platform now integrates with third-party EDC systems

Oracle Clinical One Digital Gateway now allows you to configure and manage study-level integrations between Oracle Clinical One Platform and a third-party EDC system. The integration behaves in a similar way as the Oracle Clinical One Platform to Oracle InForm integration in that data flows from Oracle Clinical One Platform to the third-party EDC system, based on the configuration settings you specify in the Oracle Clinical One Platform to EDC template that you want to use. Oracle Clinical One Digital Gateway then transforms Oracle Clinical One Platform data in to CDISC ODM version 1.3 format for use with your third-party EDC system.

You can send the following categories of data to a third-party EDC system:

- Code Break
- Kit Replacement
- Randomization
- Screening
- Subject Complete
- Subject Withdrawal
- Visit Complete

See [Manage an integration](#) for more detailed descriptions of the categories of data that you can send.

First steps

If you are interested in this integration, please reach out to your Oracle project manager for additional information and guidance.

Stability improvements

- [Oracle InForm to Oracle Argus Safety integration stability improvements](#)

Oracle InForm to Oracle Argus Safety integration stability improvements

Deletion of the SAE form is now recognized by Oracle Argus Safety (Former Known Issue)

Integration managers: The HS_TRUE_FALSE codelist now includes the following additional mapping for nullification, and if a user deletes the Serious Adverse Event form in Oracle InForm, the pending E2B file in Oracle Argus Safety now shows up as a nullification. (Issue 28806112)

```
<Entry Source="TRUE" Description="True" Target="1"/>
```

Retracted workaround: For new integrations, integration managers no longer need to manually add the mapping for nullification to the HS_TRUE_FALSE codelist.

Pending E2B screen now shows the correct study drug (Former Known Issue)

Oracle Argus Safety users: When you specify concurrent medications, Oracle Clinical One Digital Gateway now correctly generates the E2B file for Oracle Argus Safety so that the correct drug appears as the study drug on the Pending E2B screen in Oracle Argus Safety. (Issue 28925428)

The narrative, medhidExtension, and testunit mappings are now correct in the template (Former Known Issue)

Integration managers: The mappings for the following fields are now correct in the Oracle InForm to Oracle Argus Safety integration template. (Issue 28931266)

- narrative
- medhidExtension
- testunit

Retracted workaround: For new integrations, integration managers no longer need to do the following:

1. Populate the values for the HS_YES_NO_UNKNOWN codelist with the values that are being sent for the takenPreviouslyAndToleratedCode field.
2. Change

```
<field>  
  <a>takenPreviouslyAndToleratedCode.value</a>  
  <b>takentoleratedExtension.content</b>  
</field>
```

to

```
<field custom-  
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.DefaultCodeLis  
tMapper" custom-converter-param="INTHUBCODELIST~HS_YES_NO_UNKNOWN">  
  <a>takenPreviouslyAndToleratedCode.value</a>  
  <b>takentoleratedExtension.content</b>  
</field>
```

Link breaks and tabs correctly appear in the narrative field (Former Known Issue)

Oracle Argus Safety users: Line breaks and tab characters now appear as expected in narrative fields that are sent from Oracle InForm to Oracle Argus Safety. As a result, the fields are easier to read, and you no longer need to manually reformat them. (Issue 28925367)

Retracted workaround: For new integrations, Oracle Argus Safety users no longer need to reformat the field for ease of use.

Updated study name is validated against other integrations (Former Known Issue)

Integration managers: When you update the study name for an existing integration, it is no longer possible to use a study name that is already used for a different Oracle InForm to Oracle Argus Safety integration. If you attempt to use an existing integration's study name, an error occurs. This change prevents Oracle Clinical One Digital Gateway from unintentionally running the wrong integration. (Issue 28774523)

Correct value is sent for breastFeedingIndicator (Former Known Issue)

Integration managers: In the integration template for the Oracle InForm to Oracle Argus Safety integration, the breastFeedingIndicator field is no longer incorrectly set to use the HS_TRUE_FALSE codelist. Instead, it now uses the EVENT_LEVEL_YES_NO codelist, and as a result, the value for the breastFeedingIndicator field appears correctly in Oracle Argus Safety. (Issue 28806137)

Retracted workaround: For new integrations, integration managers no longer need to manually populate the values for the EVENT_LEVEL_YES_NO codelist or change the codelist that is used for the field from HS_TRUE_FALSE to EVENT_LEVEL_YES_NO.

The Taken Previously and Tolerated field contains accurate information (Former Known Issue)

Integration managers: The integration template for the Oracle InForm to Oracle Argus Safety integration now correctly maps the Taken and Previously Tolerated field in Oracle Argus Safety to the HS_YES_NO_UNKNOWN codelist. As a result, the value sent from Oracle InForm for the field Taken Previously and Tolerated now appears correctly in Oracle Argus Safety for the drug. (Issue 28806066)

Retracted workaround: For new integrations, integration managers no longer need to manually populate the values for the HS_YES_NO_UNKNOWN codelist with the values that are being sent for the takenPreviouslyAndToleratedCode field.

Adverse Event/Serious Adverse Event (AE/SAE) added as a reason for subject withdrawal

Integration managers: The Reason codelist in the integration template for the Oracle InForm to Oracle Argus Safety integration now includes Adverse Event/Serious Adverse Event (AE/SAE) as a reason for subject withdrawal. (Issue 28878812)

Oracle Clinical One Platform 1.3 (January 2019)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Create and assign study roles](#)
Getting access to Oracle Clinical One Platform and performing your tasks in the product is now easier thanks to study roles!
- [Manage sites more efficiently](#)
Site managers can now limit the activities a site can perform, such as enrollment, screening or dispensation.
- [Randomize into cohorts](#)
- [Create queries](#)
- [Improved calculated doses](#)
- [New Study Enrollment report](#)

Randomize into cohorts

Oracle Clinical One Platform now allows you to create adaptive cohorts, allowing you to open treatment arms in a gradual manner so that you can measure safety and efficacy as the study progresses. With adaptive cohorts, you're in control of your subject population: You decide when to open and close each cohort, and you can place appropriate limits on the subjects who are enrolled in each cohort.

- [Details for study designers](#)
- [Details for study managers](#)
- [Details for clinical supply managers and randomization managers](#)
- [Details for sites](#)

This enhancement is easy for you: There aren't any changes that affect you.

Details for study designers

To build a study that uses adaptive cohorts, you define your cohorts and treatment ratios in your randomization design.

For details about the changes you'll see, keep reading.

How to: Create a randomization design that uses cohorts

A randomization design that uses cohorts has only two pages in the wizard:

- On the first page, choose **Adaptive** from the new **Cohort** drop-down.

Create Randomization

Progress bar: 1 of 2 steps (Randomization Design)

Randomization Design

* Title	Cohort randomization
Description	<i>Description</i>
* Type	Unblinded ▼
→ Cohort	Adaptive ▼
* Randomization	Central ▼

When you choose **Adaptive**, the **Randomization** drop-down has fewer options: Stratified randomization options aren't available, and neither is the None option.

- On the second page, create your cohorts by clicking the plus sign in the upper-right. Next, specify the appropriate treatment ratio for each cohort you created. Typically, cohorts and treatment arms have a 1:1 ratio, as shown below, but Oracle Clinical One Platform allows you to specify the appropriate ratio for your study.

Create Randomization

Progress bar: Randomization Design (left) | Cohorts & Treatment Arms (right)

Tip: Enter a whole number for each treatment arm that subjects in the cohort will be randomized into. The numbers determine the ratio of subjects that are randomized into each arm. Click the plus sign (+) to add more cohorts.

Cohorts	High Dose	Low Dose	Mid Dose
Low Dose		1	
Mid Dose			1
High Dose	1		

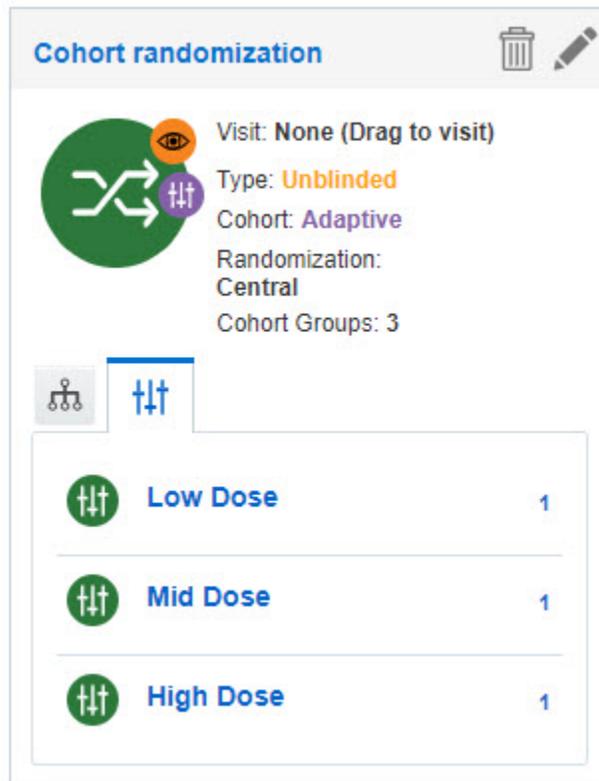
How to: Add the randomization design to a visit

You drag the randomization design to the visit, the same as before, but there are a couple rules you should know:

- Only one randomization design in the study can randomize into cohorts.
- A randomization design with cohorts must be the first randomization event in the study.

New color coding for cohorts

A randomization design that uses cohorts is labeled as an Adaptive Cohort with a purple icon.



Need to add cohorts later?

Try to get your cohorts finalized before moving the study version to Approved on the Home page because some fields for a randomization design become read-only after a study design is approved.

However, the following changes are allowed after a study version has been approved:

- Adding cohorts and specifying their treatment ratios.
- Changing the treatment ratios of existing cohorts, but you can set them only to 0 or blank. For example, you can change a value of 1 to 0, but you can't change 1 to 2.

Report updates

The Study Design report has been updated and now includes details about the cohorts and their treatment ratios.

Details for study managers

Your cohort-related tasks are all on the Subject Settings page, below Enrollment Settings. Here, you can:

- Open and close enrollment for cohorts.
- Set limits and notification levels.

You'll see the new options after cohorts have been created in the randomization design.

New notification

A notification is now sent when the specified notification level (for example, 80% of subjects randomized into a cohort) is met.

Managing cohorts

- All cohorts are closed by default. Make sure you open at least one cohort before the study goes live, or **sites won't be able to randomize subjects**.
- After the limit is reached for a cohort, sites won't be able to randomize subjects until you open the next cohort or increase the limit.

Details for clinical supply managers and randomization managers

Randomization in a cohort study

During randomization, subjects are assigned the first available randomization number associated with an open cohort. This rule is true whether one, two, or more cohorts are open.

Changes for randomization lists

- Generating randomization lists
When you generate a randomization list for a randomization design with cohorts, the Length field has a new option: **Number of Blocks per Cohort**. Select this option and specify the number of blocks required for each cohort.

Generate Randomization List

Select Randomization | List Settings | Finish

* Title: Randomization List v1

Description:

* Mode: Testing

* Multiplier for Blocks: 4

* Starting Number: 1

* Length: Number of Blocks per Cohort 4

< Back | Cancel | Generate >

- **Uploading randomization lists**
If you need to upload a randomization list for a cohort study, make sure the list defines the cohort for each randomization number. When you upload the file, you'll be prompted to identify and column with cohort information. Then you'll map each cohort in the file to the cohorts you created in Oracle Clinical One Platform.
- **Viewing the cohort for each randomization number**
On the Randomizations tab, the new **Cohorts** column now appears when a randomization list was created for a randomization design with cohorts. The Cohorts column lists the cohort associated with each randomization number.

Reporting changes

In the Randomization List (Unblinded) report, you can now view the cohort associated with each randomization number. This information appears in the new **Cohort** column.

Details for sites

This enhancement is easy for you: There aren't any changes that affect you.

Create queries

Data management is a crucial component of clinical studies, and we're making sure sponsor and site users have access to the best features when it comes to collecting and managing data. So, in this update, you can use queries to flag data issues that need to be resolved. Whether you need to correct data in forms, or track data management tasks, queries are here to make your life easier.

Sponsor users can now create and monitor queries, while site users can answer those queries. Together, the two groups can communicate and better manage subjects' data.

Already working in a live study?

This new feature does not affect your live studies in any way. You can start creating queries on questions at any time after the system update, once you've assigned the appropriate roles to your study and site managers.

Read more about how this change affects...

- [Details for user managers](#)
- [Details for users who will create queries](#)
- [Details for sites](#)
- [Details for user managers](#)
- [Details for users who will create queries](#)
- [Details for sites](#)

Details for user managers

What roles do I need to assign so my organization can start using queries?

All you have to do is assign the **Sponsor Query Manager** role to the appropriate sponsor users and **Site Query User** role to the appropriate site users, and query functionality will be available in the study.

Details for users who will create queries

You can now raise queries in case there are any errors or inconsistencies in the data collected by site users.

How to: Create a query

It's easy! Just open a visit, point to a question, and click the gray question mark that appears to the right of the answer.

The screenshot shows the Oracle Clinical One interface for Study-ORS 123. The user is logged in as Ralph Parsons. The main content area displays subject information for CA002-... (Active) at Week 4. A 'Forms' section is visible, containing a 'Demography' table with the following data:

Field	Value
* Visit Start Date	01-Oct-2018
* 1. Initials	JSR
* 2. Gender	Male
* 3. Date of Informed Consent	01-Oct-2018
* 4. Did the Subject meet all criteria?	Yes

A gray question mark icon is positioned to the right of the 'Yes' answer for the fourth question, with a tooltip that says 'Create a query'. The right-hand sidebar contains sections for 'Question Hint', 'Answer & Visit History' (showing 'Value: JSR' on '01-Nov-2018'), 'Visit History', 'Subject History', and 'Queries'.

A newly created query with a **Candidate** status is visible only to sponsor users. Use the Candidate status when you want to review the query internally before assigning it

to the site. After you review the query internally, set its status to **Open**, so it is assigned to the site.

When site users answer your queries, these are shown in an **Answered** state. After reviewing answered queries, you can set their status to **Closed** which means the query is resolved and no longer needs an answer.



Note:

You can't reopen a closed query. If you ever need to do that, just create a new one.

How to: Monitor queries

Look for Open or Answered queries (they are red and marked with a question mark), click them, and look at their answer history on the right side.

Additionally, you can also check the new Subject Queries report. To access this new report, you need the Sponsor Query Manager role.

In this report, you can see your listing of queries so that you can:

- Encourage timely responses from the site.
- Prepare for study closeout activities.
- Prepare interim analyses with all queries from a certain period of time.
- Constantly review the history of site queries, so you can resolve any open items.

Site users who have the Site Query User role can also run this report.

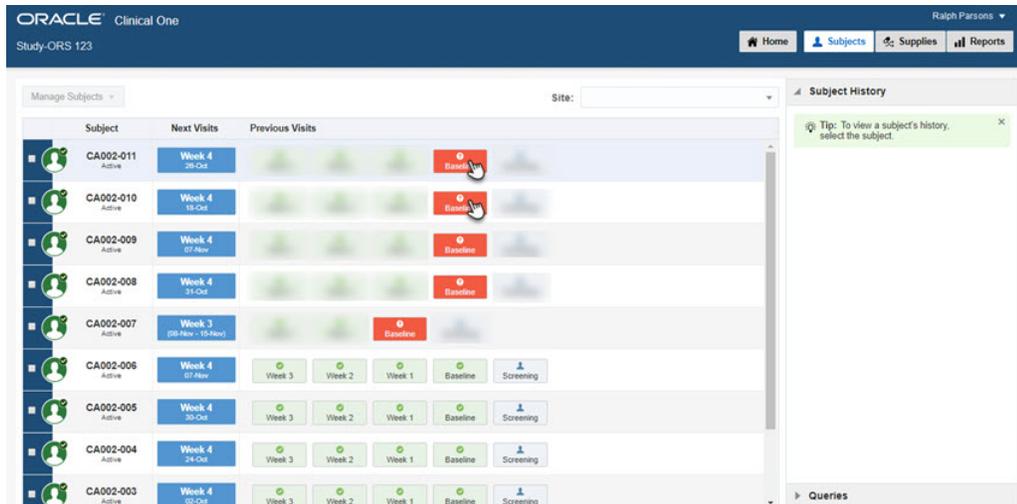
Details for sites

The risk of adding incomplete or incorrect data in Oracle Clinical One Platform is now minimized, and you get to properly manage data along with sponsor users.

How to: Answer an Open query

On the Subjects page, look for a visit that is red and marked with a question mark. Click the visit, and answer the query (or queries) in it.

After you answer a query, it's sent back to the sponsor for review. The sponsor can then either close the query or reopen it. A closed query is resolved, and a reopened query is sent back to you. Just look for a red visit with a question mark to find it.



How to: Determine the age of queries

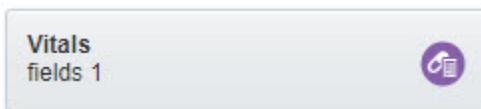
You can see the age of queries and more information in the new Subject Queries report. Anyone who can answer queries can also run the report.

Improved calculated doses

Now it's easier to tell when a form has a question that's used in a calculated dose, so you have a visual reminder that updating a question on the form could have consequences to your calculated doses. You'll now see this icon on any question that's used in a calculated dose:



The same icon appears on the form:



Already working in a live study?

You'll need to create a new study design to see the new icons.

New Study Enrollment report

The new Study Enrollment report helps you track and manage enrollment in your study.

In the report, which is available to study managers in all 3 modes, you can view details about enrollment for a study, including:

- Open or closed status for enrollment for a study, site, country, and cohort.
- For each location, the number of screened and randomized subjects, as well as the screening and randomization limit.
- For each cohort, the number of randomized subjects, as well as the randomization limit.

Stability improvements

- [Randomization and kit stability improvements](#)
- [Report and notification stability improvements](#)
- [Site user and subject data stability improvements](#)

Randomization and kit stability improvements

Use non-required visits in calculated doses (Former Known Issue)

Study designers: You now can use non-required visits in calculated doses. (Issue 28639244)

Retracted workaround: If you added steps to work instructions to ensure that only required visits are used in calculated doses, you now can remove this requirement.

Report and notification stability improvements

Kit Chain of Custody (Unblinded) report updated (Former Known Issue)

The Kit Chain of Custody (Unblinded) report was updated so that it's now consistent with other reports:

- The Study Organization ID column now lists the site ID. Previously, this field listed a 32-character identifier.
- The Study Organization Name now lists the site name. Previously, this field included the site ID and the site name. (Issue 27373702)

Site user and subject data stability improvements

Change to notification percentage for new studies

In a new study created after this system update, the following fields now have blank values on the Subject Settings tab in Study Settings (below Enrollment Settings):

- Screening Limits
Previously, this value was 1,000 in all new studies.
- Randomized Limits
Previously, this value was 1,000 in all new studies.
- Notification
Previously, this value was 20% in all new studies.

Existing studies aren't affected by this change. (Issue 28749939)

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Releases in 2018

Browse the content of all Oracle Clinical One Platform and Oracle Clinical One Digital Gateway releases in 2018.

- [Oracle Clinical One Digital Gateway 1.1.0.1 \(November 2018\)](#)
- [Oracle Clinical One Platform 1.2 \(October 2018\)](#)
- [Oracle Clinical One Digital Gateway 1.1 \(October 2018\)](#)
- [Oracle Clinical One Platform 1.1.2.2 \(September 2018\)](#)
- [Oracle Clinical One Platform 1.1.2.1 \(September 2018\)](#)
- [Oracle Clinical One Platform 1.1.2 \(September 2018\)](#)
- [Oracle Clinical One Platform 1.1.1.3 \(July 2018\)](#)
- [Oracle Clinical One Platform 1.1.1.2 \(July 2018\)](#)
- [Oracle Clinical One Platform 1.1.1.1 \(June 2018\)](#)
- [Oracle Clinical One Digital Gateway 1.0 \(May 2018\)](#)
- [Oracle Clinical One Platform 1.1.1 \(March 2018\)](#)
- [Oracle Clinical One Platform 1.1 \(March 2018\)](#)

Oracle Clinical One Digital Gateway 1.1.0.1 (November 2018)

- [Stability improvements](#)

Stability improvements

- [Oracle Clinical One Platform to Oracle InForm integration stability improvements](#)
- [Oracle InForm to Oracle Argus Safety integration stability improvements](#)
- [Interface stability improvements](#)

Oracle InForm to Oracle Argus Safety integration stability improvements

- [Improved partial date handling](#)

Improved partial date handling

Integration managers:

If Oracle Argus Safety is configured to accept partial dates, Oracle Clinical One Digital Gateway now automatically converts these dates from the format that Oracle InForm captures into a format that Oracle Argus Safety can accept for all default Oracle Argus Safety date fields (E2B standard fields). (Issue 28913590)

Which fields can now receive partial dates? Partial dates are converted to the required format for the following Oracle Argus Safety fields:

- patientlastmenstrualdate
- patientmedicalstartdate
- patientmedicalenddate
- patientdrugstartdate
- patientdrugenddate
- patientdeathdate
- reactionstartdate
- reactionenddate
- testdate
- drugstartdate
- drugenddate

What about other date fields? For other date fields outside the E2B standard, such as custom fields, by default an unknown month is sent to Oracle Argus Safety as January (01), and an unknown day is sent as first of the month (01). For example, a partial date of 2018-UNK-15 appears in Oracle Argus Safety as 2018-01-15 and 2018-11-UNK appears as 2018-11-01. When mapping these fields, use the same **field** tag used for the standard date fields to apply partial date handling to those fields as well (see lines 847 and 851 in step 3b below).

What are the possible formats that appear in Oracle Argus Safety for these fields?

- CCYY: A partial date with an unknown month and day is converted to a partial date with only the year. For example, dates of the form 2018-UNK-UNK are converted and sent as CCYY, which is 2018.
- CCYYMM: A partial date with an unknown day of the month is converted to a partial date with only the year and month.
- CCYYMMDD: A complete date is converted to a complete date but with no timestamp, if any.

What if we don't allow partial dates in Oracle InForm?

Then this feature is not for you. You don't need to make any changes and your integration will continue to run as usual after the update.

How can I start using this feature?

- For a **new integration**, download and use the latest Oracle InForm to Oracle Argus template where partial date handling is already set up for the listed fields.
- For an **existing integration**, you need to update the field mapping for the listed fields to take advantage of this new feature. Here's how:
 1. Sign in to Oracle Clinical One Digital Gateway and download the latest template for this integration.
 2. Download your current integration file.
 3. Search for and update the field tag of the mapping for each of the 11 fields.

Here's how to do this for the first field, `patientlastmenstrualdate`:

- a. Open the template file in an XML-friendly editor.
- b. Search for the field, which is `patientlastmenstrualdate` for this example. You'll find two mappings for each field, like so:

```
      <!-- This is the mapping that sends the date format -->
      847   <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.Partial
DateTruncatorForArgus" custom-converter-param="FORMATCODE">
      848     <a>lastMenstrualDateTimePoint.value</a>
      849     <b>lastmenstrualdateformat.content</b>
      850   </field>
      <!-- This is the mapping for the date itself -->
      851   <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.Partial
DateTruncatorForArgus" custom-converter-param="">
      852     <a>lastMenstrualDateTimePoint.value</a>
      853     <b>patientlastmenstrualdate.content</b>
      854   </field>
```

- c. Copy the field tag for the date format mapping (line 847).
 - d. Open your current integration file and replace the corresponding tag with the one you copied from the template.
 - e. Repeat this process for each of the 11 fields.
4. Save changes to the integration file.
 5. Upload the file to your current Oracle InForm to Oracle Argus Safety integration.
 6. Re-enable the integration.

Interface stability improvements

- [Now you can edit only a disabled integration \(Former known issue\)](#)

Now you can edit only a disabled integration (Former known issue)

Integration managers:

You can no longer edit any aspects of an existing integration unless you disable it first. This includes its name, any settings for the integration, or uploading a new integration file. You will also see information on this in the Edit Integration File dialog box for an enabled integration. (Issue 28832297)

The instructions in Manage an integration have been updated to reflect this change.

Oracle Clinical One Platform 1.2 (October 2018)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Study periods](#)
- [Calculated doses](#)
- [Age question](#)
- [New subject numbering options](#)
- [Screening and randomization limits](#)
- [Subject status changes](#)
- [Role and right changes](#)
- [Report improvements](#)
- [Oracle Clinical One Platform training improvements](#)
- [Additional usability improvements](#)

Study periods

This system update allows even more studies to be built in Oracle Clinical One Platform, including:

- [Open-label studies](#)
- [Studies with both blinded and open-label periods](#)
- [Studies with re-randomizations](#)

Now in an open-label period or study, unblinded information can be made visible to blinded users.

Not planning to use these features?

You'll still see some changes to the interface, including some improvements that will help you even if you're not doing an open-label study or a second randomization. Keep reading for details.

Read more about how this change affects...

- [Sponsors](#)
- [Study designers](#)
- [Site users, and sponsor users who view subject data](#)
- [Details for sponsors](#)
- [Details for study designers](#)
- [Details for sites and sponsor users who view subject data](#)

Details for sponsors

Which studies can now be built in Oracle Clinical One Platform?

- [Open-label studies](#)
An open-label study must have one or more randomization events.

- Blinded studies
A blinded study can now have one or more randomization events.
- Blinded and open-label studies
Studies with both blinded and open-label periods can have one or more randomization events, and can:
 - Start blinded, and then have an open-label extension.
 - Start open label, and then become blinded.
To start as open label, a study must randomize subjects when the open-label period begins.

What options are available for subjects changing treatment arms during the second randomization event?

You have the following options for both open-label and blinded periods:

- Randomize all subjects again.
- One of the following:
 - Move all subjects to new treatment arms.
 - Keep all subjects in their treatment arms.
 - Move some subjects to new treatment arms, and keep other subjects in their treatment arms.

When subjects in 1 treatment arm are split into 2 or more treatment arms, randomization determines their new treatment arms. For example, consider a study with 3 treatment arms: 5 mg dose, 10 mg dose, and placebo. Subjects in the 5 mg dose and 10 mg dose arms remain in their treatment arms throughout the study, and subjects in the placebo arm are randomized to determine whether they move into either the 5 mg dose or 10 mg dose arms.

More variations are possible. For instance, the study can add or drop treatment arms, and subjects can be mapped or randomized into an added treatment arm.

Tip:

If you're doing a crossover study where all subjects swap treatment arms without being re-randomized, you don't need to create a second randomization design. Instead, you can simply update the dispensation schedule so that subjects receive the appropriate treatment for each visit. This functionality was available before this system update.

In an open-label period or study, what unblinding information is visible, and where is it?

The Kit Reconciliation tab, which provides unblinded users with the same view that site users have, has a new **Kit Description** column, which lists **Blinded** for any kits with blinded descriptions. Unblinded users will continue seeing the kit type description on the Inventory tab; this functionality isn't changed.

For details about what site users and blinded users at your organization see, see [Details for sites and sponsor users who view subject data](#).

Any reporting changes?

Yes! For details, see [Report improvements](#).

Any other changes?

The code view pop-up was modified to provide details about each randomization event in the study. The pop-up provides the same details as before, including the treatment arm title and kit description, but the new organization of information makes it easier to find what you're looking for.

Details for study designers

This section describes the changes to the user interface. For instructions on creating kit types and randomization designs for open-label and multiple-randomization studies, see [Design a study](#).

Everyone will see all of the changes described in this section, even if a study doesn't use the new open-label and multiple-randomization features. For details about how to create a study with multiple periods, see [What is my workflow for setting up a study with multiple periods?](#)

- [Renamed options](#)
- [New kit type fields](#)
- [New icon on kit types](#)
- [New tip for treatment arms](#)
- [New fields for randomization](#)
- [Treatment ratios on randomization designs](#)
- [Scheduling changes](#)
- [Map subjects to treatment arms](#)

Renamed options

Some options were renamed in the **Open Label / Blinded** drop-down on the General tab in study settings:

- **Open Label and Blinded (Single or Double)** was renamed to **Blinded and Open Label**.
- **Blinded (Single or Double)** was renamed to **Blinded**.

Some settings have consequences further down the road, but this one doesn't—it's informational only.

New kit type fields

You'll see the following changes when you create kit types.

- **Distribution Settings:** This drop-down now has unblinding consequences (and has moved to the top of the pop-up). Make sure you select the appropriate option for all kit types:
 - **Blinded:** Blinded users never see the kit type description.
 - **Unblinded:** Blinded users always see the kit type description.

Note:

If you select **Unblinded**, make sure that **Description** contains text that is appropriate for blinded users.

- **Unit Settings:** This new section of the pop-up contains the following fields:
 - **Single Unit Dose:** (new field) Specify how one unit in the kit is measured, both its value (such as 10) and its unit (such as mg).
 - **Units Per Kit:** This field isn't new but is now lower in the pop-up. For details about the new Calculating Doses field, see [Calculated doses](#).

Create Kit Type

Kit Settings

Calculating Doses Yes No

Distribution Settings: Blinded

* Kit Type ID: A

* Description: ORS-123 10 mg

Storage Temperature: Ambient (15° - 25° C)

Type: Blister Pack

* Minimum Kits to Ship: 1

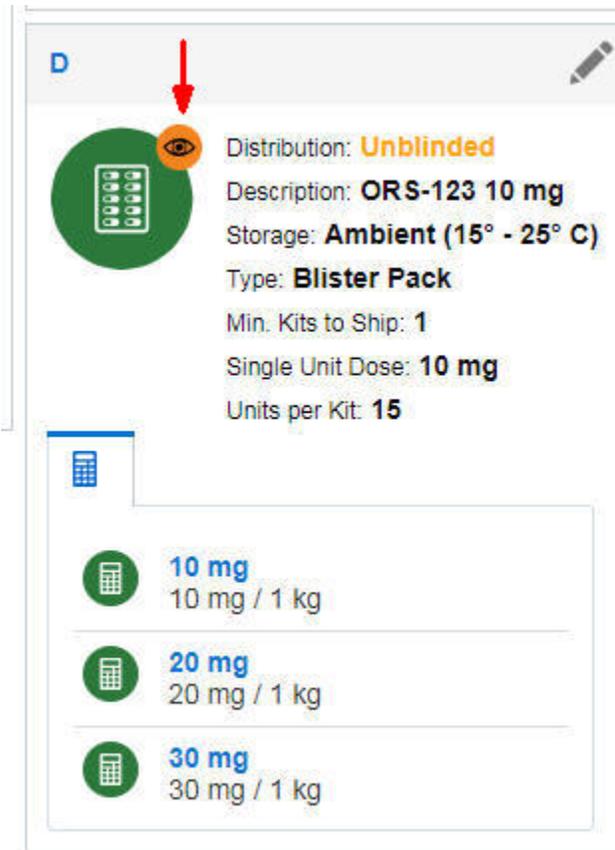
Unit Settings

	Value	Measurement
Single Unit Dose	100	mg
Units Per Kit	15	

Cancel Add

New icon on kit types

When a kit is unblinded, an orange eye icon now appears along with orange **Unblinded** text.



New tip for treatment arms

The way that you create treatment arms isn't different, but there's now a tip reminding you that the titles of treatment arms will be visible to blinded users during an open-label period.

New fields for randomization

You'll see the following changes when you create a randomization design.

- **Changes on the first page for all randomization designs**
 - **Description:** This field is no longer required.
 - **Cohort:** This field was previously reserved for a future release and has been removed.
 - **Type:** (new field) Choose the appropriate option:
 - * **Blinded:** Blinded users never see any of the titles of the treatment arms used in the randomization design.
 - * **Unblinded:** Blinded users always see all titles of the treatment arms used in the randomization design.
 - **Randomization:** The **None - Open Label** option is new and lets you start an open-label extension. When you select this option, all the other pages in the wizard are no longer relevant and are hidden.

Details on the right continue showing your selections in real time.

- **Additional changes you'll see for the second or later randomization design you create in a study**
 - **Re-Randomization:** (new field) Select **Yes** if the randomization design is the second or later randomization event in the study. If you select Yes, the wizard won't include a page for specifying treatment arm ratios. Instead, when you drag the randomization design to a visit, you'll map subjects from their current treatment arms to their new treatment arms and will specify the appropriate ratios.
 - **Treatment Arms:** (new field) Select **Randomized** if all subjects are randomized into new treatment arms according to a treatment ratio that you specify in the randomization design; or select **Mapped** to map subjects to new treatment arms (or to specify that they should stay in their current treatment arms). If subjects in one treatment arm are mapped to multiple arms, randomization determines the subjects' new treatment arms.

The screenshot shows the 'Edit Randomization' wizard. It has two main sections: 'Randomization Design' and 'Settings'.
 In the 'Randomization Design' section:
 - Title: Randomization for Protocol 12-Mar-2018
 - Description: Central randomization. 3 treatment arms: 1:1:1
 - Type: Unblinded (dropdown)
 - Randomization: Central (dropdown)
 - Re-Randomization: Yes (selected radio button), No (unselected)
 - Treatment Arms: Mapped (selected radio button), Randomized (unselected)
 In the 'Settings' section (partially visible):
 - Title: Randomization for Protocol 12-Mar-2018
 - Type: Unblinded
 - Re-Randomization: Central
 - Treatment Arms: Mapped

- **Changes on the Treatment Arms page**
If you select **Mapped** for the **Treatment Arms** drop-down, the Randomization wizard doesn't show this page. You'll specify treatment ratios when you assign the randomization design to a visit.
- **Changes on the Settings page, the last page of the wizard**
The settings that appear on this page depend on the settings that you selected earlier in the wizard.
 - **Assign New Randomization Numbers to All Subjects:** (new field; appears when you select **Yes** for **Re-Randomization** on the first page): Select **Yes** if subjects should receive new randomization numbers after they are randomized as part of this randomization design.
 - **Restrict Randomization to Available Kit Types:** Doesn't appear if you select **Mapped** for the **Treatment Arms** drop-down.
 - **Limits Include Terminated Subjects:** Previously, this setting was reserved for a future release. This setting has been removed from the wizard.

Treatment ratios on randomization designs

You'll see the following changes when you view randomization designs on the Randomizations tab.

- For the first randomization design in a study, the list of treatment arms now includes treatment ratio information for non-stratified randomization designs.

The screenshot shows a configuration window for a randomization design. At the top, it says "Randomization for Protocol 09-..." with a trash icon and a pencil icon. Below this is a green circular icon with two arrows forming a loop. The configuration details are: Visit: Baseline; Central randomization. 3 tre...; Type: Blinded; Randomization: Central; Restrict Randomization: Yes; Assign Skipped: Yes. Below these details is a table of treatment arms:

Treatment Arm	Count
10 mg dose A ORS-123 10 mg	1
5 mg dose B ORS-123 Monad 5 mg	1
Placebo C ORS-123 Matching placebo	1

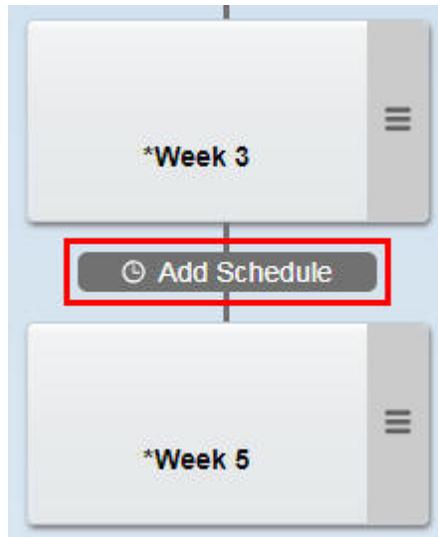
- For any re-randomizations and stratified randomization designs, treatment arm details don't appear.

The screenshot shows a configuration window for a re-randomization design. At the top, it says "Randomization for Protocol 12-..." with a trash icon and a pencil icon. Below this is a green circular icon with two arrows forming a loop and a small orange eye icon. The configuration details are: Visit: Week 6; Central randomization. 3 tre...; Type: Unblinded; Re-Randomization: Central; Treatment Arms: Mapped; New Randomization Numbers: Yes.

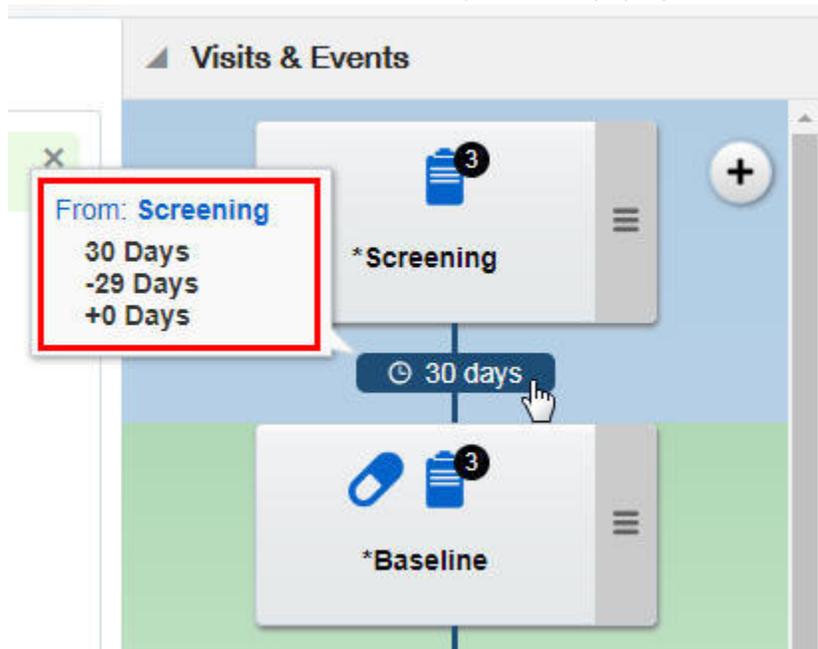
Scheduling changes

You'll see the following changes when you view visit details in Visits & Events on the right.

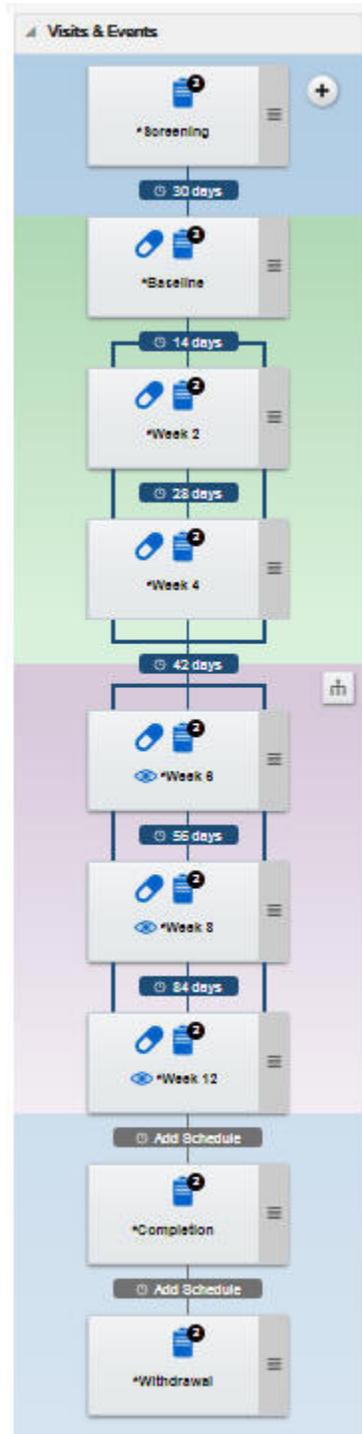
- Scheduling a visit is now more straightforward. Instead of clicking the clock that leads to a visit, you now click the **Add Schedule** button that leads to a visit.



- The time between visits now appears in Visits & Events. Point to the scheduling information to see additional scheduling details in pop-up text.



- Additionally, color coding now appears in Visits & Events:
 - Blue background: Appears behind visits that occur prior to randomization as well as behind any unscheduled visits.
 - Green background: Appears just above the first randomization visit and continues until just above the second randomization visit.
 - Purple background: Appears just above the second randomization visit and continues until just above the third randomization visit, or until just above the first unscheduled visit, if there is no third randomization event. If there is a third randomization visit, an orange background appears.

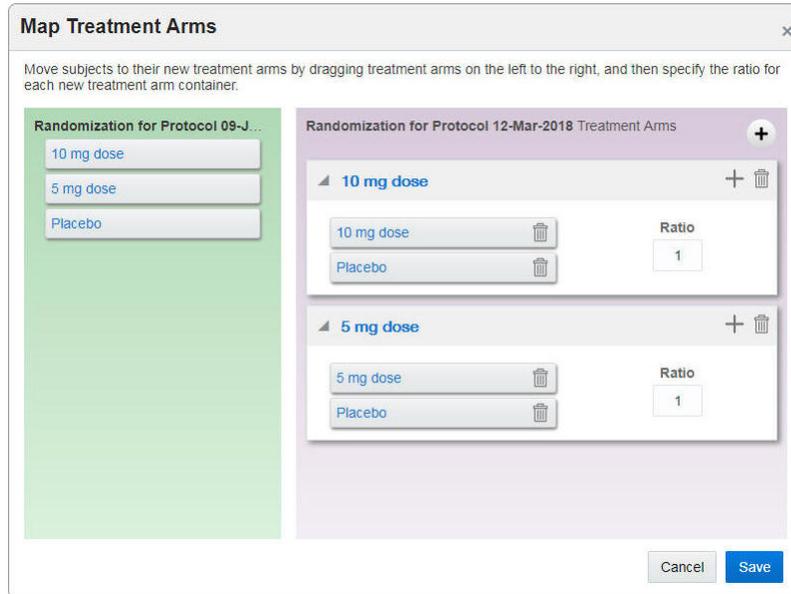


Map subjects to treatment arms

When you drag the second or later randomization design to a visit, the new Map Treatment Arms pop-up now appears. In this pop-up, you map the subjects in each treatment arm to their next treatment arm and choose the appropriate ratio for each new treatment arm.

In the following example, subjects start out on 3 treatment arms. During the second randomization event, subjects on the 5 mg dose and 10 mg dose arms remain in their

treatment arms. For subjects who started out on the Placebo arm, randomization determines whether they continue in the study on either the 5 mg dose or 10 mg dose arms.

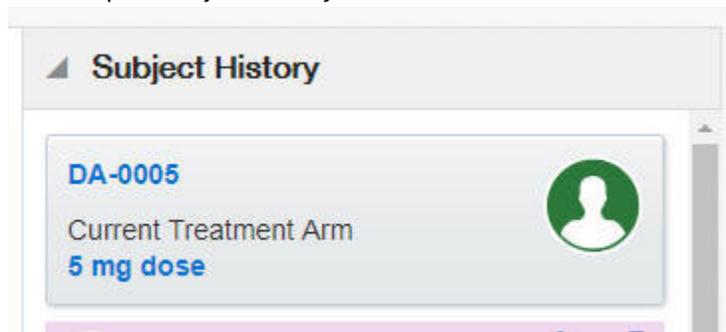


Details for sites and sponsor users who view subject data

Where can I view unblinding details during an open-label study or period?

Depending on how the study is set up, two types of information might be visible:

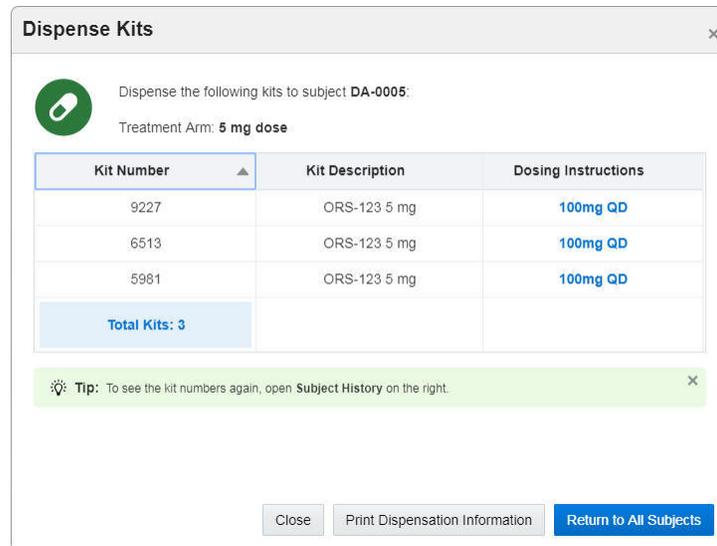
- Subjects' current treatment arms
In an open-label period or study, you now can view details about treatment arms in the following locations:
 - In the pop-ups that appear when you randomize a subject and dispense kits.
 - At the top of Subject History.



- Kit details
When kits have unblinded distribution, you now can view details about them in a few places:
 - A tooltip on Subject History.



- In the pop-up that appears when you dispense kits.



- On the Inventory tab, in the new **Kit Description** field. If the text is truncated, point to a cell to view the full description.

Any other changes I should know about?

- You can't skip a visit that starts an open-label period.
- The Code Break pop-up was modified to provide details about each randomization event in the study. The pop-up provides the same details as before, including the treatment arm title and kit description, but the new organization of information makes it easier to find what you're looking for.

Calculated doses

You can now determine doses based on calculations!

Oracle Clinical One Platform can now calculate the appropriate doses for subjects based on their answers to questions, including demographics and medical history questions. And as the study progresses, you can base the calculation for each dispensation on a subject's answer in that visit, allowing you to ensure subject safety as well as compliance with protocol requirements.

- [Details for user managers](#)
- [Details for study designers](#)
- [Details for site users](#)

Details for user managers

Do I need to provision users differently to use calculated doses?

Yes. There's a new role, **Site User with Detailed Dosing View**, and it can reveal **potentially unblinding information** to users, so assign it carefully. The role is appropriate for pharmacists and other site users who must know the dispensation instructions for blinded kits.

- **Users with this role can see:** Subjects' calculated doses, including the dosing frequency and the dose measurement. A study designer specifies these requirements when creating the calculated doses on each kit type.
- **And there's a new notification for this role:** Dosing instructions are available in the new **Subject Dispensation** notification, which is created every time a kit with dosing instructions is dispensed. For more details, see [Details for site users](#).

Details for study designers

How do I use calculated doses in my study?

There are a few additional tasks in your usual processes:

1. When you design forms, make sure that the question(s) you will use to calculate doses are **required numeric questions**, such as Number or Age questions.
2. Add forms as appropriate to each visit. The forms you need to add depend on how you will set up each calculated dose. For example, consider a scenario where a calculated dose is based on a subject's weight:
 - If you collect a weight value in every dispensation visit, and you want the calculation to use a subject's answer in the current visit, every dispensation visit must have a form with the weight question.
 - On the other hand, if you want the calculation to use the same weight value throughout the study, the form with the weight question has to be only in the visit with the first calculated dose or an earlier visit.

Tip:

If you don't add forms to visits as required for the calculated doses, Oracle Clinical One Platform will prompt you about adding the forms when you define the dispensation schedule.

3. While creating kit types, select **Yes** for the new **Calculating Doses** field. Selecting Yes changes the Create Kit Type pop-up to a wizard. See the next step for details.

- 4. For each kit type, define one or more calculated doses. For descriptions of the new fields, see Define the kits.

 **Note:**
Minimum Kits to Ship was renamed to **Minimum Units to Ship**.

Edit Kit Type: A

Kit Design | Calculated Doses

A ORS 123 10 mg | Units Per Kit: 15 | Single Unit Dose: 10 mg

10 mg

* Form Question for Calculated Doses
Vitals | Weight

* Visit Where Form is Collected
Current Visit | Select Visit

* Precision for Each Dose: 1 | * Round Up For: 0.5

* Dosing Frequency: QD | * Use Leftover Units in Next Dose: Yes No

* Kit Measurement: 10 mg | * Subject Measurement: 1 kg

< Back | Cancel | Finish >

The following kit type has 3 calculated doses.

Edit Kit Type: A

Kit Design | Calculated Doses

A ORS 123 10 mg | Units Per Kit: 15 | Single Unit Dose: 10 mg

▶ 10 mg / 1 kg

▶ 20 mg / 1 kg

▶ 30 mg / 1 kg

< Back | Cancel | Finish >

5. Drag each kit type to the appropriate visit, as usual. In the Add Kit to Visit Schedule pop-up, you'll notice a few changes:
 - The **Quantity** column is now named **Doses**.

- There's a new column, **Calculated Dose**, for choosing the calculated dose for each visit. See the next step for details.

Edit Kit on Visit Schedule

A ORS 123 10 mg 10 mg dose x

Treatment Description ORS-123 10 mg

Visits	Doses	DND (Days)	Dispense Outside Window	Calculated Dose
<input checked="" type="checkbox"/> Baseline	1	74	<input checked="" type="checkbox"/>	10 mg
<input checked="" type="checkbox"/> Week 2	1	74	<input checked="" type="checkbox"/>	10 mg
<input checked="" type="checkbox"/> Week 4	1	74	<input checked="" type="checkbox"/>	10 mg

Cancel Save

6. For each visit that requires it, choose a calculated dose.
If the calculated dose you choose requires forms to be added to the visit, Oracle Clinical One Platform will add the forms for you after confirming that it's okay.

Any other UI changes I should know about?

Just a couple:

- When you click a visit to view details, you can point to a kit type to see the calculated doses on the kit type.

Baseline Type Scheduled Visit Required

Forms 3 Total + Randomization

Tip: Drag forms to reorder them.

- Pregnancy 2 fields
- Randomization 1 fields
- Vitals 1 fields

Randomization for Protocol 09-June...

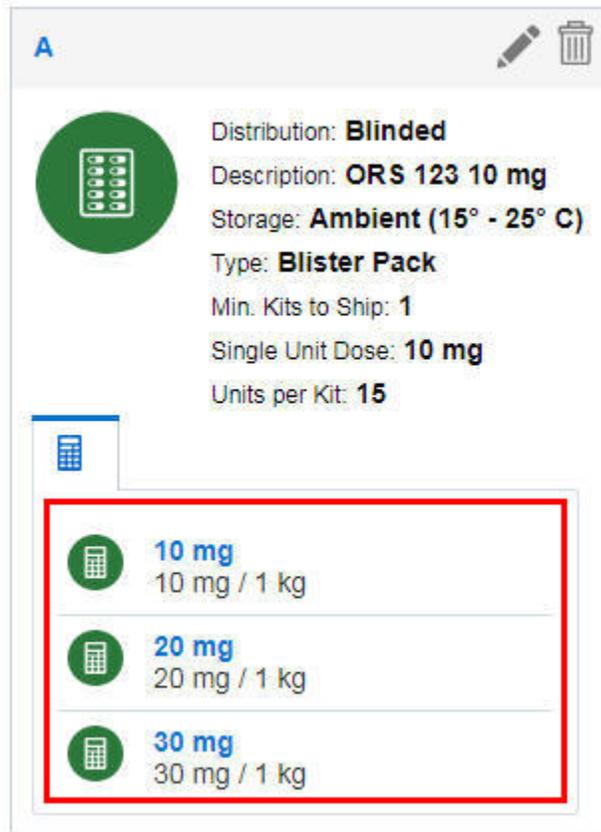
Visit: Baseline
Central randomization. 3 tre...
Type: Blinded
Randomization: Central
Restrict Randomization: Yes
Assign Skipped: Yes

10 mg dose + A ORS 123 10 mg 10 mg 20 mg 30 mg

B ORS 123 5 mg + C ORS-123 match... +

Cancel Delete Visit Save

- A kit type now shows details about its calculated doses:



Details for site users

How will my workflow change if a study calculates doses for subjects?

When a dispensation event has dosing instructions, which include a calculated dose amount and the frequency of the dose, your roles determine whether you can see the dosing instructions:

- If you have the new **Site Users with Detailed Dosing View** role, you'll see dosing instructions in a couple places:
 - The Dispense Kits pop-up, in the new **Dosing Instructions** column. There's also a new button for printing the instructions.

Information x

 Subject **DA-0005** has been randomized.
Randomization Number: **1003**
Treatment Arm: **5 mg dose**

Kit Number	Kit Description	Dosing Instructions
10178	ORS-123 5 mg	100mg QD
8890	ORS-123 5 mg	100mg QD
Total Kits: 2		

 **Tip:** To see the randomization number or kit numbers again, open **Subject History** on the right. x

Close
Print Dispensation Information
Return to All Subjects

- The new **Subject Dispensation** notification, which you receive every time a kit with dosing instructions is dispensed.
The information in the Subject Dispensation notification is also available in the [new Kit Dispensation report](#).
- If you don't have the **Site Users with Detailed Dosing View** role, someone else at your site who does have the role will receive a notification with the dosing instructions for the subject.

What if a kit is unblinded?

For unblinded kits, everyone can view and print dispensation requirements from within Oracle Clinical One Platform, even if they don't have the **Site Users with Detailed Dosing View** role.

Age question

Good news for study designers and site users, as well! With the new Age question, site users can enter a subject's date of birth and then immediately see the subject's age. And like Number questions, Age questions can be used in both stratum groups and calculated doses, so you can stratify subjects or calculate doses based on the calculated age value.

Already working in a live study?

You can update existing forms to use the new Age question, and then release a new study version, but keep in mind that the old and new forms will collect slightly different data.

Read more about how this change affects...

- [Study designers](#)
- [Site users](#)
- [Details for study designers](#)
- [Details for site users](#)

Details for study designers

Now you have a dedicated Age question that includes both Date of Birth and Age, so you no longer need to create 2 questions to collect those pieces of information.

How do I add an Age question to a form?

The steps for adding an Age question are similar to those for adding any other question in the form, so if you're familiar with that, things will be easy.

Here's what's new for you:

- You can choose whether to calculate subjects' ages in years, months, or days.
- If you want to use the Age question for a stratum group or dosing calculation, you must create a Range validation rule for which Include Your Value in Range is selected.



Does the subject's age adjust over time?

No, the subject's age is calculated for the date of the visit and doesn't change over time.

Details for site users

When a study includes the new Age question, all you have to enter is a subject's date of birth, and the age is calculated for you.

The way that age is measured (typically years, though months and days are also possible) appears in Answer & Visit History.

Demographics

New subject numbering options

You now have additional options for numbering subjects! You now can choose:

- The number of zeros to include in the first subject number.
- Whether to include a hyphen in subject numbers.

- Whether subject numbers are sequential across all sites in a study or are sequential at each site.

Read more about how this change affects...

- [Study managers](#)
- [Site users](#)
- [Details for study managers](#)
- [Details for site users](#)

Details for study managers

How do I specify these new subject settings?

On the Subject Settings tab, select values for the following new settings:

- **Leading Zeros in First Subject Number**
Enter the number of leading zeros in the first subject number. The number of leading zeros decreases as the number of digits in the subject number increases. For instance, if you choose to use 3 zeros, your first subject number might be 0001. Subject 99 has a subject number of 0099 (with only 2 leading zeros), and subject 100 has a subject number of 0100 (with only 1 leading zero).

Default: 3

- **Include Hyphen in Subject Numbers**
Choose whether to include a hyphen between the subject number and site ID.

Default: No

- **Subject Numbering**
Choose whether subject numbers are sequential across all sites in a study or are sequential at each site.

Default: Sequential at Sites

Reminder: You have to specify these settings for all 3 modes.

Another change on this tab: The buttons for Production, Testing, and Training Settings are now always along the top of the tab rather than the left side. If you use Oracle Clinical One Platform on a smaller screen, such as a laptop, that's probably the place you've been seeing the buttons all along.

The screenshot shows the 'Subject Settings' configuration page. At the top, there are tabs for 'Production Settings', 'Testing Settings', and 'Training Settings'. Below these, the 'Subject Settings' section is visible. It contains several settings:

- 'Include Hyphen in Subject Numbers': Radio buttons for 'Yes' (selected) and 'No'.
- 'Leading Zeros in First Subject Number': A numeric input field with the value '3'.
- 'First Subject Number': A text input field with the value '0001'.
- 'Subject Numbering': Radio buttons for 'Sequential in Study' and 'Sequential at Sites' (selected).
- 'Withdraw Subjects After Code Break': Radio buttons for 'Yes' (selected) and 'No'.

A 'Subject Number Example: 001-0001' is shown in a light blue box on the right side of the settings area.

Important related changes for the first subject number

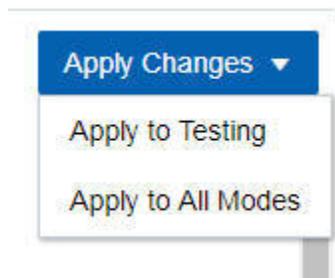
- In a new study created after this system update, the default value for **First Subject Number** is now blank.

Previously, the field had a default value of 4,000.

- Additionally, you now can't activate a site until a value is specified for the **First Subject Number** field for the mode that the site is in (for instance, you have to specify the first subject number for Testing mode before you can activate a Testing site).

New: Specify settings 1 time and apply them to all modes

You no longer need to specify the same subject settings 3 times. Now you can specify settings for one mode and then apply your changes to all 3 modes. You still have the option of applying your changes to a single mode.



Already working in a study?

- The First Subject Number setting won't change after the system update. The value that existed before the system update, whether it was the default value or a value that you set, will still be saved.
- You can specify values for the new fields, but keep in mind that changes will apply only to subjects created after the system update. Existing subject numbers won't be updated to follow the new formatting rules.
- Need to change First Subject Number after you've screened subjects?
 - If you move to a higher value, keep in mind that there will be a gap in the subject numbers.
 - If you move to a lower value, no need to worry about having duplicate subject numbers because subject numbers are never reused. Any previously assigned subject numbers are skipped when new subjects are added.

Any reporting changes?

Yes. For details, see [Report improvements](#).

Details for site users

This change has minimal impact for you, though if you work on multiple studies, you might notice that subject numbering is different in the studies. If you have questions about how subjects are numbered in a study, contact your clinical research associate.

Screening and randomization limits

Study managers: You now have more control over the number of subjects who are screened and randomized in your study. Additionally, you can:

- Choose when to receive notifications about progress toward reaching the limits.

- Close enrollment for an entire study.

You can specify different limits and alert requirements for each mode.

Read more about how this change affects...

- [Study managers](#)
- [Site users](#)
- [Details for study managers](#)
- [Details for site users](#)

Details for study managers

How do I specify the new limits?

You'll find these new settings on the Subject Settings tab.

Enrollment Open/Closed	Screening Limits	Randomized Limits	Notification
<input checked="" type="checkbox"/> Study Total	1500	1350	80%
<input checked="" type="checkbox"/> Site Total			
<input checked="" type="checkbox"/> Country			
<input type="button" value="Add Countries"/>			
<input checked="" type="checkbox"/> Canada			
<input checked="" type="checkbox"/> Mexico			
<input checked="" type="checkbox"/> United States			

You can now:

- Click a toggle button on a row to close and open enrollment for the study.
- Specify screening and randomization limits:
 - For the entire study
 - For every site in the study (the same limit for each site)
 - For every country in the study, or for each country individually. The same limit applies to each country.

Not using limits? Just leave the fields blank.

- Specify when to receive a notification about your progress toward reaching your limits.

Any other changes?

- The buttons for selecting a mode are now along the top of the tab. Previously, they were along the left side of the tab.

- The following limit fields were removed from the Subject Settings tab because the new limit fields offer better control for limits:
 - **Limit Screened Subjects** and the related **Limit** field
 - **Limit Randomized Subjects** and the related **Limit** field
 - **Notify When Randomized**

Details for site users

When a study reaches its screening limit, you won't be able to screen any more subjects. Similarly, when a study reaches its randomization limit, you won't be able to randomize, and when enrollment is closed, you won't be able to add any subjects.

Subject status changes

Subject statuses now change to Screen Failed when appropriate, and changing back to Screened is now easier:

- When you successfully screen a subject but then change an answer, resulting in a question error and a screen failure, the subject status now changes from Screened to Screen Failed. Previously, the subject status remained Screened, and only the status of the visit changed to Screen Failed.
- Additionally, it's now easier to change the subject's status back to Screened. When you open the Screening visit with the question error, the **Screen** button now appears at the bottom of the form, so you can update values as needed and then click **Screen**. Previously, only the **Save** and **Save & Close** buttons appeared at the bottom of the visit.

Role and right changes

New role for the SaaS Services team

Now when you want help from SaaS Services on your study, you can provision the users with a new role that's just for them: **Production Admin**. This role is available in Testing, Training and Production modes.

A user manager can assign this new role to users after they've been provisioned in OHSIAMS Oracle Identity Self Service. Users with this role can:

- Specify subject and supply settings
- Upload and generate kit lists and randomization lists
- Assign study versions to sites
- View unblinding inventory details
- Run the following reports:
 - Audit Report Sites and Depots
 - Kit Chain of Custody (Unblinded)
 - Kit Inventory (Unblinded)
 - Randomization List (Unblinded)

- Study Design

Users with this role cannot view subjects or subject data.

Already working in a live study? You can start assigning this role right after the system update.

Additional role changes

For details about the new **Site Users with Detailed Dosing View** role, see the [calculated doses details for user managers](#).

Report improvements

- [New report: Kit Dispensation](#)
- [Changes to the Study Design report](#)
- [Changes to the Audit Report Sites and Depots report](#)
- [No need to select a report to see the reports you've run](#)
- [Tables are now sorted in several reports](#)

New report: Kit Dispensation

We've created the Kit Dispensation report, which allows you to keep track of - you guessed it! - kit dispensation, including replacement kits. You can run this report in Testing, Training, and Production modes for all sites and subjects, or filter by specific sites and subjects. This report lets you see subjects' full kit dispensation history and any kits that were replaced, so you can track details like the date, visit, and reason for replacement.

You can run this report if you have one of the following roles:

- CRA
- Clinical Supply Manager
- Lead Site User
- Site Inventory User
- Site User
- View Only - Support



Note:

You can also open the Kit Dispensation report from the new [Subject Dispensation notification](#).

Changes to the Study Design report

For the new Age question type

Any [Age questions](#) that you create appear in their own rows in the Forms section. The **Answer Type** for Age questions is Calculation.

For the open-label and multiple randomization designs change

- The Study Design Summary section has a new Blinded Status column. This status is set in the randomization design that was applied to the visit or a prior visit. N/A appears for unscheduled visits, including screening, withdrawal, and study completion visits.
- The Randomizations section has a new Blinded column, which indicates whether a randomization design is blinded or unblinded.
- When a study has multiple randomization designs, the Randomizations section now has columns for the new settings for a randomization design, including:
 - Blinded Status
 - Re-Randomization
 - Treatment Arms Randomized or Mapped
 - Assign New Randomization Numbers to All Subjects
- The Treatment Arms section now shows columns for **New Treatment Arms** and **Previous Treatment Arms**, so you can easily track how subjects are mapped to new treatment arms in a randomization design. **Previous Treatment Arms** has a value only when the randomization design is a re-randomization in which subjects are mapped to treatment arms. Otherwise, N/A appears. **New Treatment Arms** always has a value for every type of randomization design.

For calculated doses on kit types

- In the Kits section, a new Calculating Doses column lists either Yes or No for each kit type.
- When Calculating Doses is Yes, a new Calculated Doses section appears within the Kits section and includes all the details specified in the calculated dose, including the title, the kit measurement, and the dosing frequency.

For the new subject numbering fields

The values of the new subject number settings now appear in the Subject Settings section.

Changes to the Audit Report Sites and Depots report

The [new fields for sites](#) , including the DEA Number fields and the new PI fields, now appear in the Audit Report Sites and Depots report in the Site Additional Information section.

Additionally, a new column in this section, Operation Type, helps you better track changes to fields. The Operation Type column indicates whether the value for the field is the result of the site being created or modified.

No need to select a report to see the reports you've run

Now when you open the Reports page and expand Download Reports on the right, the last twenty reports that you ran appear without your having to select any reports.

Want to see all instances of a particular report? Just select the report on the left. (Issue 27338951)

Tables are now sorted in several reports

Thanks to sorting, skimming the following reports is now a little bit easier:

- Kit Inventory (Unblinded) report
 - The **Study Organization Name** column is now sorted alphabetically.
 - For each set of rows for an organization, the **Kit Type ID** column is now sorted alphabetically.
 - For each set of rows for a kit type ID, the **Manufacturing Lot ID** column is now sorted alphabetically.
- Kit Chain of Custody (Unblinded) report
 - The **Kit Number** column is now sorted numerically.
 - For each set of rows for a kit number, the **Transaction Date** column is now sorted from the earliest date to the latest date.
- Randomization List (Unblinded) report
 - The **Randomization Number** column is now sorted numerically.
 - For each set of rows for a randomization number, the **Date** column is now sorted from the earliest date to the latest date.
- Subject Data report
 - Sites are now sorted alphabetically in the **Site** column.
 - For each set of rows for a given site, data in the **Subject Number** column is now sorted.
 - For each set of rows for a subject number, data in the **Visit Title** column is now sorted.
 - For each set of rows for a visit, data in the **Form Title** column is now sorted.
 - And finally, for each set of rows for a form, data in the **Question Label** column is now sorted.

Oracle Clinical One Platform training improvements

Sign out from Home page training overlay

The training overlay for the Home page now has a Sign Out button, in case you need to sign out before you complete all assigned training.

In-product training videos available for everyone

You can now access the in-product training videos, even when the training requirement is turned off for your organization. Previously, the videos were available only on the Oracle Help Center when your organization didn't require in-product training. Now it's easier to pinpoint those important details you want to remember!

How to watch the in-product training videos: In the upper-right corner, click your name, and then click Help. An overlay appears, showing all videos that are applicable for your roles and the page that you're on.

Reminder: If the training requirement is turned on for your organization, you'll be required to watch all videos in their entirety before you can start working on a page. This requirement hasn't changed.

Additional usability improvements

- [Randomization and kit usability improvements](#)
- [Site, depot, and user management usability improvements](#)
- [Shipment and supply usability improvements](#)
- [Site user and subject data usability improvements](#)

Randomization and kit usability improvements

Use region-blocked randomization

You now can group countries into regions and then assign blocks in your randomization list to each region, either dynamically or automatically.

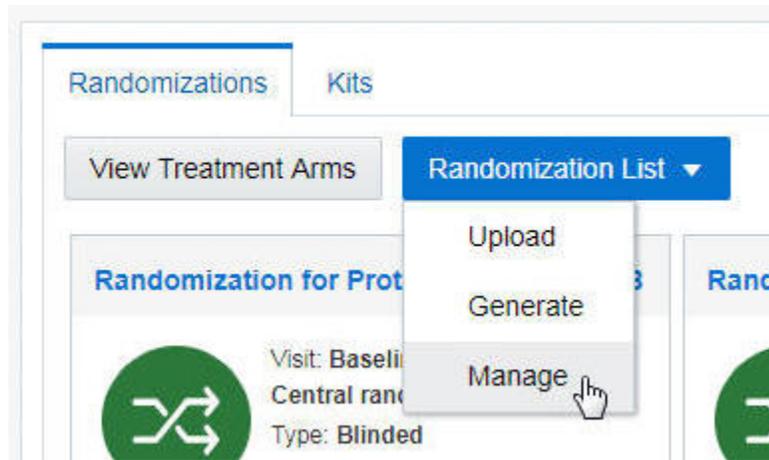
- You specify regions on the Subject Settings tab, in Study Settings, in the new Randomization Regions section on the right.
- The following randomization types are now available when you create a randomization design:
 - Region Blocked Dynamic randomization
 - Region Blocked Fixed randomization
 - Region Blocked Dynamic Stratified randomization

Manage your randomization lists the same place you create them

Previously, you associated randomization lists with study versions on the Supply Settings tab, in **Randomization List Assignment** (on the right). The Randomization List Assignment sidebar has been removed.

Now you can create multiple randomization designs and randomization lists in a study, and you can also manage all your lists in the same place that you create them: on the Randomizations tab. The **Randomization List** drop-down on the Randomizations tab has a new option: **Manage**.

Reminder: You won't see the **Randomization List** drop-down until you move your study design below the Testing container on the Home page.



Select the new **Manage** option to open the Manage Randomization Lists pop-up, where you can associate each randomization list with the appropriate study version and randomization design.

Unused randomization designs are hidden when you generate a randomization list

Randomization list managers: Now when you generate a randomization list, the only randomization designs that appear are those that randomize subjects and that are assigned to a visit.

This change is helpful because studies now might have multiple randomization designs, and it will be easier to create a randomization list if you see only the randomization designs that require a randomization list.

Site, depot, and user management usability improvements

Easier to find sites

New filters on the Sites tab make it easier to find the sites that you need to update, such as when you need to activate a site or assign a resupply strategy. You can now filter sites by status, country, and study version.

There's also a new Search field, which lets you search for and find a site in no time. This new field searches the site name, site ID, and the PI's last name.

New PI name fields for sites

The Principal Investigator Name field has been split into the following 3 fields:

- Principal Investigator (PI) Prefix (for example, Dr.)
- PI First Name
- PI Last Name

Important: You must specify a value before you can activate a site.

Already working in a live study? After the system update, the name that was in Principal Investigator Name will appear in PI Last Name. Consider moving the prefix and first name details to the other fields.

New DEA number fields for sites

The following fields have been added to the wizard for creating sites, so you now have access to more relevant data about your sites in the same place:

- DEA Number
- Expiration (for the expiration date)

Already working in a live study? After the system update, you can edit existing sites and add DEA numbers and expiration dates.

The PI and DEA fields appear in the [Audit Report Sites and Depots report](#).

Cannot delete a site that has been activated

Now you can delete a site only if it has a New status. Any site that has been activated or retired can't be deleted.

Creating depots just got (a bit) easier!

We added new filters and made everything easier for sites, but we didn't forget about depots.

Now when you create a depot, you can search for a depot that you used in a previous study, select it, and see some fields from the depot in the wizard. The search field looks for depots based on name, city, state, or province.

Shipment and supply usability improvements

Inventory tab now displays number of available kits

The Inventory tab for unblinded users (typically clinical supply managers) now displays the number of kits that are available to be dispensed. This new metric is useful when you're troubleshooting inventory issues at a location because you no longer need to select a kit type to see the number of kits that can be dispensed.

Kit Type	Total Kits	Available	Dispensed	Damaged
A ORS 123 10 mg	2000	2000	0	0
B ORS 123 5 mg	2000	1994	6	0
C ORS-123 matching placebo	2000	1997	3	0
D ORS-123 10 mg	2000	1989	11	0
E ORS-123 5 mg	2000	1995	5	0

The same metric is available when you select a kit type.

Shipments Inventory Kit Reconciliation Randomizations

Location: All Unassigned Sites Depots Lots: All

Status: All Number Range: Kit Sequence Add to Lot

2000 Total Kits 1989 Available 11 Dispensed 0 Damaged

Kit Number	Sequence Number	Status	Label Group	Location	Manufacturing Lot	Blinded Lot
1717	6001	Dispensed		DA-Dermatology Associates	10 mg dose	Blinded Lot
9268	6002	Dispensed		DA-Dermatology Associates	10 mg dose	Blinded Lot

Site user and subject data usability improvements

Improvements to Subject History

Subject History is now color coded and more graphical.

Subject History

DA-0004

- Withdrawn**
23-Aug-2018 | 12:45 (EDT -04:00)
- Kit - Damaged by Subject**
8571 23-Aug-2018
- Kit - Lost By Subject**
9831 23-Aug-2018
- Kit - Dispensed**
7362 23-Aug-2018
- Randomized**
1003
23-Aug-2018 | 11:31 (EDT -04:00)
- Screened**
21-Aug-2018 | 08:58 (EDT -04:00)

Additionally, you can replace a subject's lost or damaged kit using a new button in Subject History:



You can still replace kits using the Manage Subjects drop-down.

Stability improvements

- [Report and notification stability improvements](#)
- [Study and study version stability improvements](#)
- [Form and visit stability improvements](#)
- [Randomization and kit stability improvements](#)
- [Shipment and supply stability improvements](#)
- [Site, depot, and user management stability improvements](#)
- [Site users and subject data stability improvements](#)

Report and notification stability improvements

Reports now include data for start and end dates (Former Known Issue)

Users who run reports: When you run a report for a range of dates, the report now includes data for the dates that you specify rather than the days between those dates. For example, if you run a report for 1-Jan through 3-Jan, the report now includes data for 1-Jan, 2-Jan, and 3-Jan. Previously, the report included data only for 2-Jan. The following reports are affected by this fix:

- User Training
- Audit Report Sites and Depots (Issues 27429893, 27531891)

Icons now appear in HTML reports

Icons now appear as expected in HTML reports. Previously, the icons on the left of each section header sometimes didn't download correctly. For example:



Values for incomplete visits in Subject Events report (Former Known Issue)

Users who run the Subject Events report: In the Subject Events report, the Randomization Number and Dispensation Kit Number columns now contain values only when the status of the visit in the Visit Status column is COMPLETE. (Issue 27414962)

User Assignment report created as expected

Users who run the User Assignment report: When you run the User Assignment report for a study with no sites, the report now generates. Previously, the report wasn't created. (Issue 27713742)

Long reports created correctly

Users who run reports: Reports containing a lot of data (5,000 or more entries) now generate and display as expected. (Issue 27521904)

Repeating column headers fixed

Users who run reports: Column headers no longer appear multiple times in HTML reports when the reports have more than 5,000 records. (Issue 27857954)

View Chinese characters in reports

When you follow the new required steps to open CSV reports in Microsoft Excel, you now can view Chinese characters in the reports. To see the new required steps, see [What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?](#) (Issues 27635303, 27537840)

Study and study version stability improvements

Character limit working correctly for study title (Former Known Issue)

Users who move a study version to the Approved container on the Home page: Oracle Clinical One Platform now enforces the 8500-character limit for the Title field. (Issue 27401395)

Form and visit stability improvements

Buttons in the same order in both browsers (Former Known Issue)

Study designers: In the visit pop-up, which appears when you click a visit in Visits & Events, the buttons in the lower-right corner are now in the same order in both the Google Chrome and Microsoft Internet Explorer browsers. The delete button is on the left, and the Cancel button is on the right. (Issue 27355956)

Randomization and kit stability improvements

Clinical supply managers can now see the Supply Settings tab (Former Known Issue)

User managers: Users with the **Clinical Supply Manager** role for Testing mode now can see the **Supply Settings** tab in Study Settings. (Issue 27095168)

Retracted workaround: Clinical supply managers no longer need the View Design role in the Study Design Roles list to see the Supply Settings tab.

Helpful error for duplicate kit lists and numbers (Former Known Issue)

Users who upload kit lists, such as clinical supply managers: A helpful error message now appears when you try to upload a kit list that has already been uploaded in a study isn't helpful. Previously, an Oops error with no details appeared. (Issue 27498479)

No randomization issues after moving to a new study version (Former Known Issue)

Users who create new study versions and manage randomization: The randomization list that was associated with an approved study version is now automatically associated with a new approved study version, so sites no longer will experience randomization issues after they

start using new study version. Previously, a randomization list was sometimes not associated with a new study version when you moved the study version to Approved on the Home page, leading to randomization issues. (Issue 28042130)

Retracted workaround: After moving a study version below Approved on the Home page, you no longer need to check that a study version is associated with the right randomization list in Production mode.

Randomization List Manager role now required as expected (Former Known Issue)

Randomization list managers: You now can upload and generate randomization lists in Production or Training modes when you have the Randomization List Manager role for only one mode. (Issue 27457515)

Retracted workaround: User managers no longer need to assign the Randomization List Manager role to users for both Production and Training mode in order for the user to create lists in just one of the modes.

Shipment and supply stability improvements

Sites are sorted in Inventory tab filter (Former Known Issue)

Clinical supply managers: The drop-down list that allows you to filter by site now sorts sites alphabetically. (Issue 27393220)

Site, depot, and user management stability improvements

Additional rights for Support role

User managers: The View Only – Support role now allows users to:

- View inventory at a site.
- View supply settings. (Issue 27725052)

Manage Users drop-down hidden

Users who aren't user managers: The Manage Users drop-down is no longer visible when your roles don't allow you to edit user details. (Issue 27469817)

Confirmation on deleting global users

Global users: You are now prompted to confirm the deletion of a global user. This confirmation will help prevent the accidental deletion of users. (Issue 26941128)

Site users and subject data stability improvements

Next visit now available after internet outage

Site users: When a network interruption occurs after you complete the forms in a visit but before you click **Screen**, **Randomize**, or **Dispense**, the table of subjects now updates appropriately after your internet connection comes up. Previously, the subject's status updated appropriately after the internet connection came up, but the visit you submitted remained in the Next Visit column, so you couldn't start the next visit.

What you need to do to update the table: Open the visit that you submitted, and click **Return to All Subjects** in the upper-left. The table then updates so that the next visit is available. (Issue 28134991, 28143340)

Reason for change appears as expected for Visit Start Date (Former Known Issue)

Site users: The reason for change for a Visit Start Date now always appears as expected in Answer & Visit History. Previously, the reason sometimes didn't appear for the Visit Start Date when you started a skipped visit. (Issue 27342160)

Retracted workaround: Previously, you had to click into the Visit Start Date field to see the reason for change. Now the change appears as expected in Answer & Visit History when you open the visit.

HTML tags no longer appear in tooltip (Former Known Issue)

Site users who replace subjects' kits: The tooltip that appears when you point to the tip in the kit replacement pop-up now appears as expected. Previously, it contained HTML tags. (Issue 27468457)

Code break and code view allowed on retired sites (Former Known Issue)

Site users who do code breaks and sponsor users who do code views: Code break and code view are now allowed when a site is retired.

Retracted workaround: You no longer need to reactivate a site to perform a code break or code view. (Issue 27469387)

Complete Study button no longer grayed out (Former Known Issue)

Site users who enter subject data: The Complete Study button can now be clicked for a study completion visit after you complete a subject, undo the study complete, complete the subject again, remove an answer without selecting a reason for change, and enter the same reason again without selecting a reason for change. (Issue 27483082)

Retracted workaround: You no longer need to refresh the page to enable the button.

Updating screening visit after randomizing (Former Known Issue)

Site users who enter subject data: When a subject has already been randomized, and you change an answer in the screening visit to an invalid answer, the status of the screening visit now changes to Complete with Errors. (Issue 27483700)

No randomization after screen failure

Site users: When you screen a subject successfully and then return to the screening visit and enter a value that results in a screen failure, the subject can no longer be randomized. (Issue 27539749)

Oracle Clinical One Digital Gateway 1.1 (October 2018)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Oracle InForm to Oracle Argus Safety integration](#)
- [New events for the Oracle Clinical One Platform to Oracle InForm integration](#)
- [The Oracle Clinical One Digital Gateway user interface is here](#)
- [New Integration Viewer global role](#)
- [Email notification on integration failure](#)

Oracle InForm to Oracle Argus Safety integration

Oracle Clinical One Digital Gateway now allows you to configure and manage study-level integrations between Oracle InForm and Oracle Argus Safety. The integration can be set up to automatically send Serious Adverse Event (SAE) data from Oracle InForm to Oracle Argus Safety as soon as it's entered, saving time and eliminating the paperwork required to get the information from your site users to your safety experts.

More information

The full process for setting up the integration is documented in the new [Send InForm Safety Data to Argus Safety](#) infographic.

First steps

If you are interested in this integration, please reach out to your Oracle project manager for additional information and guidance.

New events for the Oracle Clinical One Platform to Oracle InForm integration

The Oracle Clinical One Platform to Oracle InForm integration can now share data for the following events:

- **Study Complete:** When a subject completes the study in Oracle Clinical One Platform, the completion date and any other relevant information that is configured to be shared for this event is sent to Oracle InForm.
- **Undo Study Complete:** When you undo marking a subject as completed in Oracle Clinical One Platform, the information in the study completion form in Oracle Clinical One Platform remains, but the completion date and other details that were sent are cleared out in Oracle InForm. The update to the fields is audited in both Oracle Clinical One Platform and Oracle InForm.
- **Early Withdrawal:** When you withdraw a subject in Oracle Clinical One Platform, the study completion form in Oracle InForm is updated with the withdrawal date and reason, along with any other data that is configured to be shared for this event.
- **Undo Early Withdrawal:** When you undo the early withdrawal in Oracle Clinical One Platform, Oracle Clinical One Platform retains the information in the withdrawal form, but the completion date and other details that were sent are cleared out in Oracle InForm. The update to the fields is audited in both Oracle Clinical One Platform and Oracle InForm.
- **Screen Failed:** When a subject is marked as Screen Fail in Oracle Clinical One Platform or fails the screening visit, the screen failure date and reason, along with

any other relevant information related to the screen failure event that is configured to be shared, is sent to Oracle InForm. You can map these fields to any form in Oracle InForm you use to collect the screen failure reason. The integration does not change the status for the subject in Oracle InForm, though rules can be created in Oracle Central Designer so that the subject's status is updated in Oracle InForm when the subject fails the screening visit.

- **Undo Screen Failure:** When you undo the screen failure in Oracle Clinical One Platform, the screen failure date and reason are updated to blank in Oracle InForm. The integration does not change the status for the subject in Oracle InForm.

When can I see the data in Oracle InForm?

All event data is sent to Oracle InForm at the intervals selected for the integration schedule in Oracle Clinical One Digital Gateway.

Will this change affect my existing integration?

Not unless you want it to. If you don't want to share data for the above events, your integration will continue to run as usual.

How can I add these events to my existing integration?

Reach out to your SaaS Services project manager for the integration and request that they update your integration to add the new events.

More information

You can review the full list of data that this integration sends to Oracle InForm in [Which data can be shared with Oracle InForm?](#)

The Oracle Clinical One Digital Gateway user interface is here

Oracle Clinical One Digital Gateway now has an easy-on-the-eyes and easy-to-use interface where you can create, configure, customize, monitor, and manage your integrations.

Roles

You need the following roles to access Oracle Clinical One Digital Gateway:

- From Oracle Life Sciences Identity and Access Management Service: ClinicalOne_Production role. Your delegated administrator can assign this role.
- From Oracle Clinical One Platform: Integration Manager global role or new Integration Viewer global role. Your Oracle Clinical One Platform system administrator can assign these global roles.

Accessing the Oracle Clinical One Digital Gateway interface

The Services project manager will supply your company-specific URL for accessing Oracle Clinical One Integration Hub. It is up to you to provide it to your users who need it.

More information

For more information and instructions, see [I'm new. Where do I start?](#) in the new *User Guide*.

New Integration Viewer global role

The Integration Viewer global role is now available in Oracle Clinical One Platform. Oracle Clinical One Platform system administrators can assign this role to users who need view-only access to the Oracle Clinical One Digital Gateway interface.

More information

For details about the role, see the table in [Create a global user](#).

Email notification on integration failure

Oracle Clinical One Digital Gateway now automatically sends an email notification whenever a job has failed. Now you'll always know if it's time to check in on your integrations and can enjoy the silence in the meantime.

Who gets the emails?

When setting up the integration in the Oracle Clinical One Digital Gateway interface, you can now specify, for each integration, one or more email addresses that should receive automated email notifications. See [Step 5.2: Upload the test integration file](#) for details.



Note:

The job status changes to Failed only after the configured number of reattempts have all failed.

Stability improvements

- [Multiple dispensed kit numbers in Oracle InForm](#)

Multiple dispensed kit numbers in Oracle InForm

If you are using the Oracle Clinical One Platform to Oracle InForm integration and your Oracle Clinical One Platform study dispenses multiple kits in a single visit, it is now possible to show all dispensed kit numbers in Oracle InForm. Previously, Oracle InForm could only show one kit number per visit.

What if I don't need this feature?

If you are happy with the way kit information is currently shared with Oracle InForm, you don't need to do anything after the update and your integration will continue to run as usual.

How do I set this up?

If you want to leverage this new feature, reach out to your SaaS Services project manager for the integration and request that they update the integration for you.

Oracle Clinical One Platform 1.1.2.2 (September 2018)

- [What's new](#)

What's new

All changes in this release were related to HS Learn - Manager. There were no changes to clinical studies.

Oracle Clinical One Platform 1.1.2.1 (September 2018)

- [Stability improvements](#)

Stability improvements

- [Subject Events report displays randomization and kit numbers \(Former Known Issue\)](#)
- [Sign in using a bookmark](#)

Subject Events report displays randomization and kit numbers (Former Known Issue)

The Subject Events report now contains subjects' randomization and kit numbers. Previously, **N/A** appeared in the Randomization Number and Dispensation Kit Number columns. (28152984)

Sign in using a bookmark

When you open Oracle Clinical One Platform using a bookmark, you now are able to sign in successfully and start working. Previously, after you entered your user name and password, the sign-in page appeared again, and you couldn't access Oracle Clinical One Platform. (28282283)

Oracle Clinical One Platform 1.1.2 (September 2018)

- [What's new](#)
- [Stability improvements](#)

What's new

- [Search field on the Users tab](#)
- [Technology refresh](#)

Search field on the Users tab

The Users tab in Study Settings now has a search field, so it's easier to find the user you're looking for in a long list. The following fields are searched for each user:

- First name

- Last name
- Email address

(Issue: CLINONE-11983)

Technology refresh

In this system update, we're refreshing the technology on the middle tier. The most important thing you need to know is that no product functionality has changed. And if that's all you care about, feel free to skip the rest of this section.

What is a middle tier?

The middle tier helps the Oracle Clinical One Platform interface communicate with the database. The interface is where you work, and the database is where all of the study data is saved.

How does this change help you?

Going forward, you can expect less downtime for system updates. That means that you'll continue getting new features with less interruption in your workday.

Additionally, the new middle tier is extremely stable and enables high availability. If a server experiences an issue, its responsibilities can be transferred to another server instantly, with no interruption for anyone working in Oracle Clinical One Platform. Pretty cool, huh?

Stability improvements

- [Stability improvements for all users](#)
- [Report and notification stability improvements](#)
- [Randomization and kit stability improvements](#)
- [Shipment and supply stability improvements](#)
- [Site, depot, and user stability improvements](#)
- [Site user and subject data stability improvements](#)

Stability improvements for all users

A training reminder is no longer sent when training is off

When your organization turns off the in-product training feature, you no longer receive a training reminder notification. Previously, you got one reminder email 24 hours after training was turned off, but that must have been confusing to anyone who got it - sorry about that! (Issue 27731645)

Report and notification stability improvements

Kit Reconciliation report lists correct number of reconciled kits (Former Known Issue)

In the Kit Reconciliation report, the Total Kits Reconciled value now displays the correct number of reconciled kits. Previously, the value displayed the number of returned units. (Issue 27679794)

Study Design report is created successfully with subject and supply settings (Former Known Issue)

You no longer get an error when you try to include subject settings or supply settings in the Study Design report. (Issue 27715687)

Retracted workaround: Previously, you had to move the study version to Testing and then Approved on the Home page so that you could run the report without any errors. You no longer need to do that and can run the report even when the study version is below Draft on the Home page.

Reports created successfully with special characters (Former Known Issue)

You no longer need to worry about special characters such as a backslash (\) or text in double quotes ("abc") interfering with your ability to run reports. Previously, these characters sometimes prevented reports from running. (Issue 27462031)

Retracted workaround: Previously, we recommended not entering a backslash (\) or any text in double quotes ("abc") anywhere in Oracle Clinical One Platform. Now they're safe to use.

Notifications sent successfully when email address contains a dash (-)

When the domain portion of an email address contains a period followed by a dash (for instance, name@division.company-region.com), notifications are now successfully sent to the user. Previously, notifications weren't sent to email addresses that contained a period followed by a dash. (Issue 28424005)

Randomization and kit stability improvements

Get notified when a kit type is missing the kit type ID

If you don't specify the ID while creating a kit type, you now get a message that tells you the field is both required and missing so you know why you can't save the kit type.

We also fixed a related issue: If you entered a description but no kit type ID, tried to save and ran into an error, then added the ID and deleted the description, the description was still saved. (Issue 27772149)

Shipment and supply stability improvements

Sites are sorted in the Inventory tab filter (Former Known Issue)

On the Inventory tab for clinical supply managers, the drop-down list that allows you to filter by site now sorts sites alphabetically. (Issue 27393220)

Site, depot, and user stability improvements

New rights added to the View Only - Support role

Users with the View Only - Support role now can:

- View details about sites and depots.
- Run the following reports:
 - Audit Report Sites and Depots report
 - Health Sciences Learn Training report
 - User Assignment and User Assignment by Site report (Issues 27779099, 27779130)

Site user and subject data stability improvements

Visit status and subjects table now update as expected

When you complete all fields on a visit, click away from the form, and then submit the form, the status of the visit and the subjects table are now updated as expected. Previously, when you clicked away from the form and then quickly clicked to submit the form, the form data was saved, but sometimes the status of the visit wasn't updated, and sometimes the visit remained in the Next Visit column when it should have moved to the Previous Visit column. Similar issues occurred if an internet outage occurred while a form was being saved. (Issue: 27500422)

Oracle Clinical One Platform 1.1.1.3 (July 2018)

- [What's new](#)

What's new

All changes in this release were related to HS Learn - Manager. There were no changes to Oracle Clinical One Platform studies.

Oracle Clinical One Platform 1.1.1.2 (July 2018)

- [What's new](#)

What's new

All changes in this release were related to HS Learn - Manager. There were no changes to Oracle Clinical One Platform studies.

Oracle Clinical One Platform 1.1.1.1 (June 2018)

- [What's new](#)

What's new

All changes in this release were related to HS Learn - Manager. There were no changes to Oracle Clinical One Platform studies.

Oracle Clinical One Digital Gateway 1.0 (May 2018)

- [Send study data from Oracle Clinical One Platform to Oracle InForm](#)
- [Automate shipments when you distribute using the Almac global depot network](#)
- [How can I get these integrations?](#)

Send study data from Oracle Clinical One Platform to Oracle InForm

Great news for site users who work in both Oracle Clinical One Platform and Oracle InForm for a study! Study data from Oracle Clinical One Platform can now synchronize directly in Oracle InForm. Working in Oracle Clinical One Platform and Oracle InForm becomes much easier, since you no longer need to answer the same question in both products.

Sponsors: How can I share my Oracle Clinical One Platform study data to Oracle InForm studies?

All you have to do is reach out to your Oracle Sales contact! The Oracle Services team will help you define the integration points between your Oracle Clinical One Platform and Oracle InForm studies.

Sponsors: Which Oracle InForm releases can I use with Oracle Clinical One Platform?

See the *Oracle Health Sciences Compatibility Matrix*, which is available as an attachment in My Oracle Support article [Oracle Health Sciences Applications Supported Technology Stack \(Doc ID 180430.1\)](#).

Sponsors: How long does it take for Oracle Clinical One Platform study data to appear in Oracle InForm?

After you save a form in Oracle Clinical One Platform, data that is mapped to Oracle InForm is sent to Oracle InForm on a regular basis. The schedule for when this job runs is configurable.

Sponsors: What are the configuration options?

You decide on the data that is sent from Oracle Clinical One Platform to Oracle InForm and the frequency together with Oracle Services. For details, reach out to your Oracle Sales contact.

Automate shipments when you distribute using the Almac global depot network

If you distribute your investigational product using Almac, some steps in the lifecycle of a shipment are now automated in Oracle Clinical One Platform. The benefits?

- It's a time-saving feature for clinical supply managers and depot users.

- You can see in Oracle Clinical One Platform if the depot has received your shipment request.

Sponsors: How can I connect my Oracle Clinical One Platform study with Almac?

Reach out to your Oracle Sales contact if you're interested in automating the shipment workflow. The Oracle Services team will define the integration between your Oracle Clinical One Platform study and Almac the global depot network.

Clinical supply managers and depot users: How can automation help me?

You'll see these changes in Oracle Clinical One Platform only after the Oracle Services team sets up a study so that it is connected with Almac. These changes don't affect site users.

See how automation can help you in the following table.

Activity in the study	Activity that is now automated in Oracle Clinical One Platform
A new shipment is raised.	The status of the shipment changes to Processed.
The depot receives the shipment request.	The status of the shipment changes to Confirmed, a new status.
An issue occurs, such as a system outage, and the depot is unable to process the shipment request.	The status of the shipment changes to Invalid, a new status. Clinical supply managers: <ul style="list-style-type: none"> First, cancel the shipment so that you can set the status of the kits back to Available. Next, do one of the following: <ul style="list-style-type: none"> Allow the resupply process to create a new shipment the next time inventory runs. Create a new manual shipment.
The depot fulfills a shipment.	The ship date is set, and the status of the shipment changes to In Transit.

How can I get these integrations?

Just reach out to your Oracle Sales representative to get started! Next, Oracle Services will identify the integration details and then configure the integration for you.

Delegated administrators: What roles do Oracle Services users need in Oracle Life Sciences Identity and Access Management Service?

To set up an integration, Oracle Services users need:

- The access role IntegrationHub_Production.
- The access role ClinicalOne_Production.

You must set up the new Oracle Clinical One Digital Gateway roles so that Oracle Services team members can request access to them and so that you can approve all requests. For instructions, see Activate approvals, and publish roles.

Oracle Clinical One Platform administrators: What roles do Oracle Services users need in Oracle Clinical One Platform?

Oracle Services users must have:

- Oracle Services users who configure the integration need the Integration Manager global role.
- The Oracle Project Manager needs the Study Creator global role.

For instructions on how to assign these roles, see [Create study team members](#).

Oracle Clinical One Platform 1.1.1 (March 2018)

- [What's new](#)

What's new

All changes in this release were related to HS Learn - Manager. There were no changes to Oracle Clinical One Platform studies.

Oracle Clinical One Platform 1.1 (March 2018)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Drug accountability and reconciliation](#)
- [Get trained in Oracle Clinical One Platform as you work](#)
- [Improved reporting capabilities](#)
- [Capture a visit start date](#)
- [Collect data during withdrawal, and undo withdrawal](#)
- [Complete a study for a subject](#)
- [Subject data is displayed according to sites' time zones](#)
- [Skip visits that subjects miss](#)
- [New and renamed roles](#)
- [New notifications](#)
- [Additional usability improvements](#)

Drug accountability and reconciliation

Great news for clinical supply managers! You can now manage the return or destruction of any unused product from within Oracle Clinical One Platform.

- **Clinical supply managers:** The new drug accountability features allow you to demonstrate that the study drug was dispensed and administered according to the protocol.

- **Clinical supply managers:** The new drug accountability features allow you to demonstrate that the study drug was dispensed and administered according to the protocol.
- **CRAs:** You can now verify site returns and confirm that each site followed appropriate procedures for product destruction. In addition, you can approve either destruction or return of the drug, thus ensuring that sponsor and regulatory requirements for product handling are met.

Who is responsible for each step of kit reconciliation?

The workflow is flexible so that you can opt to use the parts that are required for the protocol and any relevant SOPs. All of these steps are available in Oracle Clinical One Platform when you require kit reconciliation, but they're not required.

1. Reconcile and verify kits:
 - a. A subject returns a kit to the site.
 - b. A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.
 - c. A CRA verifies the kit.
2. Destroy kits:
 - a. A CRA marks kits that are ready for destruction, including the returned kits that the CRA verified as well as damaged, expired, and undispensed kits.
 - b. The next step depends on the location of the drug destruction facility:
 - If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to Destroyed according to the protocol and relevant SOPs.
 - If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility, where they are destroyed according to the protocol and relevant SOPs. The receiving depot can be either the depot that shipped the product to the site or a tertiary depot that provides destruction capabilities. If required, the clinical supply manager can change the status of the kits to Destroyed, or sponsors can opt to skip this final step.

New kit status: Returned to Site

When a subject returns a kit to the site, site users can now change the status of the kit to **Returned to Site** when they reconcile the kit. CRAs can filter for kits with this status when they do source data verification (SDV) of kits during their site visits.

The **Pending Destruction** status (renamed from Processed for Destruction) and **Destroyed** status aren't new but are now used for kit reconciliation.

Any other related changes?

There's a new report named Kit Reconciliation. For details, see the [changes to reports](#).

- [Details for clinical supply managers](#)
- [Details for clinical research associates \(CRAs\)](#)
- [Details for sites](#)
- [Details for depots](#)

Details for clinical supply managers

How do I turn on kit reconciliation in a study?

In Study Settings, open the Supply Settings tab, and select Yes for the new **Kit Reconciliation Required** setting. If you select No, drug reconciliation features aren't available in the study.

How do I specify whether sites and depots are drug destruction capable?

In each wizard for creating and editing sites and depots, there is a new **Drug Destruction Capable** option.

- If you select Yes for a site, site users are responsible for marking kits as Destroyed. Shipments aren't created for the kits that are ready for destruction because kits are destroyed at the site.
- If you select No for a site and Yes for its depot, shipments are created for the kits that need to be destroyed, and only clinical supply managers can mark kits as Destroyed.
 - Kits are shipped back to the depot that shipped them, if the depot is a drug destruction facility.
If the depot that shipped a kit isn't a drug destruction facility, the kit is sent to a depot that supports shipping to the country that the site is in. This depot could be an alternate depot that ships kits to sites in the country, or it could be a tertiary depot that receives kits for destruction but doesn't ship kits. Create a destruction-only depot the same way you create a shipping depot; make sure you choose the countries that the depot supports, and indicate that the depot is Drug Destruction Capable.
 - Shipments are created so that kits with the same temperature requirements ship together.
If the study doesn't have temperature requirements for kits that will be returned, consider combining multiple packing lists into a single shipment.
 - The shipments have a status of Pending Destruction, a new status.

Where do I check the status of kit reconciliation?

A new tab is available on the Supplies page: Kit Reconciliation. On this tab, you can view all kits in the study and filter your view by subject, kit status, number range, and kit number.

The tab has two panels on the right:

- On Inventory Management, you can update the status of the kit and view and edit reconciliation details.
- On Kit History, you can view the history of a kit across all sites.

Where do I mark kits as Destroyed?

On the Inventory tab.

What if I'm working in a live study?

After the system update, neither Yes nor No is selected for the new **Kit Reconciliation Required** setting. You can select either **Yes** or **No** at any time, including in a live study. If you're going to set **Kit Reconciliation Required** to **Yes**, we recommend that you specify the **Drug Destruction Capable** setting for sites and depots first.

Details for clinical research associates (CRAs)

How do I perform source data verification (SDV) on the kits that subjects return to sites?

You have to perform SDV before marking the kits as Pending Destruction.

1. On the Inventory tab, select a kit that has been reconciled, and review details about the kit to the right under **Inventory Management**.
2. If reconciliation details are correct, click the gray checkbox in the new Verify column. The checkbox turns green.
If reconciliation isn't correct, update the kit on the right in Inventory Management. After you save, the checkbox in the Verify column turns green.

If a site user updates a kit that you verified, the green verified checkbox is removed.

How do I mark kits that are ready for destruction?

1. On the Inventory tab, select the kits that are ready for destruction.
2. On the right below Inventory Management, click **Update Kits**, and change the status of the kits to **Pending Destruction**.
If the site is drug destruction capable, the site can now destroy the kits.

If the site isn't drug destruction capable, a shipment and packing list are created so either you or someone at the site can send the kits to the depot.

Usability improvements on the Subjects tab

See the following changes in Subject History, which is to the right of the Subjects table when you select a subject:

- **You can now update the status of a kit.**
Kit numbers are now hyperlinks. Click a kit to change update the status of a kit.
- **One click brings you to the Inventory tab, filtered for the selected subject.**
Click the arrow to the right of Dispensation History () to see all kits dispensed to the subject on the Inventory tab.

Usability improvements on the Inventory tab

- **New filtering options, including subject number and multi-select for kit statuses**
 - The Subject Number filter is now available.
 - The Status filter moved to the left and now allows you to select multiple statuses.
 - There is a new Clear Filters option that appears after you select filtering criteria.
- **New table columns, including a column for confirming site reconciliation**
The new columns appear only when kit reconciliation is required for the study.
 - The following columns are new:
 - * Verify: This column is clickable if the site has reconciled the kit.
 - * Last Modified

- * Units per Kit
- * Returned Units: Point to the talk bubble to see the reason for change.
- * Missing Units
- * Balance Units
- Additional changes:
 - * The icon for a kit type now appears in the Kit Number column.
 - * The following columns were removed: Shipment Number and Comments.
- **New details available on the right**
 - Inventory Correction was renamed to Inventory Management
This section now contains additional details about a kit, including the subject the kit was dispensed to (if the kit was dispensed) and the number of returned, missing, and balance units (if the kit has been reconciled).
 - New section on the right: Kit History
This new section lists all status changes for the selected kit at the site, including when it was dispensed and who made the change.

Details for sites

How do I do kit reconciliation?

Best practice: We recommend reconciling kits as the study progresses. For instance, ask subjects to bring any unused investigational product to their next dispensation visit.

1. Select a subject, and to the right in Subject History, click the kit that the subject returned.
2. From the Kit Status drop-down, select **Returned to Site**.
3. Specify the number of returned and missing units and an optional reason, and click **Update Kit**.

How do I know when kits can be destroyed?

After your CRA marks the kits as Pending Destruction, you can either:

- Destroy the kits, if your site is drug destruction capable.
- Send the kits to the depot for destruction, if your site isn't drug destruction capable.

Usability improvements on the Inventory tab

- **New filtering options, including subject number and multi-select for kit statuses**
 - The Subject Number filter is now available.
 - The Status filter moved to the left and now allows you to select multiple statuses.
 - There is a new Clear Filters option that appears after you select filtering criteria.
- **Changes to table columns**
 - The Last Modified column is new.
 - The icon for a kit type now appears in the Kit Number column.
 - The following columns were removed: Shipment Number and Comments.
- **New details available on the right**

- Inventory Correction was renamed to Inventory Management
This section now contains additional details about a kit, including the subject the kit was dispensed to (if the kit was dispensed) and the number of returned, missing, and balance units (if the kit has been reconciled).
- New section on the right: Kit History
This new section lists all status changes for the selected kit at the site, including when it was dispensed and who made the change.

Details for depots

Depot users manage the kit destruction process outside Oracle Clinical One Platform. When depots are responsible for drug destruction, clinical supply managers can mark destroyed kits as Destroyed.

Get trained in Oracle Clinical One Platform as you work

Short training videos are now available on each page, so you can now get trained as you work! After you finish watching the training for a page, you can start working on the page.

How do I rewatch training for a page?

In the upper-right corner, click your name, and select **Help**.

How do I track my training?

After you complete all assigned training, you'll receive a notification with a list of the completed training. The training administrator at your organization can also send reminders so you know your outstanding training.

Already working in a live study?

- After the update, all users will be required to watch training after signing in, unless you turn off the training requirement for your organization.
- After future system updates, users won't have to retake any completed training, unless the video has changed or a new video was added.

Read more about how this change affects...

- [Training administrators](#)
- [Details for training administrators](#)

Details for training administrators

How do I assign training to users?

No need to! Users are automatically assigned training based on their roles. And training is tracked by email address, so as long as a user's email address is the same for all user accounts, the user needs to be trained only one time.

How do I see and track the training assigned to each user?

- To see the training completed by users, run the new [User Training report](#) .
- To see both assigned and completed training, open the Users tab:

- The new Training column in the table shows the number of assigned and completed videos for each person.
- The new User Training section, to the right of the table, lists all assigned training for the selected user.

How do I turn off the training requirement for all studies in my organization?

You must have the Global User Manager global role to turn off the training requirement.

1. On the Home page, in the upper right, click **Global Settings**.
2. Above the table and to the right, turn off **Product User Training**.

Improved reporting capabilities

Reports available for a study design

You can now run reports for a study design. Previously, you could run reports only in Testing, Training, and Production modes. The following new reports are available for the study design:

- Study Design
- User Access

The reports are described in the following table.

New reports

Some new reports are available in PDF, a new format.

Report	Formats	Description	Available for these roles
Audit Report Sites and Depots	HTML, PDF PDF is a new report format.	View the audit history for site and depot properties to see the changes that were made and the user who made them.	<ul style="list-style-type: none"> • Clinical Supply Manager • Site Manager • Study Manager
Kit Reconciliation	HTML, PDF	View the kits that will be or have been destroyed and see whether the kits were reconciled	<ul style="list-style-type: none"> • Clinical Supply Manager • CRA • Lead Site User • Site Inventory User • View Only - Support
Study Design	HTML, PDF	View study design information including a list of visits and forms in the study, kit and randomization information, and subject and supply settings. You can run this report both in the study design and in each mode.	<ul style="list-style-type: none"> • Randomization List Manager • Study Design Report (new role) • Unblinded Designer • View Only - Support • View Study Design

Report	Formats	Description	Available for these roles
User Assignment User Assignment by Site	CSV, HTML HTML, PDF	<p>For Testing, Training, and Production modes:</p> <p>These reports contain the same data organized differently. The reports list users, organized by the site or depot they're associated with, along with their roles, last sign-in date, and other details. You can run the report only for the locations that you are assigned to.</p> <ul style="list-style-type: none"> • User Assignment is most useful to users who want to sort and filter the data in the CSV file, such as sponsor users. • User Assignment by Site is most useful for users who don't need to sort and filter data, such as CRAs and site users. <p>For the study design, only the User Assignment report is available:</p> <p>View each user who has access to the study design, along with the users' roles, access dates, and other details.</p> <p>For all the reports, you must choose which data to include:</p> <p>If you include historical data, you see every change that has been made to the user. If you include only current data, you see each user's access as of right now.</p>	<p>Both reports are available in Testing, Training, and Production modes for these roles:</p> <ul style="list-style-type: none"> • Lead Site User • Site Manager • Site User • Study Manager • User Manager • View Only - Support <p>The User Assignment role is available for the study design for these roles (for each row, users must have both roles to see the report):</p> <ul style="list-style-type: none"> • User Manager and View Design • User Manager and Unblinded Designer • User Manager and Designer

Report	Formats	Description	Available for these roles
User Training	HTML, PDF	View the training that users have completed.	<ul style="list-style-type: none"> • CRA • Lead Site User • Site Manager • Study Manager • User Manager

Changes to reports

Report	Changes
All reports	When you generate a report, N/A now appears instead of a blank cell when data cannot be populated.
Subject Events	<p>The report now contains data for the following events:</p> <ul style="list-style-type: none"> • A visit is started • A visit is completed • A visit is skipped • A visit that was skipped is started • A visit date is entered or modified • A manual screen failure is undone <p>All existing columns in the report remain unchanged, and the data in the new columns appears for both new and existing subjects.</p>

Capture a visit start date

Does your study have long forms? This change is just for you.

When studies allow it, site users now can start working on forms before a subject comes in and can update the visit start date when the subject arrives for a visit. Recording an accurate visit date is important because the visit schedule is calculated based upon it.

Read more about how this change affects...

- [Sponsors](#)
- [Sites](#)
- [Details for sponsors](#)
- [Details for sites](#)

Details for sponsors

How do I allow site users to enter and edit a visit start date?

- In Study Settings, open the **Subject Settings** tab, and specify the following settings in the new **Visit Settings** section:
 - The visit types for which site users can specify and edit visit dates.

- For randomization (and dispensation) visits, choose whether the Visit Start Date must be the same or later than the date when the site user clicks the Randomize (or Dispense) button for the subject.

How can I see whether a visit date was updated?

- Open a visit, click into the date field for the Visit Start Date, and expand **Answer & Visit History** on the right.

Already working in a live study?

After the system upgrade, site users can:

- Enter visit dates for screening, randomization, non-dispensation, optional, and withdrawal visits (but not dispensation visits).
- Edit dates for all visits.
- Skip both dispensation and non-dispensation visits.
- Edit the randomization visit date so that it is earlier than the system date for randomization.
- Edit a dispensation visit date so that it is earlier than the system date for dispensation.

You can change these requirements at any time without creating a new study version. Your changes go into effect immediately for site users.

If forms already contain questions for collecting visit dates: Consider removing those questions.

Details for sites

How do I specify a visit start date?

1. Start a visit. The new Visit Start Date field (on every form) is either:
 - Read-only.
 - Editable the first time you start the visit.
 - Editable every time you open the visit.
2. Choose the current date or a date in the past—future dates aren't allowed.

If you started a screening, randomization, or dispensation visits before the subject came in, Oracle Clinical One Platform might prompt you to update the visit date so that it matches the date when you screen or randomize.

Already working in a live study?

- The Visit Start Date field now appears above the forms on all visits, even those that were started or completed prior to the update.
- If editing the Visit Start Date is allowed, you can edit the date on all visits, including completed visits.
Reminder: If you edit the visit start date for a completed visit, and other visits are scheduled based on the visit, you will change the visit schedule.
- If the randomization visit has date restrictions relative to when randomization occurred, or a dispensation visit has date restrictions relative to when dispensation

occurred, these restrictions are applied only to visits that you hadn't started before the system update.

Collect data during withdrawal, and undo withdrawal

When a subject is withdrawn, either manually by a site user or automatically after a code break, you now can collect additional information in a new withdrawal visit. You can now report on detailed reasons and circumstances related to subject withdrawal.

Additionally, now if site users withdraw a subject in error, they now can undo the withdrawal so the subject can continue participating in the study. If a subject is withdrawn due to a code break, the withdrawal cannot be undone.

Read more about how this change affects...

- [Study designers](#)
- [Sponsors](#)
- [Sites](#)
- [Details for study designers](#)
- [Details for sponsors](#)
- [Details for sites](#)

Details for study designers

How do I create a withdrawal visit?

- Create a visit, and in the Create Visit or Event pop-up, select **Withdrawal Event** from the new **Type** drop-down.

Next steps: Add one or more forms to the visit. You can't add kits to the visit or schedule it.

Details for sponsors

How can I tell whether a subject had a withdrawal undone?

1. On the **Subjects** page, in the subject table, select a subject.
2. On the right, below **Subject History**, view the audit history for the subject, including whether the subject was withdrawn and had a withdrawal undone.

Details for sites

How do I know whether I'll be required to collect data during the withdrawal visit?

If a withdrawal visit is required, the visit appears immediately after you withdraw a subject or after you view the unblinding results for a subject during a code break (if the study requires withdrawal after a code break).

How do I undo when I withdraw a subject in error?

You can't undo if the subject was withdrawn due to a code break.

- Select a subject with a status of **Withdrawn**, and select **Undo Withdrawal** from the **Manage Subjects** drop-down.

The subject state reverts to the state the subject had before being withdrawn. The change is audited. Select a subject in the subjects table, and view withdrawal details on the right, under Subject History.

Complete a study for a subject

Subjects who complete the minimum required visits can now be marked as Completed, and data can be collected during a new Study Completion visit. This change makes it easier to identify subjects whose involvement in the study is finished and allows for additional data collection during the completion visit.

Read more about how this change affects...

- [Sponsors](#)
- [Study designers](#)
- [Sites](#)
- [Details for sponsors](#)
- [Details for study designers](#)
- [Details for sites](#)

Details for sponsors

What can't be done after a subject completes a study?

- Forms that weren't started prior to study completion can't be started.
- Other subject actions, such as screening, randomizing, withdrawing, dispensing, and skipping a visit, can't be done.

How do I tell whether a subject has been marked as Complete or has had that change undone?

- The status for a subject who completed a study is Complete, and the avatar is gray with a checkbox ().
- Select a subject, and look in Subject History, to the right, for information about whether the subject was completed and had the action undone.

Details for study designers

How do I create a Study Completion visit and specify when it can be started?

When you create a visit, select **Study Completion Event** from the **Type** drop-down, and then choose the visit that subjects must complete before they can complete the study. For instance, select Visit 10 if subjects can complete the study after completing Visit 10.

What else do I need to know?

- The Study Completion event is last in the Visits & Events panel.
- You can't schedule it.
- You can't dispense kits in it.

- It has to be after the randomization event.

Already working in a live study?

You can mark an existing visit as the study completion event.

Details for sites

How do I mark a subject as Complete?

1. In the table of subjects, select a subject with green avatar with a checkmark in the upper-right corner, indicating that they completed the minimum required visits.
2. From the Manage Subjects drop-down, select **Complete or Withdraw** . Depending on how the study is set up, a study completion visit might appear. You can complete it now or later.

Need to undo? No problem! Select the subject, and select **Undo Study Complete** from the Manage Subjects drop-down. If you complete the subject again later, the data you entered is still saved.

Subject data is displayed according to sites' time zones

Sponsors can now specify the time zone for each site, and after this value is set:

- Subject data is displayed according to the site's time, in consideration of the time zone's observation of daylight saving time. Previously, all data was displayed according to the UTC (Coordinated Universal Time) time zone, which corresponds to the Greenwich Mean Time zone. Data is still captured according to the UTC time zone.
- Dates on the Subjects page, including visit windows, are calculated using the site's time zone, rather than the UTC time zone.
- [Details for sponsor users](#)
- [Details for site users and sponsor users who review subject data](#)

Details for sponsor users

How do I specify a site's time zone?

- Edit a site, and on the second page of the wizard, select a time zone from the new **Time Zone** field.

What if I created sites prior to the system updated?

No time zone is selected for these sites, and subject information is still displayed in the UTC time zone until you specify a time zone for each site. The next time you edit each site, you'll be prompted to select a time zone.

We recommend selecting a time zone for each site after the system update.

Details for site users and sponsor users who review subject data

What values now appear in a site's local time zone?

Only values on the Subjects page use the site's local time zone. All values on this page are in the local time zone with the exception of the data in Answer & Visit History, which appears when you open a visit. Times in this panel are labeled as UTC.

The [new Visit Start Date](#) field is also saved based on the site's time zone.

Is data that was collected prior to the system update affected?

No. Previously, all values were displayed in the UTC time zone (the Coordinated Universal Time, which corresponds to the Greenwich Mean Time), and all values for data collected prior to the system update remain in the UTC time zone. Additionally, after the system update, all data at a site will be displayed in the UTC time zone until you specify a time zone for the site.

How does a site's time zone affect subjects' visit schedules?

Previously, all subject data, including visit dates, were displayed in the UTC time zone. Now Oracle Clinical One Platform calculates visit windows using the time zone of each site.

What if a subject transfers to a site with a different time zone?

The visit window might shorten or extend by a day if the difference between the time zones is significant.

Skip visits that subjects miss

When a study allows it, site users can now skip a visit that a subject misses. Site users can also skip any optional visit.

Read more about how this change affects...

- [Sponsors](#)
- [Sites](#)
- [Details for sponsors](#)
- [Details for sites](#)

Details for sponsors

How do I allow visits to be skipped?

1. In Study Settings, open the **Subject Settings** tab.
2. In the new Visit Settings section, select **Visit Can Be Skipped** as appropriate in the rows for **Dispensation** and **Non-Dispensation** visits.

How can I tell whether a visit has been skipped?

A skipped visit is purple and has an X above the visit name. You can also view whether a visit was skipped or unskipped by opening the visit and expanding Answer & Visit History, to the right. Previously, this section was named Answer History.

Already working in a live study?

You don't need to create a new study version to update the new visit settings, and your changes go into effect immediately for site users.

Details for sites

How do I mark a subject's visit as skipped?

Important: You won't be able to dispense for a visit if you skip it.

- Open a visit, and select **Skip this Visit** from the **Manage Subject** drop-down. View audit history for a visit in Answer & Visit History, which appears to the right when a visit is open. Previously, this section was named Answer History.

Didn't mean to skip a visit? No problem! To undo a visit you skipped, open the skipped visit, and confirm that you need to enter data for the visit.

Does skipping a visit affect the visit window?

The visit window is affected only when one or more visits are scheduled from the visit that is skipped. When another visit is scheduled from the skipped visit, Oracle Clinical One Platform uses the expected visit date to calculate the schedule for subsequent visits. For example, consider the following visit schedule:

- Visit 1 occurs on January 1
- Visit 2 is scheduled for 7 days after Visit 1
- Visit 3 is scheduled for 7 days after Visit 2

Visit 2 should occur 7 days after Visit 1, on January 8. If you skip Visit 2, Oracle Clinical One Platform sets the visit date as January 8. The expected visit date of Visit 3 is then January 15.

New and renamed roles

New roles

Type of role	Name	Description
Global	Training Administrator	This role is reserved for a future release.
Global	Integration Manager	For Oracle employees, this role allows users to manage integrations for your organization's Oracle Clinical One Platform studies.
Study Design	Integration Designer	This role is reserved for a future release.
Production, Testing, and Training	Lead Site User	This role is intended for Principal Investigators or their delegate and allows site users to enter subject data, manage supplies, and perform a code break.

Type of role	Name	Description
Production, Testing, and Training	Randomization List Manager	<p>This role allows users to work with randomization lists, including generating them, uploading them, and assigning them to a study version.</p> <p>Previously, these rights were included in the Clinical Supply Manager role, but they've been moved to a separate role to provide flexibility to your organization.</p> <p>Important: The Clinical Supply Manager role no longer allows you to upload and generate randomization lists and assign a randomization list to a study version. Any clinical supply managers who are responsible for these tasks must be assigned this new role.</p>
Production, Testing, and Training	Study Design Report	<p>This role allows you to run the new Study Design report. In some organizations, details about randomization are considered potentially unblinding, so this role allows you to control access to the report.</p>
Production, Testing, and Training	Subject Notifications	<p>This role subscribes users to the following notifications:</p> <ul style="list-style-type: none"> • Code break • Subject withdrawal • Subject transfer <p>You can assign this role to any user.</p>
Production, Testing, and Training	Training Manager	<p>This role is reserved for a future release.</p>

Type of role	Name	Description
Production, Testing, and Training	View Study Design	<p>This role allows you to see the study design for a particular mode:</p> <ul style="list-style-type: none"> When the study version is below Testing on the Home page, you can view the study design if you have this role for Testing mode. When the study version is below Approved on the Home page, you can view the study design if you have this role for Training and Production. <p>This role is similar to and different from the View Design role, a study design role:</p> <ul style="list-style-type: none"> Only View Design allows you to view details about a study version that is below Draft on the Home page. View Study Design can be assigned by any user administrator, whereas View Design can be assigned only by a global user who is also a user administrator. <p>Users who need to upload or generate randomization lists and kit lists must have either View Design (a study design role) or View Study Design for the appropriate mode.</p>
Production, Testing, and Training	View Only - Support	<p>This role allows an Oracle Support representative to view your study and help you troubleshoot issues. Oracle users are responsible for creating users as needed and assigning them this role.</p>

Renamed global roles

Previous role name	New role name
Global User Manager Role - Sponsor	Global User Manager

Renamed Study Design roles

Previous role name	New role name
Designer Role - Blinded	Designer
Designer Role - Sponsor	Unblinded Designer
User Manager Role - Sponsor	User Manager

Previous role name	New role name
View Design-Sponsor	View Design

Renamed Production, Testing, and Training roles

Previous role name	New role name
Blinded Site Inventory User - Site	Site Inventory User
Blinded Site User - Site	Site User
Clinical Supply Manager - Sponsor	Clinical Supply Manager
Code View - Sponsor	Code View
CodeBreak - Site	Code Break
CRA - Sponsor	CRA
Data Manager - Sponsor	Data Manager
Design Import	Import Design
Site Manager Role - Sponsor	Site Manager
Study Manager - Sponsor	Study Manager
Subject Transfer	Transfer Subject

New notifications

Notification	Created when...	Available for these roles
Shipment failure	A shipment couldn't be created. For example, there might have been an inventory issue.	<ul style="list-style-type: none"> Clinical Supply Manager Shipment Notification This role also subscribes users to notifications for new shipments. Unblinded Depot User
Subject withdrawal	A subject withdraws from a site that you're assigned to.	<ul style="list-style-type: none"> Subject Notifications (new role) Any user can be assigned this role. This role also subscribes users to the code break and subject transfer notifications.

Additional usability improvements

- [Improvements that help all users](#)
- [Form and visit usability improvements](#)
- [Randomization and kit usability improvements](#)
- [Site and user management usability improvements](#)
- [Supply setting usability improvements](#)
- [Shipment and supply usability improvements](#)
- [Site user and subject data usability improvements](#)

Improvements that help all users

View hint text for fields

When you tab into a field, hint text now appears for helping you complete the field.

Form and visit usability improvements

Changes to the Create Visit pop-up

Study designers: The Create Visit pop-up has been renamed to Create Visit or Event. Other changes include:

- A new field named **ID** was added for the short identifier for a visit.
- The **Repeating Visit** field, which was always grayed out, was removed.
- **Required Visit** was renamed to **Required**.
- A new drop-down named **Type** was added for specifying the type of visit.

Schedule Visit pop-up redesigned for usability; Hours field grayed out

Study designers: The Schedule Visit pop-up, which appears when you schedule a visit, was redesigned. It's now easier to distinguish the scheduled time between visits and the visit window.

Additionally, you can now schedule visits, including visit windows, using only days. Previously, the visit window could include values for both days and hours. Now the Hours field is grayed out.

Easier to select Dispense Outside Visit Window checkbox; kit type description added

Study designers: In the Add Kit to Visit Schedule pop-up, which appears when you drag a kit to a visit, there is now a column-level checkbox for Dispense Outside Visit Window, allowing you to select this checkbox for every visit.

Additionally, the description of the kit type now appears below the name of the kit in this pop-up.

Randomization and kit usability improvements

New type of randomization: Country Blocked Dynamic Stratified

Sponsors and study designers: A new type of randomization is available: Country Blocked Dynamic Stratified. Now you can balance treatment arms within the stratum groups in each country.

Select multiple values for a stratification factor

Sponsors and study designers: You can now select multiple values for a stratification factor in a stratum group.

For example, when a drop-down question has 2 values, such as Smoker and Non-Smoker, you can select both values for a stratum group. Previously, you could select only one.

Randomization lists automatically associated with a new study version

Users who move study versions to Approved on the Home page: When the study version that you move to Approved is different from the study version you generated or uploaded the randomization lists in for Production and Training modes, you no longer need to assign the randomization lists to the new study version. When you move a study version to Approved on the Home page, the randomization list for Production mode and the randomization list for Training mode are automatically associated with the study version.

Reminder: A randomization list isn't automatically associated with a study version when you move a study version to Testing on the Home page.

Randomization list selected on Randomizations tab

Clinical supply managers: We're now saving you a step on the Randomizations tab. If a study has only one randomization list, the list is now selected by default from the drop-down.

Improved view of a randomization design

Study designers: On the Randomizations tab, the expanding **Treatment Arms** and **Stratum Groups** sections at the bottom of the summary for a randomization design have been replaced with tabs for easier viewing.

Site and user management usability improvements

Easier to save changes after editing a user

User managers: When you edit an existing user, a **Save** button now appears on each page in the wizard so you don't have to click through the whole wizard before you can save your changes.

Easily view the roles and sites a user is assigned to

User managers: You can now easily see all the roles and sites a user is assigned to on the Users tab in Study Settings. Just select a user and expand the new Roles and Sites panels on the right.

Previously, limited role and site information appeared in the Roles and Sites columns on the Users tab; these columns have been removed.

Allow users continual access to studies

User managers: When you create or edit a user, you no longer need to provide an end date for the user's study access in the Effective Date Range field. In addition, you now can indicate that you want the user to have continual access to the study by selecting the new **No End Date** checkbox.

Supply setting usability improvements

Helpful message when you can't specify supply settings yet

Clinical supply managers: On the Supply Settings tab, when you can't specify study settings because your study design is still in the Draft container on the Home page, a message now lets you know what you need to do before you can specify settings.

Easier to create resupply strategies

Clinical supply managers: Save a little time when creating resupply strategies! The Create Min/Max Resupply Group and Create Predictive Resupply Group pop-ups, which open from the Supply Settings tab, now have column-level fields for specifying the same value for every kit type.

Shipment and supply usability improvements

Easier to complete fields for a manual shipment

Clinical supply managers: In the Create Shipment pop-up, there are now column-level fields, so completing the fields is a little faster:

- A new column-level checkbox lets you select all kit types for the shipment.
- A new column-level field for Quantity lets you enter a quantity for all kit types.

New kit status: Not Dispensed to Subject

CRAs and clinical supply managers: What happens when Oracle Clinical One Platform dispenses a kit but the subject doesn't leave with it, such as when a subject doesn't need additional supply? There's a new status for that: Not Dispensed to Subject.

Kit statuses use color coding

Clinical supply managers: Kit statuses now include color coding in the following locations:

- In the pop-up for cancelling a shipment, when you choose the new status for the kits in the shipment.
- In Kit Settings, which is on the right on the Inventory tab, in the Status drop-down.

Clear selections in Kit Settings on Inventory tab

Clinical supply managers: In Kit Settings, which is on the right on the Inventory tab, there is a new button, **Clear Settings**, for clearing your selections in the drop-down lists.

Easier to add countries to label groups

Clinical supply managers: In the Create Label Group pop-up, you can now double-click a country in the Available Countries list to move it to the list of selected countries.

Field name changed in confirmation for canceling a shipment

Clinical supply managers: In the confirmation pop-up that appears when you cancel a shipment, the **Status of Kits in Shipment** drop-down was renamed to **Change Kits Back To**.

Site user and subject data usability improvements

Undo a manual screen failure

Site users: You now can undo after manually screen failing a subject.

Subject History is in chronological order

Site users and sponsor users who view subject data: Reviewing a subject's history is now easier! All events in Subject History (to the right of the Subjects table) are now in chronological order.

Save and close a visit with one button

Site users: Previously, if you wanted to save answers on a form but not screen, randomize, or dispense, you had to click **Save**, and then click **Return to All Subjects**. Now a new button, **Save & Close**, saves your answers and returns you to the subjects table.

Request Shipment button no longer appears if shipment requests aren't allowed

Site users: When a study doesn't allow sites to request shipments, the **Request Shipment** button no longer appears on the Shipments tab.

New withdrawal reason: Pregnancy

Site users: Pregnancy is now available as a reason for withdrawal.

Stability improvements

- [Stability improvements that help all users](#)
- [Report and notification stability improvements](#)
- [Study and study version stability improvements](#)
- [Form and visit stability improvements](#)
- [Randomization and kit stability improvements](#)
- [Site, depot, and user stability improvements](#)
- [Shipment and supply usability improvements](#)
- [Site users and subject data usability improvements](#)

Stability improvements that help all users

No need to clear cache anymore (Former Known Issue)

All users: You don't need to clear your cache after each system update anymore. (Issues: CLINONE-5059; 27022641)

Performance improvements

The performance of the following activities has been improved:

- All users:
Loading all notifications on the Notifications page. (Issue: 25814087)
- Users who move study versions on the Home page:
Moving a study version to either Testing or Approved on the Home page. (Issue: 25338267)
- Site managers:
Opening the Sites tab in Study Settings. (Issue: 25133265)

- Site users and sponsor users who review subject data:
Opening the Subjects page in any mode. (Issue: 25134466)

Report and notification stability improvements

Reports button hidden if you can't run reports

Users whose roles don't allow them to run reports: The button for the Reports page is no longer visible if your roles don't allow you to run any reports. (Issue: 25173416.)

Filter by Active and Retired sites and depots

Users who run reports: The Study Organization Name filter, which is available for many reports, now lists only Active and Retired sites and depots. Previously, new sites and depots were also included. (Issue: 25237460.)

Line break in kit type description

Users who run the Kit Chain of Custody (Unblinded) report: When a kit type includes a line break in its description, the description in the Kit Chain of Custody (Unblinded) report now appears on a single line. Previously, the description was split into two lines. (Issue: 25352892.)

Version End removed from Subject Data report

Users who run the Subject Data report: The Version End column has been removed from the Subject Data report. (Issue: 25366130.)

Appropriate study versions available for Subject Data report

Users who run the Subject Data report: For the Subject Data report, the Study Version filter now includes only the Testing study versions when you run the report in Testing mode and only the Approved study versions when you run the report in Production and Training modes. Previously, all study versions were available in all modes. (Issue: 26495309.)

Notifications include site name and ID

Users with access to multiple sites: Notifications now include the site name and site ID. Studies allow duplicate site names, so both labels are useful for determining the site that's affected by each notification. (Issue: 25286281.)

Study and study version stability improvements

Sites must be removed before archiving

Users who archive studies: You now can move a study version from Approved to Archived only after there are no sites associated with the study version. (Issue: 24965275.)

Form and visit stability improvements

Change a question type on a new question (Former Known Issue)

Study designers: When you create a new study design from an Approved study version and add a question to a form, you can now change the question's answer type.

Reminder: You still can't change the answer type of questions that existed in the Approved study version. This change is only for new questions. (Issue: 26408450.)

Error appears when a validation rule is missing data (Former Known Issue)

Study designers: When a drop-down question has an Answer Must Be validation rule and you don't include the required answer in the Required Answer field for the validation rule, an error message and a red border around the field now appear without your having to click away from the field. (Issue: 25828735.)

Save scheduling changes after clicking Clear Schedule

Study designers: When you enter scheduling information in the Schedule Visit pop-up, click **Clear Schedule** to erase your selections, and then enter new scheduling information, an error no longer occurs when you save, and the scheduling information is saved. (Issue: 25297130.)

Second value in range check must be higher

Study designers: When you create a validation rule on a Number question, the second value now must be higher than the first. Previously, you could create a range check in which the second value was lower than the first (for instance, a range of 20 to 0). (Issue: 26762660.)

Get notified when visit windows overlap

Study designers: You are now notified when you create a visit schedule with overlapping windows, such as when the window for Visit 5 opens before the window for Visit 4 closes. (Issue: 24572859.)

Randomization and kit stability improvements

Resupply strategies are saved on the first try (Former Known Issue)

Clinical supply managers and site managers: When you select a resupply strategy for a site and save, the resupply strategy is saved on the first try. Previously, you sometimes had to save multiple times. (Issue: 26597880.)

Upload randomization lists with duplicate names (Former Known Issue)

Clinical supply managers: An error no longer occurs when you upload a randomization list that has the same file name as a list that another user already uploaded in the same mode. (Issue: 25868413.)

Blinded Randomization Numbers option removed

Study designers: On the last page of the wizard for creating a randomization design, the Blinded Randomization Numbers option was removed. This field was reserved for a future release, so no functionality has changed. (Issue: 25526448.)

Can associate only one randomization design (Former Known Issue)

Study designers: When a randomization design is already associated with a visit, and you try to drag a second randomization design to another visit, a Confirmation message now asks you whether you want to remove the first randomization design. Previously, you could associate a second randomization design with a visit, but randomization errors occurred for site users. (Issue: 26308447.)

Treatment ratios are no longer deleted (Former Known Issue)

Study designers: When you open an existing randomization design and click directly to the Settings page (the last page) of the wizard, rather than clicking Next to advance to the page, treatment ratios are no longer deleted from the randomization design. (Issue: 25899082.)

Commas acceptable in kit types and randomization designs (Former Known Issue)

Study designers: You can now include commas in text fields for kit types and randomization designs, and the fields appear as expected in CSV (comma-separated values) reports.

Retracted workaround: Previously, we recommended not including commas in text fields for kit types and randomization designs. This restriction is no longer in place. (Issues: 26608514; 25526375.)

Kit types are removed with the randomization design (Former Known Issue)

Study designers: When you remove randomization from a visit in a Draft study version that you created from an Approved study version, kit types are now also removed from the visit.

Retracted workaround: Previously, we recommended that you first remove kits before removing a randomization design from a visit if you were working in a Draft study version created from an Approved study version. This restriction is no longer in place. (Issue: 25428322.)

Trash icon removed for kit types that can't be deleted

Study designers: When a kit type is part of a study version that has been approved, the trash icon no longer appears on the kit type. Previously, the trash icon appeared, but you couldn't delete the kit type. (Issue: 25091689.)

Generate Kit List wizard helps prevent duplicate numbers

Users who generate kit lists: When you generate a kit list for a mode that already has a kit list, the First Kit Number and First Sequence Number fields now auto-populate with values so that you don't create a list with duplicate values. The values are calculated by determining the highest kit and sequence numbers and adding 1 to them. (Issue: 25651789.)

Site, depot, and user stability improvements

Role changes for randomization lists (Former Known Issue)

User managers: Clinical supply managers no longer need the Designer Role - Sponsor role (renamed to Designer in this release) to upload and generate randomization lists. You can now remove this role for those users. (Issue: 25315012.)

Related change: The ability to manage randomization, including uploading and generating randomization lists and assigning a randomization list to a study version, is no longer part of the Clinical Supply Manager role. It's now part of the new [Randomization Manager role](#). Update users as needed.

Finish button disabled for a user with no data (Former Known Issue)

User managers: When you create a new user but don't specify any roles, sites, or depots for the user, the Finish button on the last page of the Create User wizard is now grayed out, and a tooltip on the Finish button indicates that you need to select a role, site, or depot to create

the user. Previously when you clicked Finish, a success message appeared, but the user wasn't created. (Issue: 25932050.)

Can assign users to sites and depots in Testing mode (Former Known Issue)

Site and user managers: When you are assigned the User Manager role in the Study Design Roles list and the Site Manager role in Testing mode, you now can assign users to sites and depots in Testing mode.

Retracted workaround: You no longer need to assign site and user managers to the Site Manager Role - Sponsor role for all three modes for the user to be able to work in Testing mode. (Issue: 26909374.)

New message for duplicate site IDs

Site managers: When you create a site for use in multiple modes and the site ID is already used in one mode, a message now informs you that the site will be created only for the mode that the site ID isn't used in. Previously, sites weren't created in any modes when the site ID was in use in one or more modes. (Issue: 25084399.)

Sites are now sorted

Site managers: Sites are now sorted on the Sites tab so that the most recently created site appears first. (Issue: 24897978.)

Error when you don't select a country for a site

Site managers: When you don't select a country for a new site, an error now notifies you that you missed the required field. Previously, no error appeared. (Issue: 25260246.)

No more success message for no site changes

Site managers: When you open the Edit Site wizard for an existing site and click Save or Finish without making any changes, the wizard now closes. Previously, a message said that your changes were saved successfully, even though you hadn't made any changes. (Issue: 24556424.)

Duplicate site and depot entries resolved

Site and depot managers: Duplicate entries no longer appear on the Sites and Depots tabs. Previously, when you edited an existing site or depot and double-clicked the **Save** button in the site or depot wizard, a duplicate entry was sometimes created for the site or depot. (Issue: 25366078.)

Improved error message for retiring depots

Depot managers: When you retire multiple depots at one time, the confirmation pop-up now contains user-friendly language. Previously, the pop-up included technical details that weren't useful to end users. (Issue: 26666811.)

Message appears for duplicate depot ID

Depot managers: You are now notified when you create a depot with a depot ID that is already used. Previously, the depot wasn't created, and no message appeared. (Issue: 25366772.)

Country lists renamed in depot wizard

Depot managers: In the wizard for creating depots, the country lists on the Countries page have been renamed:

- **Available Countries** was renamed to **All Countries**.
- **All Supply Depot Countries** was renamed to **<depot_name> Depot Countries**. (Issue: 25049597.)

Shipment and supply usability improvements

Add many kits to a lot (Former Known Issue)

Clinical supply managers: You now can add a large number of kits to a manufacturing lot, such as 5,000 or more. Previously, large numbers of kits weren't added, and no error message appeared.

Retracted workaround: You no longer need to add large numbers of kits in smaller group. (Issue: 25992817.)

Kits no longer appear unselected (Former Known Issue)

Clinical supply managers: When you select the checkbox in the column header on the Inventory tab, all kits are selected. Previously, only the first 100 kits had a selected checkbox, though the issue was visual only. Updates affected all kits, even those without a selected checkbox. (Issue: 25888665.)

Change a kit from Available to Missing (Former Known Issue)

Clinical supply managers and depot users: You can now change the status of a kit from Available to Missing.

Retracted workaround: Previously, we suggested changing a kit to Temporarily Unavailable or Not in Use. You no longer need to use this workaround. (Issue: 25651625.)

Notification when initial shipments aren't created (Former Known Issue)

Clinical supply managers and site managers: When initial shipments should be created after site activation, and you activate a site before all settings are specified, including the resupply strategy for each site, a new shipment failure notification is now created so you know that the shipments weren't created. (Issue: 25543255.)

Shipments tab is now sorted

Clinical supply managers: Shipments on the Shipments tab are now sorted so that the most recently created shipments appear first. (Issue: 25310482.)

Search field for adding countries to label groups

Clinical supply managers: The Create Label Group pop-up now has a search field for countries, so now it's easier to find countries and add them to a label group. (Issue: 25520386.)

Site users and subject data usability improvements

Unscheduled visits can be started (Former Known Issue)

Site users who enter subject data: You now can start unscheduled Completion and Withdrawal visits from the Manage Subjects drop-down. Previously, study designers had to schedule every visit because there was no way for site users to start unscheduled visits. (Issue: 26234714.)

Spinning circle appears when you request a manual shipment (Former Known Issue)

Site users who request shipments: When you request a manual shipment, a spinning blue circle now appears as the request is processed. Previously, no indicator appeared during the processing of the request, so sometimes users clicked the Request Shipment button a second time and ended up requesting two shipments. (Issue: 25552184.)

Select today's date using only a keyboard (Former Known Issue)

Site users who enter subject data: You can now use only the keyboard to select today's date in a date question. Previously, you had to select a different date and then could select today's date. This issue affected users who work exclusively with a keyboard and don't use a mouse. (Issue: 25550562.)

View audit history for date/time and drop-down questions (Former Known Issue)

Sponsor users who review subject data: You now can view the history for date/time questions and drop-down questions on forms. Click a question, and view audit history to the right below Answer & Visit History.

Retracted workaround: You no longer need to run the Subject Data report to see this information. (Issue: 25202134.)

Dispensation allowed during the entire calendar day (Former Known Issue)

Site users who enter subject data: Dispensation is now allowed during an entire calendar day for any day that is within the visit window. For example, if a visit window is January 1 - January 3, you can dispense any time between 12 AM on January 1 until 11:59 PM on January 3. (Issues: 26151394; CLINONE-2554.)

Visit colors and icons updated correctly

Site users who enter subject data: When you clear one or more fields from a visit, the Subjects page now uses the correct color coding and symbols for the incomplete visit. Previously, when you opened a visit and cleared a field, the Subjects page updated as expected. However, if you opened another visit for the subject by selecting the visit from above the form and then cleared a value from it, the Subjects page didn't use the correct color coding and symbols for the incomplete visit. (Issue: 25112230.)

Save buttons appear after dispensation

Site users who enter subject data: When you open a visit for which you already dispensed kits, the Save and Save & Close buttons now appear at the bottom of the forms. Previously, the Dispense button appeared, even after you dispensed kits. (Issue: 25083098.)

Subjects drop-down lists all subjects

Site users with access to multiple sites: When you open a subject's visit, the subject drop-down in the Subject column (above the list of forms) now lists all subjects in all the sites you have access to. Previously, the list included only subjects at the selected subject's site. (Issue: 25295269.)

Site selection is saved when you return to a page

Site users with access to multiple sites: The Site drop-down list now remembers the site you select on a page. (Issue: 25426946.)

Releases in 2017

Browse the content of all Oracle Clinical One Platform and Oracle Clinical One Digital Gateway releases in 2017.

- [Oracle Clinical One Platform 1.0.2 \(December 2017\)](#)
- [Oracle Clinical One Platform 1.0.1.1 \(October 2017\)](#)
- [Oracle Clinical One Platform 1.0.1 \(October 2017\)](#)
- [Oracle Clinical One Platform 1.0 \(July 2017\)](#)

Oracle Clinical One Platform 1.0.2 (December 2017)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Get notified when you've been given access to a study](#)

Get notified when you've been given access to a study

Knowing when you can start working in a study just got easier: From now on, you'll receive an email message from Oracle Clinical One Platform when you've been given access to a study.

All users: What you'll see

On the date when an administrator gives you permission to work in a study, you'll receive an email message with:

- The name of the study.
- The URL for Oracle Clinical One Platform.
- The date when you can start working.



Note:

The message doesn't contain your user name and password. That information is sent in separate email messages when your user account is created. If you need your password reset, [log a ticket in Support Cloud](#).

Administrators: How to trigger the email

Provision users as you normally do, including specifying the date when the user can start working. Users receive the email message immediately after you provision them.

Already working in a live study?

Users that you provisioned before the system update won't receive this email message.

Stability improvements

- [Rights update for clinical supply managers \(former Known Issue\)](#)
- [Can no longer start visits in a retired site](#)
- [Sites no longer duplicated on Users tab \(former Known Issue\)](#)
- [Can no longer add a second subject in error \(former Known Issue\)](#)
- [Can randomize only after all forms appear](#)

Rights update for clinical supply managers (former Known Issue)

What's changed

Clinical supply managers can no longer assign a study version to a site.

Who sees the change:

- Clinical supply managers
- Sponsor or CRO users who create users, such as clinical supply managers, study managers, and clinical research associates

Why

A user with the **Clinical Supply Manager - Sponsor** role was granted the **Assign a Study Version to a Site** right and therefore could choose and update the study version that is associated with a site.

Issue number: 26408545

Can no longer start visits in a retired site

What's changed

Now when a site is retired, any visits that haven't been started no longer appear in the Next Visits column for site users, so site users can't start any new visits.

If a retired site is made active again, visits that haven't been started once again appear in the Next Visit column, and site users can start visits again.

Who sees the change: Site users who enter subject data.

Why

Data entry wasn't allowed when a site was retired, so visits shouldn't have been allowed to be started.

Preventing a visit from being started is useful for when a site is made active again after retirement. When a site user starts a visit, the visit from the most recent study design that was assigned to the site appears.

Issue number: 26585564

Sites no longer duplicated on Users tab (former Known Issue)

What's changed

On the Users tab in Study Settings, the Sites column no longer includes duplicate entries for a site.

Who sees the change:

- Sponsor or CRO users who create users, such as clinical supply managers, study managers, and clinical research associates.
- Study designers who create users.

Why

On the Users tab in Study Settings, when a user was assigned to one or more individual sites, the Sites column listed each site two times.

This issue was visual only. Users were assigned to sites as expected.

Issue number: 26611188

Can no longer add a second subject in error (former Known Issue)

What's changed

You can no longer add a second subject in error while you are adding the first subject to a site.

Who sees the change: Site users who add subjects.

Why

When you added the first subject to a site, it was possible to add a second subject in error at the same time.

The issue occurred when you clicked **Add Subject** for the first subject added to a site. The page refreshed, and for a very brief period of time before the visit appeared, the **Add Subject** button appeared again. If you clicked the **Add Subject** button during that period of time, a second subject record was created. You saw the second subject on the Subjects page after you entered data for the first subject.

Issue number: 26986404

Can randomize only after all forms appear

What's changed

The Randomize button now remains grayed out until all forms have loaded and all required fields have been completed.

Who sees the change: Site users who add subjects.

Why

When network conditions resulted in slow loading times, sometimes the Randomize button became enabled before all forms in a visit appeared. Site users then could randomize subjects without completing all required fields.

Issue number: 27191041

Oracle Clinical One Platform 1.0.1.1 (October 2017)

- [Stability improvements](#)

Stability improvements

- [26578052](#)

26578052

What's changed

In Data Capture, if you belong to only one site, adding a subject to a study is now a little easier. When you open a study, your site is now automatically selected in the Site drop-down above the table of subjects.

Who sees the change:

- Site users.
- Sponsor users who validate a study.

Why

It is common for users to have access to only one site, but you used to have to select that site in Data Capture, while in Supplies view the site was selected automatically. Now this feature works the same in all views, reducing your number of clicks.

Oracle Clinical One Platform 1.0.1 (October 2017)

- [What's new?](#)
- [Stability improvements](#)

What's new?

- [Depots now receive an email for a new shipment](#)
- [You can now specify the PI and the person who receives shipments at a site](#)
- [Decommissioned studies no longer appear on the Home page](#)
- [Depot users now have their own role](#)
- [Now it's easier to assign sponsor users to all sites and depots](#)

Depots now receive an email for a new shipment

Good news for depot employees! From now on, you can find out what contents are in a new shipment without having to sign in to Oracle Clinical One Platform.

Sponsor and CRO users: Where to specify the depot's email address

1. On the Home page, open **Study Settings**, and select the **Depot** tab.
2. Edit a depot, and make sure you specify an email address in the **Email** field. The address can be for an individual or a group and doesn't have to be associated with a Oracle Clinical One Platform user.

Depot users: What's new

When a new shipment is created in Oracle Clinical One Platform, you'll receive an email message including the site that requires the shipment and the contents of the shipment.

Already working in a live study?

The email address for each depot will start receiving these email messages.

Has the email address for a depot changed? No problem! You can change it without having to create a new version of the study.

You can now specify the PI and the person who receives shipments at a site

Now it's easier to manage sites when multiple principal investigators work at the same facility. And it's easier to tell which fields are for the shipping address and which are for the physical location of the site.

Sponsor and CRO users: Where to find the new fields

- On the Home page, open **Study Settings**, and select the **Sites** tab.
 - On the **Settings** tab, you'll find the new and required **Principal Investigator Name** field.
 - On the **Site Address** tab, you specify the site's physical location.
 - **New tab!** On the **Shipping** tab, you specify:
 - * The site's shipping address.
 - * An attention entry for the shipping label in the new optional **Attention** field. For example, specify the person who receives shipments at the site.

Already working in a live study?

The next time you edit a site, you'll be prompted to specify the name of its principal investigator.

Reminder: Searching for a site hasn't changed. When you search for a site that was used in another study and modify one or more fields, your changes update only to the current study.

Decommissioned studies no longer appear on the Home page

Who doesn't want a clean Home page?

All users: What's new

After a study is decommissioned, the study no longer appears on the Home page for any users.

In the previous release, a decommissioned study remained on the Home page, though you couldn't open it or access any data.

Depot users now have their own role

Previously, a depot role wasn't available, so we recommended assigning depot users the **Clinical Supply Manager - Sponsor** role. Depot users now have a role of their own that grants them the access they need—and nothing else.

Sponsor and CRO users: Where to find the new role

1. On the Home page, open **Study Settings**, and select the **Users** tab.
2. Edit any depot users, and assign the **Unblinded Depot User** role as needed for Production, Training, and Testing modes.

This role lets users:

- Update the status of a kit.
- Create a shipment.
- Create manufacturing and blinded lots.

Depot users: What's new

If you're assigned to the new **Unblinded Depot User** role, your access in Oracle Clinical One Platform will change after you're assigned to the Unblinded Depot User role.

Already working in a live study?

Consider updating any depot users that you've created so that they have the **Unblinded Depot User** role instead.

Now it's easier to assign sponsor users to all sites and depots

Need to assign someone at the sponsor to all production, training, and testing sites or depots? Now we have a checkbox for that.

Sponsor and CRO users: Where to find the new checkboxes

1. On the Home page, open **Study Settings**, and select the **Users** tab.
2. Edit a user account, and navigate to the Sites & Depots tab, which now has two new checkboxes:

- **All Sites**
- **All Depots**

Reminder: The checkboxes for assigning users to all sites and depots for a particular mode are still available. Now when you select **All Sites**, for example, the **All Production Sites**, **All Training Sites**, and **All Testing Sites** checkboxes are also selected.

Stability improvements

- [All Pages](#)
- [View a Study Design](#)
- [Run Reports and View Notifications](#)
- [Manage Users](#)
- [Set up Sites and Depots](#)
- [Review Site Data \(Sponsor and CRO\)](#)
- [Enter Visit Data and Manage Supplies \(Site\)](#)

All Pages

- [25595323 \(former Known Issue\)](#)
- [25896779](#)
- [25908854 \(former Known Issue\)](#)

25595323 (former Known Issue)

What's changed

If you are signed in with no activity for 15 minutes, a countdown timer now appears in your browser window to notify you that your session will end soon. You can choose to keep working or sign out. If you don't click a button in the pop-up message and the countdown timer reaches 0, you are required to sign in again.

Who sees the change: All Oracle Clinical One Platform users.

Why

If you were signed in for too long without any activity, the next time you tried to work, an error occurred, but the message didn't make it clear that your session had timed out. For example, the error might have said, "Oops! Something went wrong. You might be able to try again."

25896779

What's changed

When you stop working in Oracle Clinical One Platform for 20 minutes or longer and leave your internet browser open, you are now signed out of Oracle Clinical One Platform.

See [issue 25595323](#) for additional changes related to session timeouts.

Who sees the change: All Oracle Clinical One Platform users.

Why

When you stopped working in Oracle Clinical One Platform for 20 minutes or longer, you weren't signed out, you couldn't sign out, and sometimes an error occurred and then opened the sign-in page.

25908854 (former Known Issue)

What's changed

You are no longer signed out if you work for 20 minutes without saving. As long as you are actively working, you are no longer signed out.

You still need to save to prevent your changes from being lost. For example, if you spend 30 minutes creating a large form and don't click Save, your changes are lost if you then stop working for 20 minutes and are signed out.

Who sees the change: All Oracle Clinical One Platform users.

Why

Your changes were lost if you worked on the same page for 20 or more minutes without saving or applying your changes.

View a Study Design

- [26174762](#)

26174762

What's changed

If you have the **View Design-Sponsor** role, you can now successfully open any study version, including the Draft version of the study. You can now review any study version, but you can't edit a study version unless you have a designer role (either **Designer Role - Sponsor** or **Designer Role - Blinded**).

Who sees the change: Sponsor users with read-only access to a study design.

Why

When you had the **View Design-Sponsor** role and didn't have any designer roles, an error occurred when you tried to open any study version, including the Draft version of the study, and the study version didn't open.

Run Reports and View Notifications

- [26150228 \(former Known Issue\)](#)

26150228 (former Known Issue)

What's changed

When a new notification appears on your Home page, you now also receive the notification by email.

Who sees the change: All Oracle Clinical One Platform users.

Why

There were no emails for notifications before, so you had to sign in to Oracle Clinical One Platform to check for any new notifications.

Retracted workaround

For all users: The Home page is now no longer the only location where you can view your notifications.

Manage Users

- [26299128](#) (former Known Issue)
- [26337396](#) (former Known Issue)
- [26524484](#)

26299128 (former Known Issue)

What's changed

If you have the **User Manager Role - Sponsor** role but don't have the **Site Manager Role - Sponsor** role, or if you have the **Site Manager Role - Sponsor** role for only one or two modes, you can now see users who are already added to the study on the Users tab and you can successfully add more users.

Who sees the change:

- Sponsor or CRO users who create users, such as clinical supply managers, study managers, and clinical research associates.
- Study designers who create users.

Why

When you had the roles mentioned above, you didn't see the users who were already added to the study on the Users tab, and you couldn't add users to the study.

Retracted workaround

For administrators: Previously, we recommended that you grant the following roles to users who create users:

- For Study Design Roles, the **User Manager Role - Sponsor** role.
- For Production Roles, Training Roles, and Testing Roles, the **Site Manager Role - Sponsor** role.

Users no longer need these roles to create users. If you granted these roles to users for this workaround, consider revoking the roles.

26337396 (former Known Issue)

What's changed

The **Add Users to the Study from Tenant Authorized Users** right is now named **View User Data in Reports**, and it appears under **Reports** in the list of rights.

Who sees the change:

- Sponsor or CRO users who create users, such as clinical supply managers, study managers, and clinical research associates.

- Study designers who create users.

Why

The name and category for the **Add Users to the Study from Tenant Authorized Users** right weren't correct:

- This right allowed you to view users' data in reports.
- The right appeared below Settings but should have been under Reports.

26524484

What's changed

Now only users who are created in Oracle Clinical One Platform as global users with the **Study Creator** role can assign users to the following Study Design roles and revoke the assignment of the roles from users:

- Designer Role - Sponsor
- Designer Role - Blinded
- View Design-Sponsor
- User Manager Role - Sponsor

Who sees the change:

- Sponsor or CRO users who create users, such as clinical supply managers, study managers, and clinical research associates.
- Study designers who create users.

Why

There were no restrictions on who could assign the following Study Design roles to users:

- Designer Role - Sponsor
- Designer Role - Blinded
- View Design-Sponsor
- User Manager Role - Sponsor

Set up Sites and Depots

- [26184499 \(former Known Issue\)](#)

26184499 (former Known Issue)

What's changed

The address fields for a site are now on two separate tabs:

- You now specify the site's physical location on the Site Address tab.
- You now specify the site's shipping address on the Shipping tab.

The Shipping tab also contains a checkbox that you can select when the shipping address is the same as the site's location.

Who sees the change: Sponsor or CRO users who manage sites.

Why

When you created a site, you could enter 2 addresses, but it wasn't clear which address was for the physical location of the site, and which address was the mailing address for the site.

Review Site Data (Sponsor and CRO)

- [25904561](#)
- [25904939](#)

25904561

What's changed

The Subject Data report now contains the following information after a subject transfers from Site A to Site B:

- The report for Site A (the original site) contains all data up until the subject transfers to another site.
- The report for Site B (the site the subject is transferred to) contains all data collected for the subject in the study, including the data captured at Site A.

Who sees the change:

- Sponsor or CRO users who review site data, such as clinical research associates or study managers.
- Potential downstream impact for site users.

Why

When you transferred a subject from Site A to Site B, the Subject Data report for each site contained only the data captured at the site. For example, the report for Site B contained only the data captured at Site B, not the data captured at Site A prior to the subject's transfer.

25904939

What's changed

When you transfer a subject from Site A to Site B and run the Subject Events report for Site A, the report now includes an entry for the subject transfer.

Who sees the change:

- Sponsor or CRO users who review site data, such as clinical research associates or study managers.
- Potential downstream impact for site users.

Why

When you transferred a subject from Site A to Site B, the Subject Events report for Site A didn't contain an entry for the subject transfer.

Enter Visit Data and Manage Supplies (Site)

- [25964332](#)
- [26451376](#)
- [25248511 \(former Known Issue\)](#)
- [26534864](#)

25964332

What's new

When you open a form for data entry, if the label for the unit of measure is too long to display (8 or more characters), the label now shows an ellipsis at the end. You can point to the label to see the full text.

Who sees the change:

- Study designers and other users who validate a study.
- Site users who enter visit data.

Why

Only the first 10 characters for the unit of measure appeared when you opened a form for data entry, and any remaining characters weren't visible.

26451376

What's changed

When an answer doesn't meet the requirements for a question and you save the form, you now can't screen, randomize, or dispense.

Who sees the change: Site users who enter visit data.

Why

Even when your answer didn't meet the question requirements, for a few seconds after clicking Save, you could click the Screen, Randomize, or Dispense button for the visit.

25248511 (former Known Issue)

What's changed

Site users no longer need to be assigned to a depot to see the shipments that the depot sends.

Who sees the change: Site users who manage supplies.

Why

If you weren't assigned to a depot in your user profile, you couldn't view the shipments that were sent to your site, so you couldn't ever mark the shipments as received. If you didn't mark the shipments as received, an error occurred when you performed an

action that resulted in a dispensation, including a randomization failure if randomization and dispensation occurred during the same visit.

Retracted workaround

For sponsor users who manage users: Previously, we recommended that you assign the site user who marks shipments as received to all depots that ship to the user's site. Consider revoking site users' assignments to depots.

26534864

What's changed

When you perform a code view or a code break to see information about a subject's treatment arm and the subject has been randomized but has not been dispensed any kits, you now see the correct details.

Who sees the change:

- Site users who unblind subjects' treatment arms.
- Sponsor or CRO users who reveal subjects' treatment arms, such as safety monitors.

Why

When you performed a code view (done by sponsor users) or a code break (done by site users) to see information about a subject's treatment arm, the following message appeared when a subject had been randomized but had not been dispensed any kits:

- Subject {subject number} has no data.

The message should have displayed the randomization number, treatment arm description, and the date of randomization.

Oracle Clinical One Platform 1.0 (July 2017)

- [Summary of what's new in Oracle Clinical One Platform](#)

Summary of what's new in Oracle Clinical One Platform

Everything!

We created Oracle Clinical One Platform to provide a new approach to technology solutions for your randomization and trial supply management needs. We want to help you unify people and processes so you can bring new investigational products to market faster.

Oracle Clinical One Platform uses the best technology available and offers you a great user experience.

Subject screening, randomization, and dispensation

Screening, randomizing, and dispensing to subjects was never so elegant.

Manage supplies

You can manage site inventory and shipments to sites in one place.

Ready to learn more?

Watch the training on the Oracle Help Center. Training is streamlined, quick, and easy. If you get stuck, check out our new Oracle Help Center pages, which are our new way of delivering help. Of course, you can always get help while you're working by clicking your user name and selecting Help.

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Revision history

Date	Part number	Description
May 2024	F96542-01	Original version of the document.