

Oracle® Life Sciences Clinical One Platform

Reporting Guide



Release 24.1.1

F91499-06

July 2024

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

ORACLE®

Oracle Life Sciences Clinical One Platform Reporting Guide, Release 24.1.1

F91499-06

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6 Revision History

Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [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>.

Diversity and Inclusion

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

Related resources

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

Access to Oracle Support

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

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

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

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

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1

Before you sign in

- [About this guide](#)
In the Oracle Clinical One Platform *Reporting Guide*, you can find information related to all standard reports, data extracts, and Oracle CRF Submit archives and reports.
- [Access the Reports & Archives page](#)
The Reports & Archives page is where you can access the standard reports, data extracts, and Oracle CRF Submit archives and reports that you are allowed to see in the application.

About this guide

In the Oracle Clinical One Platform *Reporting Guide*, you can find information related to all standard reports, data extracts, and Oracle CRF Submit archives and reports.




Are you looking for help with Oracle Clinical One Analytics?

The standard reports in Oracle Clinical One Platform are different from the reports you can create with Oracle Clinical One Analytics. With Oracle Clinical One Analytics you can create more robust and customized reports using your operational and clinical study data.

For more information, see the *Analytics User Guide*.

Access the Reports & Archives page

The Reports & Archives page is where you can access the standard reports, data extracts, and Oracle CRF Submit archives and reports that you are allowed to see in the application.

1. On the Home page, determine where to work. A report, extract, or archive contains only data for the location that you select, such as only data collected in Production mode.
 - To view only real data from Production mode, click the title of the study.
 - To view mock data from Testing mode, click the Testing Mode button () on the study.
 - To view mock data from Training mode, click the Training Mode button () on the study.
 - To view a report with data from the study design, click the pencil button () for the study, and below Draft, click the study version.
2. Along the top, click **Reports & Archives**.
3. Depending on what type of report you want to run, navigate to the following tabs:
 - For scheduling and running standard reports or data extracts, make sure the **Reports** tab is selected.
 - For Oracle CRF Submit archives and reports, click the **Archives** tab.

2

Oracle Clinical One Platform standard reports

- [About standard reports](#)
Standard reports in Oracle Clinical One Platform offer you access to all of your study's data organized in a functional way. You can use these reports to verify and analyze data throughout the course of your study, as well as for regulatory submissions.
- [About scheduling reports](#)
Schedules can be configured in the Oracle Clinical One Platform to have selected reports run automatically.
- [Run a report](#)
While a report is running, you can navigate away from the Reports & Archives page and do more work in the study.
- [Schedule a report](#)
Users with the appropriate permissions can schedule reports to run on a schedule defined within the Oracle Clinical One Platform.
- [Download a report](#)
You get a notification when the report is available to download.
- [Add custom fields to a report](#)
If you need to consolidate your Subject Events report with more subject data, you can now add custom fields based on study design version, visits, forms, and questions that you select in the Advanced Report Settings pop-up.
- [Report descriptions](#)

About standard reports

Standard reports in Oracle Clinical One Platform offer you access to all of your study's data organized in a functional way. You can use these reports to verify and analyze data throughout the course of your study, as well as for regulatory submissions.

About scheduling reports

Schedules can be configured in the Oracle Clinical One Platform to have selected reports run automatically.

To learn how to schedule a report, see [Schedule a report](#).

Reports that can be scheduled

- Subject Data Extract
- Subject Data
- Kit Chain of Custody (Unblinded)
- Kit Chain of Custody (Blinded)
- Order Summary Report
- Subject Events

- Subject Visits (Unblinded)
- Subject Visits (Blinded)

Required permissions

Users assigned to roles that include the *Schedule Report to Run* permission, have access to the **Schedule Reports** side panel on the **Reports** tab.

Key features

- A maximum of seven (7) reports can be scheduled to run per day, per trial.
- A schedule, once created, is visible on the **Schedule Reports** side panel on the **Reports** tab. A scheduled report can easily be enabled, disabled and edited when needed.
- The last run date for a scheduled report, is visible on the **Schedule Reports** side panel on the **Reports** tab.

 **Note:**

If a report is run manually, between scheduled runs, the manual run date is displayed as the last run date.

- When a scheduled report runs, the system validates that the user who created the schedule still has permission to generate and view the report. If permission has been revoked, the report fails and marked disabled on the **Schedule Reports** side panel.
- Report output can be delivered to the Oracle sFTP server or it can be downloaded from the **Download Reports** side panel on the **Reports** tab in the user interface.

 **Note:**

Report output, delivered to the Oracle sFTP is deleted after 30 days.

Requirements for sFTP delivery

Separate sFTP folders are created for reports that are to have output delivered to the Oracle sFTP server. The use of separate folders ensures unauthorized access to a folder containing unblinding data does not occur. No action is required on your part to create these folders.

Follow the steps below to obtain access for you and others to any of the report folders.

 **Note:**

Create these requests only after running the report for the first time. This allows the sFTP path and folder structure to be created.

1. Create a Change Request (CR) by logging in to [Oracle Life Sciences Support Cloud](#).
2. Select **Change Request** under **Create Request** in the upper right corner.
3. Click the **Maintain an application** tile.
4. Click the **Request user access** tile.

5. Complete the required fields.
6. (Important) Enter the applicable sFTP path in the sFTP path item using the details below, example provided.

 **Note:**

If you have questions about creating Change Requests, reach out to your Oracle point of contact.

Default sFTP path format: /<ShortOrgId>.clinicalone/report/<clinicalone-ae or clinicalone>/<StudyName>/<ReportName>/<Blinded or Unblinded>/<Testing or Approved or Training>/

Example: /cust1.clinicalone/report/clinicalone/abc123/Subject Visits/Blinded/Testing/

Notifications, sent to the user who created the schedule

- Scheduled Report Failure Notification.
- Scheduled Report sFTP Failure Notification.
- Scheduled Report sFTP Success Notification.

Run a report

While a report is running, you can navigate away from the Reports & Archives page and do more work in the study.

Want to see how to perform this task? Watch the video below.



- Study Organization Name includes only sites or sites and depots, depending on the report.
 - To filter and sort the data in the Microsoft Excel spreadsheet software, choose CSV as the file type.
1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).
 2. On the **Reports** tab, select the report that you want to run.

 **Note:**

Your permissions determine the reports that you can run.

3. On the right, make sure **Report Settings** is expanded, and fill in the fields. To view tips for completing a field, click into the field or choose an option.
4. Click **Run Report**.
You receive an email notification whether the report is complete or not.

Related Topics

- [About standard reports](#)
Standard reports in Oracle Clinical One Platform offer you access to all of your study's data organized in a functional way. You can use these reports to verify and analyze data throughout the course of your study, as well as for regulatory submissions.

- [Download a report](#)
You get a notification when the report is available to download.
- [Report descriptions](#)

Schedule a report

Users with the appropriate permissions can schedule reports to run on a schedule defined within the Oracle Clinical One Platform.

For more information, see [About scheduling reports](#).

To create a schedule for a report:

1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).
2. Select the report you want to define the schedule for.


Note:

For reports that cannot be scheduled, you are presented with the system message, `Scheduling this report is not supported..`

3. For valid reports, expand the **Schedule Reports** side panel and click **Create Schedule**
4. On the Schedule page, define the **Start Date**, **Time Zone**, **Frequency**, and **Send Notification To** recipients.
5. On the Settings page complete the report specific settings.
6. Click **Save**.

Once saved, the report schedule is displayed on the **Schedule Reports** side panel. From here you can easily enable, disable and edit a scheduled report.

Tip:

To edit, click on the pencil () icon next to the schedule title.

Download a report

You get a notification when the report is available to download.

Note:

All dates in reports are in the UTC (Coordinated Universal Time) time zone, which corresponds to the Greenwich Mean Time zone.

To view HTML and PDF files, make sure your browser isn't blocking pop-ups.

1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).

2. In the lower right, expand **Download Reports** and locate the report that you want to view.



Tip:

The timestamp below each report tells you when it was run.

3. Click **Download**.

Related Topics

- [About standard reports](#)
Standard reports in Oracle Clinical One Platform offer you access to all of your study's data organized in a functional way. You can use these reports to verify and analyze data throughout the course of your study, as well as for regulatory submissions.
- [Run a report](#)
While a report is running, you can navigate away from the Reports & Archives page and do more work in the study.

Add custom fields to a report

If you need to consolidate your Subject Events report with more subject data, you can now add custom fields based on study design version, visits, forms, and questions that you select in the Advanced Report Settings pop-up.

For descriptions of this report and details about who can run it, see the [Subject Events report](#).

Before adding custom fields to a report, consider the following:

- Select the latest study version to get the latest custom data in your study.
 - To run a report with custom data fields, we recommend choosing CSV as the File Type.
 - Data from repeating forms, as well as unanswered questions, appear with a value of "N/A" in the Subject Events report.
 - A site's country name (for example, United States) appears after a site's name.
1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).
 2. On the **Reports** tab, select the **Subject Events** report.
 3. On the right, make sure **Report Settings** is expanded and fill in the fields. To view tips for completing a field, click into the field or choose an option.
 4. Click **Advanced**.
 5. On the Advanced Report Settings dialog, select up to 20 visits, forms, and questions to include at the end of the report.



Tip:

Use the plus sign icon (+) to add new columns in your report.

- a. On the Visit column, select a visit from the **Select visit** drop-down.
- b. On the same row, for the Form column, select a form from the **Select form** drop-down. Only forms associated with the previously selected visit appear in the drop-down list.

- c. On the same row, for the Question column, select a question from the **Select question** drop-down.
Only questions included in the previously selected form appear in the drop-down list.
6. Click **Add**.
7. After you set the right filters and added your custom report fields, click **Run Report**.
Customized report fields appear as new columns for every selected question in each form.

Related Topics

- [About standard reports](#)
Standard reports in Oracle Clinical One Platform offer you access to all of your study's data organized in a functional way. You can use these reports to verify and analyze data throughout the course of your study, as well as for regulatory submissions.
- [Download a report](#)
You get a notification when the report is available to download.
- [Report descriptions](#)

Report descriptions

- [Annotated Case Report Forms](#)
Run this report to generate blank case report forms with specific annotations and information about forms' names, question names, and validations associated with questions in forms.
- [Clinical One Training report](#)
In this report, you view all the in-product training that users have completed for Oracle Clinical One Platform. This report provides evidence that users have completed appropriate system training before they take any actions in the user interface.
- [Global Study Roles report](#)
In this report, you view information about all study roles created for all studies at your organization, including pre-defined study roles created by Oracle and retired study roles.
- [Kit Chain of Custody \(Blinded\) report](#)
In this report, you receive a blinded view of all kits in a study. When run at the site level, the report describes every transition a kit has made throughout the study, both virtual and physical. The report also includes details on changes made to each kit.
- [Kit Chain of Custody \(Unblinded\) report](#)
In this report, you get an unblinded view of all the kits in a study. The report shows every transition that a kit has made throughout the study, both physical and virtual, plus the user who made the change, when the change happened, and any comments they provided.
- [Kit Dispensation report](#)
In this report, you view dispensation information for one, several, or all subjects at a site. The report lists the kits that were dispensed to a subject at each event in the study, throughout the life of the study. The report also includes information about replacement kits, so you can see the kits that were dispensed for lost or damaged kits.
- [Kit Inventory \(Blinded\) report](#)
In this report, you view the current status of all kits in inventory. The kit type descriptions appear for any unblinded kits.
- [Kit Inventory \(Unblinded\) report](#)
In this report, you view the current status of all kits in inventory, broken down by kit type and by lot. This report shows you the number of kits in each lot and can help you figure out

if you need to order another run. This report contains unblinding information, including the description of each kit type.

- [Kit Reconciliation report](#)
In this report, you view all kits with a specific status as part of your kit reconciliation work. This report is designed specifically for clinical research associates (CRAs), though other users might also find it useful.
- [Minimization report](#)
In this report, you are able to view the stratum details for impacted subjects in an existing study.
- [Randomization List \(Blinded\) report](#)
In this report, you view the current status as well as historical data for every randomization number in the study, as well as the subjects who were assigned each randomization number.
- [Randomization List \(Unblinded\) report](#)
In this report, you view the current status as well as historical data for every randomization number in the study, as well as the subjects who were assigned each randomization number.
- [Rules report](#)
This report gives you a complete view of all the rules that were created in a study and includes all the changes that were performed for each rule.
- [Shipment Order Summary report](#)
This report provides summary details about the status of each order made in a study.
- [Sites and Depots report](#)
In this report, you view the full list of all the sites, all the depots, or all sites and depots that were added to the study.
- [Study Design report](#)
In this report, you view all the settings specified for your study design, including a list of visits and forms in the study, kit and randomization information, and subject and supply settings.
- [Study Enrollment report](#)
In this report, you view details about enrollment for a study.
- [Study Roles report \(by study\)](#)
In this report, you view information on all study roles created for a specific study that you're assigned to. The report includes information on predefined study roles created by Oracle, as well as data on retired study roles.
- [Subject Data for CTMS report](#)
In this report, you view all subject data at multiple sites within your study. This report is designed specifically for studies that need to send subject information to their clinical trial management system. Only a study team member with the required user roles can run and download this report.
- [Subject Data report](#)
In this report, you view all data collected on every form in the study, including the study version that the data was collected on.
- [Subject Dispensation report](#)
In this report, you view dispensation information for a subject at a site.
- [Subject Events report](#)
In this report, you view all actions that have occurred to each subject, all in a single location.

- [Subject Queries report](#)
In this report, you view query information.
- [Subject Visits \(Blinded\) report](#)
In this report you view blinded details about each subject's visits and their treatments. With this report you get a complete view of each subject's visit scheduled, including completed visits and projected appointments.
- [Subject Visits \(Unblinded\) report](#)
This report offers details about the subject's visits and treatment, such as kit ID, kit description, and the anticipated number of kits to be dispensed in future visits.
- [Titration Summary report](#)
In this report, you view at a glance all visits for each subject, along with the titration details for each visit. This report is useful for blinded users who need to verify dispensation and titration data at a site for one or multiple subjects.
- [Titration Summary \(Unblinded\) report](#)
In this report, you view titration details for all subjects and visits at a site or at multiple sites. This report is useful for unblinded users who want to verify dispensation and titration data at a site, as well as treatment arm information.
- [User Assignment reports](#)
User Assignment reports can help you identify and resolve issues related to user management, as well as give you valuable data on study access at your organization.
- [User Upload Error report](#)
This report contains errors encountered when importing the User Upload Template.

Annotated Case Report Forms

Run this report to generate blank case report forms with specific annotations and information about forms' names, question names, and validations associated with questions in forms.



Note:

When a kit is marked as *Misallocated* but it wasn't added to a visit in study design, that kit doesn't show in this report.

Modes

Available in all 4 modes: Design, Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Study Design Report* permission can generate this report.

Filters

Filter	Description
Study version	Choose the study version to run the report for.
File Type	Choose the output type for the report: HTML or PDF.

Field descriptions

**Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report.
Asterisk (*)	Indicates that the item or question displayed in the report is required.
Check mark (✓)	Indicates that the item or question requires source data verification.
Hidden icon	Indicates that the item or question is hidden.
Report Generated By	User name of the user who generated this report.
Created Date	Date when this report was run.
Version Created	Date when the study version selected for this report was created.
Study Version	A study version's number.
Version Modified	UTC time and date of when the study version was modified.

Fields displayed for each form associated with the selected study version	Description
Form title	Indicates a form's title, reference code, as well as the visits and branches to which the form was assigned. For a lab form, this row also indicates whether a site user is allowed to add additional instances of the same lab form during the course of a study. When applicable, the text displayed states "Allow for Multiple Instances". For a form with label items, this row also indicates whether a site user is allowed to add additional rows in the form. When applicable, the text displayed states "Allow Additional Rows".
Question	Indicates a question's title, as well as the question's hint, or instructional text, if applicable.
Reference ID	A question's reference code.
Answer	A question's answer formats, such as text, date, multiselect (for drop-down questions), radio (for radio buttons), instructional text, and many more. Be aware that instructional text answers are not displayed in PDF versions of the Annotated Case Report Forms, and only appear in the HTML format.
Validations	A question's validation rules or rules related to dynamic questions and forms.

Fields displayed for each form associated with the selected study version	Description
Advanced	A question's advanced properties such as SAS variables, SAS Labels, Lab Normals Tag, Data Classifications, Source Data Verification, Allow Future Dates.

Clinical One Training report

In this report, you view all the in-product training that users have completed for Oracle Clinical One Platform. This report provides evidence that users have completed appropriate system training before they take any actions in the user interface.

All users who complete training receive email notifications, but those emails are just for their own personal records. This report is useful for anyone who needs to look at training records for an entire study, including CRAs, administrators, and user managers.

There are several use cases for running this report:

- Throughout the study, you can check users' training status to figure out whether any users haven't completed their training.
- At the end of the study, producing evidence of training is easy thanks to this report. No need to grab individual certificates for each user: All your training records are in a single report, so you can upload your evidence of training to the appropriate location.

While reviewing the report, you should be aware of the following requirements for training:

- As new features are made available, new training might become required and assigned.
- Some users might be able to enter data before they complete all their training. This behavior is expected, and here's why: Training is delivered to Oracle Clinical One Platform users just in time, when they open a new tab or page. After users complete the training for the page, all functionality on the page is unlocked. Functionality on other pages remains locked.

For example, consider a site user who hasn't performed any inventory-related tasks on a study that's been running for a while. In this situation, the site user likely completed all their data-entry training immediately after signing it, but because they haven't navigated to the Inventory tab yet, they haven't been required to complete the inventory training.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Training Report* permission can generate this report.

Filters

Filter	Description
Training Completion Date	Choose a date range for the report. The report will include only the training that was completed during the date range.

Filter	Description
User Name	Choose one or more users to view only those users' completed training, or leave this filter blank to run the report for all users.
Location	Choose a site or depot to view completed training for that location, or leave this filter blank to run the report for all locations.
File Type	Choose the output type for the report: HTML or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial Fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study
Training Completion Date	Period of time you selected when running this report
Report Generated By	User name of the user who ran this report (typically a training manager)
Created Date	UTC time and date of the current generated report
Location	The location you selected for audit history, either a site or depot
Trainee User Name	The user name of the trainee you selected to be included in the report.
Fields in the User Training section	Description
Required Training	Each row is for a training video that is associated with the permissions the user has in Oracle Clinical One Platform
Training Completion Date/ Time	UTC time and date of when the user completed training
Training Effective Date	Date the user was first assigned the role and permission that requires the training video to be viewed
Study Assignment Date	Date when a user was granted rights to the study, this can be after the dates listed above

Global Study Roles report

In this report, you view information about all study roles created for all studies at your organization, including pre-defined study roles created by Oracle and retired study roles.

If you're a global user manager who needs to view data on study roles created for your organization, then this is the report you'll typically generate. On the Home page, click the **Reports** tab to find the report, and run it any time during the duration of a study.

Modes

Available in all modes: Study Design, Testing, Training, and Production

Permission required to run the report

There is no specific permission that is required to run this report. Only users who are assigned the Global User Manager global role can generate this report.

Filters

Filter	Description
File Type	Choose the output type for the report: CSV, HTML, or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Column name	Descriptions
Customer Name	A customer's name used to purchase the cloud subscription
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of the current generated report
Study Role Name	Name of the study role name as entered by a global user manager
Permissions	Permissions a global user manager included in the respective study role
Status	Status of a study role: can be Active or Retired
Last Modified By	User name of the user who last modified a study role
Last Modified	UTC time and date of the latest update for a study role

Kit Chain of Custody (Blinded) report

In this report, you receive a blinded view of all kits in a study. When run at the site level, the report describes every transition a kit has made throughout the study, both virtual and physical. The report also includes details on changes made to each kit.

Information on the changes of kits include:

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

- Destruction of the kit

Modes

Available in 3 modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Blinded Chain of Custody Report* permission can generate this report.

Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Filters

Filter	Description
Include Audit Trail	Choose Yes to see the current kit status plus all historical changes to them; choose No to see only the current Kit status.
Transaction Date	(Available if Yes for Include Audit Trail is selected) Choose a date range for the report. The report will include only kits with status changes during the date range.
Kit Status	Select a kit's status for each event. For example, a kit may start as New and progress to Available (at the depot), In Transit, Available (at the site), and Dispensed
Shipment ID	An unique identifier for the shipment
Quarantine ID	The tracking number for a kit or shipment that has experienced a temperature excursion.
Location	Choose one or more sites or depots to include only the kits at the location in the report, or leave this filter blank to include kit types at all locations.
Subject Number	Choose one or more subjects to include only the kits dispensed to them, or leave this filter blank to include kits dispensed to all subjects.
File Type	Choose the output type for the report: CSV, PDF or HTML.

Field Descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial Fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study

Initial Fields	Description
Site Name	A site's name as entered by the site manager when they created the site
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study
Subject ID	A subject's distinct ID code
Date Range	Period of time you selected when running this report
State	The state of the kit(s) you selected when running this report
Report Generated By	User name of the user who ran this report (typically a training manager)
Created Date	UTC time and date of the current generated report
Fields in Kit section	Description
Kit Description	A kit's description is also a unique value, this description is either visible (unblinded distribution) or hidden from site users based on the study design
Kit Number	A unique number assigned to individual kits (serialized kit distribution)
Barcode	The barcode of the kit as it was either generated by the system
Device ID	ID of the device
Transaction Date	The UTC time and date of the kit transition
Dispensation Confirmation	Setting that indicates if the dispensation was confirmed or not
CRA Verified	This field indicates if the CRA verified the kit or not
Status	A kit's status for each event, for example, a kit may start as new and progress to Available (at depot), In Transit, Available (at site), Dispensed, and Misallocated.
Dispensing Visit	Indicates as part of which visit a kit was dispensed.
Instance Number	Reflects visit cycle instances whenever cycling is enabled for the study.
Units per Kit	Number of individual consumable units in a kit such as a pill count or mg
Returned Units	Number remaining in the kit as indicated by the site user or clinical research associate (CRA) in the kit reconciliation process
Missing Units	Number of units that are missing from the kit as indicated by the site user or clinical research associate (CRA) in the kit reconciliation process
Balance Units	Number of units in the kit that is assumed were consumed by the subject
Units Returned to Depot	Number of units in a kit returned to depot
Study Org ID	ID of the site or depot
Study Org Name	Long name of the site or depot
User Name	The user responsible for the transaction

Fields in Kit section	Description
Return Study Org ID	Indicates the ID of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Return Study Org Name	The full name of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Subject Number	If dispensed, the subject number is included in the report
Expiration Date	Expiration date assigned to the kit
Shipment ID	If the kit was selected for a shipment, this is a unique identifier. If a shipment from depot to site, or from site to destruction depot, is canceled , the Shipment ID will still be present. However, if a kit is removed from a shipment from depot to site, the Shipment ID will not be present on the report
Quarantine ID	A tracking number assigned to a kit or shipment that has experienced a temperature excursion.

Kit Chain of Custody (Unblinded) report

In this report, you get an unblinded view of all the kits in a study. The report shows every transition that a kit has made throughout the study, both physical and virtual, plus the user who made the change, when the change happened, and any comments they provided.

Changes for each kit include the following:

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

This report is useful for a clinical supply manager or other unblinded user. We recommend running this report as a CSV file so that you can filter and sort the data to find what you need. You might run this report during the study conduct period so you can see the kits in a given lot or at the depot. You might run the report at the end of the study if you need to get various views into some or all kits in the study.

Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Keep in mind that if you need information about one or two kits, you can open the Kit Reconciliation tab and get your answer quickly and easily. This report is more useful when you need to view data related to a number of kits.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Unblinded Chain of Custody Report* permission can generate this report.

Filters

Filter	Description
Include Audit Trail	Choose Yes to see the current kit status plus all historical changes to them; choose No to see only the current Kit status.
Transaction Date	Choose a date range for the report. The report will include only kits with status changes during the date range.
Kit Type ID	Choose one or more kit types to include in the report, or leave this filter blank to run the report for all kit types.
Shipment ID	An unique identifier for the shipment
Quarantine ID	The tracking number for a kit or shipment that has experienced a temperature excursion.
Location	Choose one or more sites or depots to include only the kits at the location in the report, or leave this filter blank to include kit types at all locations.
Subject Number	Choose one or more subjects to include only the kits dispensed to them, or leave this filter blank to include kits dispensed to all subjects.
File Type	Choose the output type for the report: CSV, HTML, or PDF.

 **Note:**

We recommend choosing CSV, so that you can narrow your view of the data. You can then sort by Sequence Number and Transaction Date to see the complete lifecycle.

Field descriptions

 **Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial Fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study
Include Audit Trail	Setting that indicates if you included audit trails in your report or not
Kit Type ID	The Kit Type ID you selected to be included in the report
Subject Number	The Subject Number(s) you selected to be included in the report
Transaction Date	Period of time you selected when running this report to view data in your study
Report Generated By	User name of the user who ran this report (typically a training manager)
Created Date	UTC time and date of the current generated report
Location	The location you selected for audit history, either a site or depot

Fields in Kit section	Description
Kit List	The name of the kit list as entered by the clinical supply manager
Kit Type ID	Unique code entered in the design of the study for a kit
Kit Description	A kit's description is also a unique value, this description is either visible (unblinded distribution) or hidden from site users based on the study design
Kit Number	A unique number assigned to individual kits (serialized kit distribution)
Sequence Number	This number is potentially unblinding. The distribution vendor uses it for filling shipment requests
Barcode	The barcode of the kit as it was either generated by the system
Device ID	ID of the device
Transaction Date	The UTC time and date of the kit transition
Dispensation Confirmation	Setting that indicates if the dispensation was confirmed or not
CRA Verified	This field indicates if the CRA verified the kit or not
Status	A kit's status for each event, for example, a kit may start as new and progress to Available (at depot), In Transit, Available (at site), Dispensed, and Misallocated.
Dispensing Visit	Indicates as part of which visit a kit was dispensed.
Instance Number	Reflects visit cycle instances whenever cycling is enabled for the study.
Reason for Change	Where applicable, user indicates a reason for change when updating a kit's status. Not all state changes require this additional comment"
Units per Kit	Number of individual consumable units in a kit such as a pill count or mg

Fields in Kit section	Description
Returned Units	Number remaining in the kit as indicated by the site user or clinical research associate (CRA) in the kit reconciliation process
Missing Units	Number of units that are missing from the kit as indicated by the site user or clinical research associate (CRA) in the kit reconciliation process
Balance Units	Number of units in the kit that is assumed were consumed by the subject
Units Returned to Depot	Number of units in a kit returned to depot
User Name	The user responsible for the transaction
Study Organization ID	ID of the site or depot
Study Organization Name	Long name of the site or depot
Return Organization ID	Indicates the ID of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Return Organization Name	The full name of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Subject Number	If dispensed, the subject number is included in the report
Manufacturing Lot	Minimal requirement for lot assignment, this lot group provides expiration, Do not count, and Do not ship dates for the inventory management system
Label Group	The name of the Label Group the kit is assigned to
Expiration	Expiration date assigned to the kit
Shipment ID	If the kit was selected for a shipment, this is a unique identifier. If a shipment from depot to site, or from site to destruction depot, is canceled , the Shipment ID will still be present. However, if a kit is removed from a shipment from depot to site, the Shipment ID will not be present on the report
Quarantine ID	A tracking number assigned to a kit or shipment that has experienced a temperature excursion.

Kit Dispensation report

In this report, you view dispensation information for one, several, or all subjects at a site. The report lists the kits that were dispensed to a subject at each event in the study, throughout the life of the study. The report also includes information about replacement kits, so you can see the kits that were dispensed for lost or damaged kits.

Additionally, the Kit Dispensation report contains details about each subject's current state, the projected dispensation event, as well as the principal investigator's full name.

Note:

If your study is designed to allow titrations, dispensing IoT-enabled devices managed with Oracle mHealth Connector or unscheduled visits, then this report also contains information about the kits designed for these features.

The report contains additional information about unblinded kits, including descriptions of the kit types and information about the calculated doses.

Run this report if you need to see all dispensation information in a single location.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Kit Dispensation Report* permission can generate this report.

Filters

Filter	Description
Location	Choose a site or depot to include dispensation history for a single location, or choose All to view dispensation history for all locations.
Subject Number	Choose a subject to include only one subject's dispensation history, or choose All to include the dispensation history of all subjects.
Visit Title	<i>(Available only if you select a subject)</i> Choose a visit to include only the kits dispensed during the visit.
File Type	Choose the output type for the report:\ <ul style="list-style-type: none"> • CSV • HTML • PDF

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial Fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study.
Subject Number	The number of the subject you selected to be included in the report.
Visit Title	The name of the visit you selected to be included in the report.
Report Generated By	User name of the user who ran this report (typically a training manager).
Created Date	UTC time and date of the current generated report.

Initial Fields	Description
Location	The location you selected for audit history, either a site or depot.
Fields in the table header	
Site ID	The site's ID as entered by the site manager when they created the site.
Site Name	A site's name as entered by the site manager when they created the site.
Principal Investigator's Full Name	A Principal Investigator's Full Name as listed when the site manager created the site.
Country	A site's country as entered by the site manager when they created or last modified the site. Report displays country abbreviation.
Subject's ID	Subject ID.
Subject's status	A subject's status at the moment when this report was run. For example, a subject might be in an Active state or a New, Screened or Withdrawn state.
Subject's Randomization Number	Unique number for the subject's randomization.
Fields in each subject section	
Visit/Event title	A visit's name. Includes unscheduled visits and events and branch visits.
Visit/Event Instance	Indicates the unscheduled visit number or the branch visit instance for a subject.
Kit Number	A unique number assigned to individual/locally sourced kits (serialized kit distribution).
Replaced Kit	Kit number of the original kit in a replacement situation.
Dose Frequency	Used in calculated dose designs (e.g. Once, QD, BID).
Titration	Indicates whether a subject received any kit type titrations (for maintaining the dose, going up, or down).
Calculated Dose	Displays information on the dose calculation unless the user running the report is blinded to this data.
Consume Unites Across Doses	A setting for calculated doses; it allows for minimization of waste when multiple doses are dispensed. Data may be blinded for some users running this report.
Kit Description	Indicates a short description of each kit dispensed to a subject. Data for this column can be either visible or blinded based on role and study design.
Type	The informational field for the packaging type (e.g. syringe, blister pack, ointment, activity watch).
Units per Kit	Number of individual consumable units in a kit such as a pill count or mg.
Projected Dispensation Date	Date when the next scheduled dispensation should take place in the study.
Dispensation Date	Date of the kit dispensation in UTC format.
Reason for Change	Where applicable, a user indicates a reason for change. Not all state changes require this additional comment.

Fields in each subject section	Description
Return Organization ID	Indicates the ID of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment.
Return Organization Name	The full name of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment.
Last Modified By	Username of the user responsible for the latest update.

Kit Inventory (Blinded) report

In this report, you view the current status of all kits in inventory. The kit type descriptions appear for any unblinded kits.

You can find all this information in the user interface, but this report is useful if you prefer to work in a report or if you need to share inventory information with someone who doesn't have access to Oracle Clinical One Platform.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Blinded Inventory Report* permission can generate this report.

Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Filters

Filter	Description
Location	Choose one or more sites or depots to include only the kits assigned to the locations, or leave the filter blank to include kits at all locations.
File Type	Choose the output type for the report: CSV or HTML.

Fields description



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.

Initial fields	Description
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study.
Report Generated by	User name of the user who ran this report (typically a training manager).
Created Date	TC time and date of the current generated report.
Location	The location you selected for the report, either a site or depot.

Fields for all kits in inventory	Description
Blinded Lot ID	Reflects the ID of a blinded lot which has been included in the report.
Blinded Lot Expiry Date	Reflects the expiry date of a blinded lot which has been included in the report.
Study Organization Name	A site's name that belongs to the study's organization where all kits are currently located.
Study Organization ID	A site's ID that belongs to your study's organization where all kits are currently located.
Each of the following column headers corresponds to a kit status	Each of the following column headers indicates the number of kits with a certain status at a site. To know more about what each kit status means, see <i>What statuses can kits have?</i> Note that these columns are populated based on what statuses your kits have in a study.

Kit Inventory (Unblinded) report

In this report, you view the current status of all kits in inventory, broken down by kit type and by lot. This report shows you the number of kits in each lot and can help you figure out if you need to order another run. This report contains unblinding information, including the description of each kit type.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Unblinded Inventory Report* permission can generate this report.

Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Filters

Filter	Description
Location	Choose one or more sites or depots to include only kits at the location, or leave the filter blank to include all locations.

Filter	Description
Manufacturing Lot	Choose one or more manufacturing lots to include only the kits assigned to the lot, or leave the filter blank to include all lots.
Kit Type ID	Choose one or more kit types to include only the kits of that type, or leave the filter blank to include all kit types.
File Type	Choose the output type for the report: CSV or HTML.

Fields description



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study.
Report Generated by	User name of the user who ran this report (typically a training manager).
Created Date	TC time and date of the current generated report.
Location	The location you selected for audit history, either a site or depot.
Manufacturing Lot ID	Manufacturing lots that you selected to include in the report.
Manufacturing Lot Expiry Date	Reflects the expiry dates of the manufacturing lots you have selected to include in the report.
Blinded Lot ID	Blinded lots that you have selected to include in the report.
Blinded Lot Expiry Date	Reflects the expiry dates of the blinded lots you have selected to include in the report.
Kit Type ID	Kit Type IDs that you selected to include in the report.

Fields for all kits in inventory	Description
Study Organization Name	A site's name that belongs to the study's organization where all kits are currently located.
Study Organization ID	A site's ID that belongs to your study's organization where all kits are currently located.
Manufacturing Lot ID	A manufacturing lot's ID that kits are associated with.
Kit Type ID	A kit type's ID as entered by a study designer when the kit was created.
Kit Description	A kit's description as entered by a study designer.
Do Not Ship	Number of days before the expiration date when a kit can no longer be shipped from a depot to a site.

Fields for all kits in inventory	Description
Do Not Count	Number of days before the expiration date when a kit is no longer counted in a site's inventory.
Each of the following column headers corresponds to a kit status	Each of the following column headers indicates the number of kits with a certain status at a site. To know more about what each kit status means, see <i>What statuses can kits have?</i> Note that these columns are populated based on what statuses your kits have in a study.

Kit Reconciliation report

In this report, you view all kits with a specific status as part of your kit reconciliation work. This report is designed specifically for clinical research associates (CRAs), though other users might also find it useful.

This report shows you all kits with a specific status but doesn't include historical status or other audit information. It is particularly useful for the following scenarios:

- When you want to see all kits that have been lost by subjects.
- When you need to find the kits that are ready for destruction.
For example, you can run the report for all kits with the Returned to Site status, and then you can compare the kits at the site with the kits in the report. Then you can verify the kits and mark them as Ready for Destruction.

You can follow the same process for kits with the Damaged by Subject status.

- When you want to see all kits that are either ready for destruction or have already been destroyed.

Keep in mind that all the information in the report is also available on the Site Inventory tab; just use the filters at the top to find kits of a particular status.

Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Kit Reconciliation Report* permission can generate this report.

Filters

Filter	Description
Kit Status	Choose one or more kit statuses to include only kits with that status, or leave the filter blank to include kits of all statuses.
Location	Choose one or more sites or depots to include only kits at that location, or leave the filter blank to include kits at all locations.
File Type	Choose the output type for the report: HTML, CSV or PDF.

Fields description



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study
Kit status	One or multiple kit statuses you selected to include in this report
Report Generated by	User name of the user who ran this report (typically a training manager)
Created Date	UTC time and date of the current generated report
Location	The location you selected for audit history, either a site or depot
Fields in the table header	Description
Site name	A site's name as entered by the site manager when they created the site
Principal's Investigator Full Name	A Principal Investigator's Full Name as listed when the site manager created the site
Site's address	A site's address as entered by the site manager when they created the site
Total Kits Reconciled	Number of kits reconciled at each site
Fields in the following sections	Description
Study Organization ID	ID of the site or depot
Kit Number	A unique number assigned to the individual kits (serialized kit distribution)
Status	Indicates specific states within the reconciliation process; Damaged by Subject, Destroyed, Pending Destruction, Lost by Subject, and Returned to Site as selected by the user who ran this report
Units per Kit	Number of individual consumable units in a kit such as pill count or mg
Returned Units	Number remaining in the kit as indicated by the site user or clinical research associate (CRA)
Missing Units	Number of lost or damaged units in the kit as indicated by the site user
Reconciliation Shipment ID	Unique ID of a shipment shipped to depot or drug destruction facility, the unique number associated with that transaction
Depot Returned Units	Number of units remaining in the kit when returned to the depot for those studies that are doing a validation at a unit level

Fields in the following sections	Description
Date Reconciled	UTC time and date of the kit reconciliation
Reconciled by	User name of the user responsible for the transaction
Subject Number	If dispensed, the subject number is included in the report
Returned Organization ID	Indicates the ID of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Returned Organization Name	The full name of the site or depot a kit has been returned to. This field appears only when a kit is returned for a kit reconciliation shipment
Verified Date	UTC time and date of the clinical research associate (CRA) transaction marking the kit as verified
Verified By	User name of the clinical research associate (CRA) who marked the kit as verified

Minimization report

In this report, you are able to view the stratum details for impacted subjects in an existing study.

Modes

Available in the following modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Unblinded Randomization Report* permission can generate this report.

Filters

Filter	Description
Randomization List	Choose a randomization list to filter the report by
Randomization Number Status	Filter the report by randomization number status, such as Not Approved, Assigned, Available, Not Released, and Randomized in Error.
Data Type	Filter the report by either Current Data or Historical Data. If you select Historical Data, the option to choose a date range becomes available.
File Type	Choose to filter the report by CSV, HTML, or PDF file.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Fields in this report	Description
Randomization Number	The unique number for the randomization
Status	Status of the randomization number, including Available, Assigned, Not Released, Not Approved, Randomized in Error
Probability Factor	Represents a measure or an estimate of the possibility, on a scale from zero (impossibility) to one (certainty), one subject may have to be assigned to a certain treatment arm and receive a certain type of drug during the course of a study.
Treatment arm	Description of the treatment arm
Subject Number	If a randomization number is assigned to a subject, the subject number is included in the report
Restricted to Available kits	Indicates randomizations that skipped a code. The design provides the option if there is a shortage of supply at a site.
Country	Indicates the name of the site's country
Stratum Factor	Represents the element the study design is stratifying subjects on, such as Age, Cancer Stage, Clot Location, etc.
User Name	User responsible for the transaction
Last Transaction Date	UTC time and date of the last transaction

Randomization List (Blinded) report

In this report, you view the current status as well as historical data for every randomization number in the study, as well as the subjects who were assigned each randomization number.

This report is especially useful at the end of a study because it shows you everything that's happened with your randomization list and who performed the action, from the creation of the list to the assignment of each number and whether any subjects were randomized in error.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Blinded Randomization Report* permission can generate this report.

Filters

Filter	Description
Date Range	Choose a date range for the report. The report will include only randomization numbers with status changes during the date range.
Location	Choose one or more sites or depots to include only the randomization numbers that were assigned at that location, or leave the filter blank to include randomization numbers for all locations.

Filter	Description
Randomization Status	Choose one or more statuses to include only the randomization numbers with that status, or leave the filter blank to include randomization numbers with all statuses.
File Type	Choose the output type for the report: CSV, HTML, PDF, or XLSX.
Historical Data	Click the radio button to view the latest records for randomization codes in the randomization list.
Audit Trail	Choose Yes to make the audit history available when selecting the date range, or choose No to only download the latest data.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study.
Location	The site or depot where the randomization numbers were assigned.
Date Range	Period of time you selected when running this report.
Report Generated By	Username of the user who generated this report.
Created Date	The date this report was run.
Randomization List	The name of the randomization list you selected to be included in the report.
Randomization Status	The status of the randomization numbers you selected to be included in the report.

Fields in this report	Description
Randomization Number	Unique number for the randomization.
Block Number	Indicates the block identifier. Randomization codes are created in blocks based on the design parameters to achieve balance.
Study Organization ID	Short name or code for the site or depot.
Study Organization Name	Long name of the site or depot.
Subject Number	If a randomization number is assigned to a subject, the subject number is included in the report.
Date	UTC time and date of the transaction.

Fields in this report	Description
Cohort	Cohort title per study design, used for Demography and Adaptive randomization.
Stratum	Stratum title per study design, used for all stratified designs excluding demography cohorts.
Status	Status of the randomization number, including Available, Assigned, Not Released, Not Approved, Randomized in Error.
Randomization List Name	Name of the randomization list.
User Name	User responsible for the transaction.
Reason for Change	Where applicable, user indicates a reason for change. Not all state changes require this additional comment.
Restricted to Available Kits	Indicates randomizations that skipped a code. The design provides the option if there is a shortage of supply at a site.
Blocked by	Displays the Site, Country, and Region when a study is blocked.

Randomization List (Unblinded) report

In this report, you view the current status as well as historical data for every randomization number in the study, as well as the subjects who were assigned each randomization number.

This report is especially useful at the end of a study because it shows you everything that's happened with your randomization list and who performed the action, from the creation of the list to the assignment of each number and whether any subjects were randomized in error.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Unblinded Randomization Report* permission can generate this report.

Filters

Filter	Description
Date Range	Choose a date range for the report. The report will include only randomization numbers with status changes during the date range.
Location	Choose one or more sites or depots to include only the randomization numbers that were assigned at that location, or leave the filter blank to include randomization numbers for all locations.
Randomization Status	Choose one or more statuses to include only the randomization numbers with that status, or leave the filter blank to include randomization numbers with all statuses.
File Type	Choose the output type for the report: CSV, HTML, PDF, or XLSX.

Filter	Description
Historical Data	Click the radio button to view the latest records for randomization codes in the randomization list.
Audit Trail	Choose Yes to make the audit history available when selecting the date range, or choose No to only download the latest data.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study
Location	The site or depot where the randomization numbers were assigned
Date Range	Period of time you selected when running this report
Report Generated By	Username of the user who generated this report
Created Date	The date this report was run
Randomization List	The name of the randomization list you selected to be included in the report.
Randomization Status	The status of the randomization numbers you selected to be included in the report.

Fields in this report	Description
Randomization Number	Unique number for the randomization
Block Number	Randomization codes are created in blocks based on the design parameters to achieve balance
Study Organization ID	Short name or code for the site or depot
Study Organization Name	Long name of the site or depot
Subject Number	If a randomization number is assigned to a subject, the subject number is included in the report
Date	UTC time and date of the transaction
Cohort	Per study design, used for Demography and Adaptive
Stratum	Per study design, used for all stratified designs excluding demography cohorts
Treatment Arm ID	A treatment arm's ID as defined by the study designer
Treatment Arm	Description of the treatment arm

Fields in this report	Description
Status	Status of the randomization number, including Available, Assigned, Not Released, Not Approved, Randomized in Error
Randomization List Name	Name of the randomization list
User Name	User responsible for the transaction
Reason for Change	Where applicable, user indicates a reason for change. Not all state changes require this additional comment
Restricted to Available Kits	Indicates randomizations that skipped a code. The design provides the option if there is a shortage of supply at a site.
Blocked by	Shows the Site, Country, and Region when a study is blocked.

Rules report

This report gives you a complete view of all the rules that were created in a study and includes all the changes that were performed for each rule.

The Rules report offers details about each rule, including rule expression, rule status, the mode in which the rule is contained, as well as information about changes that were made to that rule and the validity of that rule.

This report is available in CSV, PDF and HTML formats.

Modes

This report is available in all 3 modes.

Permission required to run the report

Any user who's assigned the *Run the Study Rules Report* permission can generate this report.


Filters

Filter	Description
Study Version	Select a study version to display the rules associated with a specific form or question or leave it blank to display all rules in the study.
Rule State	Select Draft, UAT, Approved or Published to display only rules with a specific state or leave it blank to view all rules in all states.
Form Title	Select a form title to see all rules that are associated with that form or leave it blank to view all the rules included in all the forms in that study version.
Question Label	Select a question label to see rules that are associated with that question or leave it blank to view all rules that are associated with all questions included in the form you previously selected.
Include Audit Trail	Choose Yes to see details about every change that was made to each rule or select No to view only the latest version for each rule.
File	Choose the output type for the report: CSV, PDF or HTML.

Field descriptions

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran the report.
Study Version	Number of the study version for which the report is generated.
Report Generated By	User name of the user who generated the report.
Created Date	UTC time and date of when this report was run.
Include Audit Trail	Setting that indicates if you included audit trails in your report or not.
Do Not Block Users	Setting that will filter out the names of the users in the Action Target field.
<hr/>	
Fields displayed for every selected form title	Description
Visit Name	The name of the visit for which the rule is set.
Visit RefName	The Reference name of the visit for which the rule is set.
Form Name	The name of the form that contains the rule.
Form RefName	The Reference name of the form that contains the rule.
Target Question	The name of the question that contains the rule. This is the question for which the calculated value or query will appear.
Question RefName	The Reference name of the question that contains the rule. This is the question for which the calculated value or query will appear.
Rule Version Number	The number of the rule version included in report.
Rule Reference ID	The unique ID that was generated for the rule.
Rule name	The name of the rule as entered by the rule designer.
Rule Copied	<i>Reserved for future use</i> Indicates wheter a rule is copied or not.
Rule Copied From	<i>Reserved for future use</i> The name of the rule from which the rule was copied from, if applicable.
Rule Description	The description of the rule as entered by the rule designer.
Variables	The variables that were defined for the rule.
Expression	The Javascript expression that was defined for the rule.
Rule Valid/Invalid	The validity of the rule. This field specifies whether the rule contains any errors.
Action Type	The type of action that is set for the rule: Create query or Calculate value.
Action Target	The roles or names of the targets that will be notified when the action is triggered.

Fields displayed for every selected form title	Description
Action Properties	The text of the query message as defined in the Answer type field.
Rule State	Status of the rule: Draft, UAT, Approved, Published. If audit format is selected all state changes will appear. Otherwise, only the most recent status will be provided for all rules in the study.
On Publish	Indicates if when a rule gets publish will run on All Data or Future Data , according to the configuration on the Rule Management page.

 **Note:**

If the rule gets published using the state slider in Testing mode, this setting can be configured differently when user gets prompted with these two options.

Mode	The mode where the rule is contained.
Type of change	Indicates how the rule was modified. If audit format is selected all changes will appear. Otherwise, only the most recent change will be provided for all rules in the study.
Last modified Date/Time	Date and time (DD-MM-YYYY HH:MM:SS) of when the rule was last modified.
Last modified by	User name of the user who last modified the rule.

Shipment Order Summary report

This report provides summary details about the status of each order made in a study.

This report is available in CSV, HTML, and PDF formats.

Modes

This report is available in all 3 modes.

Permission required to run the report

Any user who's assigned the *Run the Order Summary Report* permission can generate this report.



Users with *Blinded Depot User* permission can now see unblinding kit numbers to fulfill shipments. Only data from manually associated depots and sites by the user administrator will show when running the report.

Filters

Filter	Description
Date range	Choose a date range for the report. The report will include orders that were made during that date range.
Received by	Choose a site or depot to view orders that were received only at those locations, or leave this filter blank to run the report for all sites and depots.
Received date	Choose a site or depot to view order that were received on a specific date, or leave this filter blank to tun the report for all sites and depots.
Shipped by	Choose a site or depot to view orders that were shipped only by that site or depot, or leave this filter blank to run the report for all sites and depots.
Order status	Choose an order status to include only orders with that status, or leave the filter blank to include orders of all statuses.
File	Choose the output type for the report: <ul style="list-style-type: none"> • CSV • PDF • HTML

Field descriptions

Initial fields	Description
Customer name	A customer's name used to purchase the cloud subscription.
Study name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran the report.
Report generated by	User name of the user who generated the report.
Created date	UTC time and date of when this report was run.
Date Range	Period of time you selected when running this report.
Shipped By	The depot or site that shipped the order.
Received By	The depot or site that received the order.
Received Date	The date on which the order was received.
Order Status	The order's status you selected when running the report. For example, an order's status might be New, Pending, In Transit, Received, Cancelled or Lost.
Fields displayed for every order	Description
Shipped By	The depot or site that shipped the order.
Shipped To	The depot or site the order was shipped to.
Shipped To Country	The country the order was shipped to.
Shipment ID	An unique identifier for the shipment.

Fields displayed for every order	Description
Shipment Type	A shipment can be: <ul style="list-style-type: none"> • Initial • Resupply • Manual
Tracking Number	A shipment's tracking number, as entered by a clinical supply manager, used to track the expedition of a shipment to a site or depot.
Shipment status	A shipment's status at the moment the report is run. For example, a shipment's status might be New, Pending, In Transit, Received, Quarantined, Cancelled or Lost, at the time you're running this report.
<div style="border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>A shipment's status will only be Quarantined if the entire shipment has been marked as Quarantined. Otherwise, the shipment's status will be Received.</p> </div>	
Temperature Monitor Status	The status of a temperature monitor included in a shipment. For example, the temperature monitor status might be: <ul style="list-style-type: none"> • Yes: Indicates the monitor has gone off and there is a temperature excursion. • No: Indicates the monitor did not experience a temperature excursion and did not go off. • Missing: A monitor was not found in the shipment.
<div style="border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>If your study does not allow for temperature excursions, this column will display as N/A.</p> </div>	
Date Requested	The date the order request was made.
Date Received	The date when the order was received.
Days Outstanding	The number of days between the date when the shipment was created and the current date. If the shipment is received, days outstanding represent the number of days from when the shipment was in transit to when it was received.

Fields displayed for every order	Description
Date Cancelled/Marked Lost	The date when the order was marked as Cancelled or Lost.
Kit Count	The number of kits included in the order.
Kit Numbers in Shipment	The kit numbers of all the kits included in the order.

Sites and Depots report

In this report, you view the full list of all the sites, all the depots, or all sites and depots that were added to the study.

You have the following options for the level of detail to include:

- Current information for sites and depots, such as the name of the PI at a site and the site number.
- All current and historical information for sites and depots, including the users who made every change.

There are a number of use cases for running this report:

- You can run the report with current information so that you have it to reference during study management. You'll likely also run it after the study finishes so you can add the report to the trial master file.
- You can run the report with current and historical information if you notice incorrect data and want to figure out when it was changed and by whom.

Modes

Available for all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Sites and Depots Report* permission can generate this report.

Filters

Filter	Description
Date Range	Choose a date range for the report. The report will include only the sites and depots that were updated during the date range.
Location	Choose one or more sites or depots to view their audit history, or leave this filter blank to run the report for all locations.
Data Type	Choose Current Data to see the current values for sites and depots that changed during the specified date range; or choose Historical Data to see both the current values and all historical changes for the sites and depots that changed during the specified date range.
File Type	Choose the output type for the report: HTML or PDF.

Field descriptions

 **Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields in the report	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	The study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study.
Date Range	Period of time you selected when running this report
Report Generated By	User name of the user who generated this report
Created Date	The date this report was run
Data Type	The type of data selected when running the report
Location	The location you selected for audit history, either a site or depot

Fields in the Resupply Strategies section	Description
Resupply Strategy Type	Type of the Resupply Strategy: Min/Max Resupply or Predictive Resupply
Resupply Strategy Name	Name of the Resupply Strategy as entered by the clinical supply manager
Kit Type ID and Description	The Kit Type ID is a unique code entered in the design of the study for a kit. A kit's description is also a unique value, this description is either visible (unblinded distribution) or hidden from site users based on the study design
Triggers Weeks	The minimum number of weeks of supply required to be available at the site at all times

 **Note:**

This field appears only for Predictive Resupplies.

Resupply Weeks	The maximum weeks of supply at a site as a result of a resupply order
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 **Note:**

This field appears only for Predictive Resupplies.

Fields in the Resupply Strategies section	Description
Minimum Buffer	The minimum number of drug units needed to account for unpredictable events, such as new subjects who need to be randomized and lost or damaged supplies.
Maximum Buffer	The maximum number of drug units needed to account for unpredictable events, such as new subjects who need to be randomized and lost or damaged supplies.
First Shipment	Number of kits included in the first shipment
Manual Shipment	Number of kits included in a manual shipment

Fields in the Source Data Verification Strategies section	Description
Source Data Verification Strategy Name	Name of the SDV Strategy as entered by the study manager
Subject Count	Number of subjects included in the SDV strategy: Initial Subjects and Remaining Subjects
SDV Type	Type of Source Data Verification: All Questions or Critical Questions
Last Modified	The date when each SDV strategy was configured
Last Modified User	User name of the user who performed the latest change for the SDV strategy

Fields in the Sites section	Description
Site Name	A site's name as entered by the site manager when they created the site
Site ID	A site's ID as entered by the site manager when they created the site
Status	A site's status at the moment the report is run. For example, a site's status might be New, Active, or Retired at the time you're running this report
Resupply Strategy	Name of the resupply strategy that is associated with the site
SDV Strategy	Name of the SDV strategy that is associated with the site
Last Modified	UTC time and date of the most recent changes performed by a site manager
Last Modified By	User name of the user who made the latest change

Fields in Site Addresses Information	Description
Address 1	A site's first address as entered by the site manager when they created or last modified the site
Address 2	A site's second address as entered by the site manager when they created or last modified the site
City	A site's city as entered by the site manager when they created or last modified the site
Country	A site's country as entered by the site manager when they created or last modified the site. Report displays country abbreviation.

Fields in Site Addresses Information	Description
State/ Province/ County	A site's state, province, or county as entered by the site manager when they created or last modified the site
Zip/ Postal Code	The Zip Postal Code associated with a site's address
Phone	The contact phone number as entered by the site manager when they created or last modified the site
Fax	The contact fax number as entered by the site administrator when they created or last modified the site
Email	Email address of the site as entered by the site administrator when they created or last modified the site
Address Type	An address can either be Primary (the site's official address) or a Shipping address (where shipments are sent from the depot). A site's official and shipping address can be one and the same.
Address Last Modified	Most recent UTC time and date when a site manager updated a site's address
Address Last Modified By	User name of the user who last modified a site's address (typically a site manager)
Fields in Site Additional Information	Description
Attribute	Indicates text paired values such as: <ul style="list-style-type: none"> • Attention: • Whether a site is drug destruction capable or not • A principal investigator's first and last names • A site's time zone • DEA Number • DEA Expiration • Whether the following site permissions are turned on or off: <ul style="list-style-type: none"> – Add subjects – Screen subjects – Randomize subjects – Dispense to subjects
Data	Indicates corresponding data for each attribute
Type of Change	Indicates whether an attribute was created or updated
Last Modified	Most recent UTC time and date when a site manager updated a site's attribute
Last Modified By	User name of the user who last modified a site's attribute (typically a site manager)
Fields in the Depots section	Description
Depot Name	A depot's name as entered by the clinical supply manager who created the depot
Depot ID	A depot's ID as entered by the clinical supply manager when they created the depot

Fields in the Depots section	Description
Status	A depot's status at the moment the report is run. For example, a depot's status might be New , Active or Retired at the time you're running the report
Last Modified	UTC time and date of the most recent changes performed by a clinical supply manager
Last Modified By	Username of the user who made the latest change
Fields in Depot Addresses Information	Description
Address 1	A depot's first address as entered by the clinical supply manager when they created or last modified a depot
Address 2	A depot's second address as entered by the clinical supply manager when they created or last modified a depot
City	A depot's city as entered by the clinical supply manager when they created or last modified the depot
Country	A depot's country as entered by the clinical supply manager when they created or last modified
State/ Province/ Country	A depot's state, province, or county as entered by the clinical supply manager when they created or last modified the depot
Zip/ Postal Code	The Zip/ Postal Code associated with a depot's address
Phone	The contact phone number as entered by the site administrator when they created or last modified the depot
Email	Email address of the depot as entered by the site administrator when they created or last modified the depot
Address Last Modified	Most recent UTC time and date when a clinical supply manager updated a depot's address
Address Last Modified By	User name of the user who last modified a depot's attribute (typically a clinical supply manager)
Fields in Depot Countries Information	Description
Countries	A depot's country as entered by the clinical supply manager when they created or updated a depot
Primary Country	A depot's primary country as entered by the clinical supply manager when they created or updated a depot
Country Last Modified	Most recent UTC time and date when a clinical supply manager updated a depot's country
Country Last Modified By	User name of the user who last modified a depot's country (typically a clinical supply manager)

Fields in Depot Additional Information	Description
Attribute	Indicates text paired values such as whether the depot is drug destruction capable or not, as well as the kit types that a depot can supply a site with
Data	Indicates corresponding data for each attribute
Type of Change	Indicates whether an attribute was created or updated
Last Modified	Most recent UTC time and date when a clinical supply manager updated a depot's attribute
Last Modified By	User name of the user who last modified a depot's attributes (typically a clinical supply manager)

Study Design report

In this report, you view all the settings specified for your study design, including a list of visits and forms in the study, kit and randomization information, and subject and supply settings.

This report contains only blinded information when run by blinded users and contains additional unblinding information when run by unblinded users.

Note:

If your study is designed to allow titrations, dispensing IoT-enabled devices managed with Oracle mHealth Connector or unscheduled visits, then this report also contains information about these particular features.

This report can save time and help you do your job more efficiently in a couple ways:

- **Save time getting your study ready:** If your organization has historically created a specification or synopsis based on the protocol, you might find that this report can take the place of the specification or synopsis. One key benefit that this report offers over the specification is that the report always reflects the details currently specified for the study design. If you update the study design, all you have to do is run the report again to ensure that the report is up to date.
- **Save time before doing user-acceptance testing:** Run the report before moving your study version to Testing mode is a great way to catch any mistakes you might have made during the study design process. Even with a complex study, the report is still useful for double-checking your settings. The report is a great way to make sure you added validation checks to questions, set up dispensation correctly, and more.

Modes

Available for the study design, and all 3 modes: Testing, Training and Production.

Permission required to run the report

Any user who's assigned the *Run the Study Design Report* permission can generate this report.

Filters

Filter	Description
Study Version	Choose the study version to run the report for.
Include in Report	Choose the data to include in the report.
File Type	Choose the output type for the report: HTML or PDF.

Field descriptions

**Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Descriptions
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study.
Version Created	The date that study version was created.
Study Version	Number of study version currently in the mode where the report is generated.
Report Generated By	User name of the user who generated this report.
Created Date	UTC time and date of the current generated report.
Version Modified	The date that version was modified.
Include in Report	Selection of data for running this report.

Study Design Summary	Descriptions
Visits & Events	Visits and events included in the study design.
Branch	Branches included in the study design.
Forms	Forms associated with each visit.
Kits Dispensed	Every kit type associated with each visit.
Randomization Design	Every randomization design associated with each visit.
Treatment Arms	Every treatment arm associated with each kit and visit.
Blinded Status	The type of kit, either Blinded or Unblinded for every visit.

Visits & Events	Description
Visit/Event Title	Title of each visit or event in the study.
Visit/Event ID	ID of each visit or event in the study.

Visits & Events	Description
Visit/Event Type	Indicates the type of visits or events: Screening, Randomization, Dispensation, Study Completion, Withdrawal, Event, or Adverse Event.
Required	Indicates whether each visit is required or not to continue participating in the study as a subject.
Shown in Timeline	How the visit will appear in the study. Future Only - All Scheduled Visit Types shows the visit only for subjects who did not progress past this date in the schedule. If this visit is part of a cycle then the visit is added only to future cycles. Future & Past - All Scheduled Visit Types shows the visit for all existing subjects in the study, including subjects who did not progress past this date in the schedule. If this visit is part of a cycle then the visit is added to all cycles in the study.
Scheduled From	Indicates the initial visit each visit is scheduled from.
Visit Schedule	Indicates when each visit should occur during the study. For example, a visit might occur after 30 days from when the Screening visit took place.
Visit Window	Number of days before or after the specified visit day in which the visit is allowed to take place. This includes if a warning or query is set up for visits happening out of window.
Last Modified	Last time the visit was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).
Branches	Description
Branch Title	Title of the branch created in the study.
ID	ID of each branch.
Cycle the Branch	Indicates whether the visits in the branch cycle or not.
Count of cycles	The number of times the visits in the branch are repeating throughout the study.
Starting Cycle Number	The number assigned to the first cycle of the branch.
Assign Subjects Using	Specifies the setting that was used to assign subjects to the branch: Treatment Arm or Form Question.
Treatment Arm Settings	Indicates the treatment arms that were selected when assigning subjects to the branch.
Form Question Settings	Specifies the Form, Question, Answers, and Visit that were selected when assigning subjects to the branch.
Visit/Event Title	Title of each visit in the branch.
Visit/Event ID	ID of each visit in the branch.
Visit/Event Type	Indicates the type of visit.
Required	Indicates whether each visit is required or not to continue participating in the study as a subject.

Branches	Description
Scheduled From	Indicates the initial visit each visit is scheduled from.
Visit Schedule	Indicates when each visit should occur during the study. For example, a visit might occur after 30 days from when the Screening visit took place.
Visit Window	The allowed duration of a visit.
Last Modified	Last time the visit was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).

Unscheduled Visits & Events	Description
Visit/Event Title	Title of each unscheduled visit or event in the study.
Visit/Event ID	ID of each unscheduled visit or event in the study.
Visit/Event Type	Indicates the type of unscheduled visits or events: Adverse Event, Unscheduled Visit, Study Completion, Withdrawal or Event.
Required	Indicates whether each visit is required or not to continue participating in the study as a subject.
Not Before	The visit after which the unscheduled visit or event can take place.
Not After	The last visit before which the unscheduled visit or event can take place .
Last Modified	Last time the visit was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).

Forms	Description
Reference Code	Reference code added for the form (reserved for a future release).
Repeating Form	Indicates whether the form is repeating or not.
Allow Additional Rows	Indicates whether site users are allowed to enter additional rows to a repeating form.
Allow for Multiple Instances	Indicates whether site users are allowed to add multiple instances of the same lab form in a visit. This column only appears for lab forms.
Copied From	The study from which the form was copied
Copied Form Modified Date	The date when the copied form was modified by the study designer.
Form Name	This header row displays a form's name, as well as the Reference Code.
Question	Text of the question.
Questions Before the Table	Consists of standard non-repeating and all question types except for Label (Repeating Table Only) .
Questions in the Table	Consists of repeating and all question types except for Question Groups .
Reference Code	Reference code added for each question (reserved for a future release).

Forms	Description
Answer Type	The type of answer chosen for each question.
List of Values	Answer options shown for a drop-down question, a question with checkboxes or radio buttons, or instructional text. Also displays the code and description of code list items, if code lists are used for questions with multiple options for an answer. Be aware that instructional text answers are not displayed in PDF versions of the Study Design Report, and only appear in the HTML format.
Read Only	Indicates whether the question present in the form is a read-only item or not.
Advanced	Any advanced properties applied to a question such as Rollover Question, Coding Question, SAS Properties or Lab Normals Tag.
Validation Rules	Indicates whether the question contains any validation rules.
Rule Error	Shows the error message for any question that contains validation rules.
Action Rules	Indicates whether the question has a Show Question, Show Form, or Show Visit rule applied to it.
Properties	<p>Properties applied to a question:</p> <ul style="list-style-type: none"> • Question Hint: Shows the question hint added for site users. • Apply Change to Study Version: The study version to which a change made in the form applies. • Required: Indicates whether the question is required or not to complete a form and a visit. • Read Only; Indicates whether the question is read-only or not. • Hidden: Indicates whether the question is hidden or not. • Data Classifications: The Data Classification that was assigned to the question. • Source Data Verification: The Source Data Verification property that was set for the question. • Allow Future Date: Indicates whether or not a validation error is raised when a future date is entered for a Date/Time question type. A validation error is only raised when a future date is entered for a Date/Time question while this setting is set to Off.
Character Limit	Indicates whether there's a character limit, typically for a text or number question.

Forms	Description
Format	Specifies the format details for each question: <ul style="list-style-type: none"> • Format of the question, typically shown for Date/Number questions. • Character Limit: Indicates whether there's a character limit, typically for a text or number question. • Partial Date Allowed: Indicates whether a partial date is allowed as answer to a date/time type of question. • Minimum Date Answer: Indicates the minimum allowed date format as specified by the study designer.
Partial Date Allowed	Indicates whether a partial date is allowed as answer to a date/time type of question.
Minimum Date Answer	Indicates the minimum allowed date format as specified by the study designer.
Last Modified	Last time the form was modified in any way.
Last Modified User	User name of the user who performed the latest change.
Logo	Indicates whether a logo has been added to the form, as well as the original name of the file uploaded as a logo.
Kits	Description
Kit Type ID	ID of each kit created for the study.
Description	Description of each kit created for the study.
Device Connection	Indicates whether a kit contains a connection to a device. For example, a smart watch or a heart monitor can have a connection to Oracle mHealth Connector.
Calculating Doses	Indicates whether the kit includes calculating doses or not.
Kit Type or Titration Group	Indicates the kit type or titration group sites can perform dose holds for.
Starting Visit	Indicates the visit where sites can begin performing dose holds for a specific kit type or titration group.
Starting Visit Cycle	The cycle where the starting visit applies.
Ending Visit	Indicates the visit where sites can stop performing dose holds for a specific kit type or titration group.
Ending Visit Cycle	The cycle where the ending visit applies.
Max per Subject	Indicates the maximum number of dose holds the site user can apply to the kit type or titration group.
Frequency per Subject	Indicates whether there is a limited frequency or timeframe the site user can perform dose holds for the kit type or titration group.
Distribution Settings	Indicates the type of distribution the kit has: blinded or unblinded.
Storage Temperature	A kit's ideal storage temperature to not damage it.
Type	A kit's type. For example, a kit can be a blister pack or a syringe.
Units Per Kit	Number of investigational product units in each kit.

Kits	Description
Minimum Units to Ship	Minimum number of investigational product units that should be shipped to a site.
Last Modified	Last time the kit was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).
Calculated Doses	
Calculated Doses	Description
Kit Type ID	ID of the kit type that includes calculated doses.
Calculated Dose Title	Title of the calculated doses as entered by the study designer.
Form for Calculated Dose	Form that contains the question used in a calculated dose.
Question for Calculated Dose	Question used in a calculated dose.
Visit Where Form is Collected	Indicates name of the visit that contains the form with a calculated dose question.
Selected Visit Where Form is Collected	The visit selected where form is collected for dispensing kits with calculated doses.
Precision for Each Dose	Number of places after the decimal point that the dose is calculated in.
Round Up For	How the dose calculation is rounded up according to dose precision.
Dosing Frequency	Number of doses a subject must consume.
Use Leftover Units in Next Dose	Indicates whether any remaining units after a dosing round can be consumed during the next dosing round or not.
Kit Measurement Value	Total numeric value for the product in the kit. For example, if a bottle contains 750 mg of pills, the value is 750.
Kit Unit of Measure	Informational field for a kit's unit of measure (for example syringe or sachet).
Subject Measurement	Value that determines the dose, along with the answer for the subject and the value of a single unit.
Subject Unit of Measure	Informational field for a subject's unit of measure (for example kg or kit).
Last Modified	UTC date of the last time this transaction was performed by a user.
Last Modified User	User name of the user who last performed this transaction.
Kit Type Titrations	
Kit Type Titrations	Description
Title of Dose Level	Dose level title assigned to each blinded kit type titration for down, up or maintain titrations.
Kit Type	Kit type of each kit included in a kit type titration.
Down Titration	Kit type used for each down titration.
Up Titration	Kit type used for each up titration.
Maintain Titration	Kit type used for each maintain titration.

Titration Settings	Description
Maximum Dose Changes	Maximum number for down or up titrations that site users are allowed to perform during a study.
Unscheduled Dose Changes	Dose changes that were made during an unscheduled visit.
Minimum Time Between Dose Changes	Minimum amount of time that should pass between each dose change.
Dispense when on Highest Dose and Site Wants Higher Dose	Indicates whether a site user is allowed to increase a subject's dose even though a subject is already on the highest dose specified in the study.
Message for Site Users	Displays a message for site users in case they do want to increase a subject's dose despite already being on the highest dose.
Dispense when on Lowest Dose and Site Wants Lower Dose	Indicates whether a site user is allowed to decrease a subject's dose even though the subject is already on the lowest dose specified in the study.
Message for Site Users	Displays a message for site users in case they do want to decrease a subject's dose despite already being on the lowest dose.
Dose Level	Displays the words used to describe a subjects' dose level without offering unblinding information.
Kit Dispensation	
Description	Description
Kit IDs or Kit Titrations	ID of each kit or title of each kit type titration associated with a visit.
Treatment Arm	Treatment arm associated with each kit in a visit.
Quantity	Number of kits associated with each visit.
Dispense Kits By	Indicates whether kits will be dispensed by lowest sequence number and closest expiration date or by kit number and closest expiration date.
DND (Days)	Minimum number of days before a kit's expiration date that the kit cannot be dispensed to a subject.
Dispense Outside Window	Indicates whether the kit can be dispensed outside the visit window or not.
Calculated Dose	Indicates whether the kit associated with each visit contains calculated doses or not.
Allow Titration	Indicates whether each visit allows dose changes or not during that time.
Last Modified	UTC date indicating the last time a kit's dispensation was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).
Exceptions	
Description	Description
Kit IDs	Indicates the ID of the kit with defined dispensation exceptions.
Location	Indicates the location of the dispensation exception. For example, Site specific: , followed by the site ID(s).

Exceptions	Description
Exceptions	Indicates the visit(s) the dispensation exception is applied to, along with the amount of days it is set for.

Generated Kit Lists	Description
List Name	Name of the generated kit list as entered by the clinical supply manager.
List Type	Indicates whether the list is generated or uploaded.
First Kit Number	First kit number shown in the kit list.
First Sequence Number	First sequence number shown in the kit list.
Kits	ID of each kit included in this kit list.
Date Created	UTC date when the kit list was uploaded or generated.
Created By	User name of the user who generated the kit list (typically a clinical supply manager).

Randomizations	Description
Description	Description of the randomization design.
Blinded Status	Type of blind associated with the Randomization Design.
Cohort	Indicates whether the randomization design includes cohorts or not.
Randomization Type	Indicates the type of randomization design.
Re-Randomization	Indicates whether the randomization design allows re-randomization or not.
Treatment Arms Randomized or Mapped	The treatment arms included in the randomization design.
Assign New Randomization Numbers to All Subjects	Indicates whether subjects should receive new randomization number after they are randomized as part of a randomization design. Applicable only if Re-Randomization is enabled in the study's design.
Allow Randomization to Occur Outside Visit Window	Indicates whether or not a subject can complete a randomization visit even if they are outside of the visit window.
Restrict Randomization to Available Kit Types	Indicates whether the randomization is restricted to available kits in the inventory or not.
Last Modified	UTC date of the last time a randomization design was modified in any way.
Last Modified User	User name of the user who performed the latest change (typically a study designer).
New Treatment Arms	New treatment arms mapped in the study for randomization.
Previous Treatment Arms	Previous treatment arms that existed in the study for randomization.
Stratum Group	Name of the stratum group.
Stratum Question	Question that was used to stratify subjects.
List of Values	The values by which the subjects were stratified.
Range	The range used to stratify subjects.

Fields in each cohort (only appears if your study uses cohorts)	Description
Question	Question label used in a randomization design.
List of Values	Indicates the required answer for a drop-down question used in randomization design.
Range	Indicates the required answer for a Number or Age question used in randomization design.
Fields for treatment arms in cohorts	
Fields for treatment arms in cohorts	Description
Cohorts	Name of the cohort part of the randomization design.
Treatment Arms	Title of the treatment arms included in a cohort.
Ratio	Ratio entered for treatment or cohort in the study.
New Treatment Arms	New treatment arms mapped in the study in the context of a cohort or re-randomization.
Previous Treatment Arms	Previous treatment arms that existed in the study in the context of a cohort.
Generated Randomization List	
Generated Randomization List	Description
List Name	Name of the generated randomization list.
Type	Indicates whether the list is generated or uploaded.
Assigned Study Design	The study design version each randomization list is assigned to.
Multiplier for Blocks	Number of multiplier for randomization blocks.
Starting Number	Starting number in the randomization list that was generated in a study.
Length	Length of a randomization list. For example, 1000 rows.
Date Assigned to Mode	The date that the generated randomization list was assigned to the specific mode you ran the study design report in.
Date Unassigned from Mode	The date that the generated randomization list was unassigned from the specific mode you ran the study design report in.
Created By	User name of the user who created this randomization list (typically a randomization list manager).



Study Settings	Description
Setting	<p>Name of the setting configured in the study, such as:</p> <ul style="list-style-type: none"> • Allow Subjects to be Manually Added • Replace Subject Number with Randomization Number • Allow Site to Select Subject Number • Include Hyphen Between Site and Subject Number • Leading Zeros in First Subject Number • Subject Number Format • First Subject Number • Subject Numbering • Withdraw Subjects After Code Break • Limit Screened Subjects • Screen Failed Subjects • Allow Withdrawal for Subjects before Enrollment <p>For more details about these settings, see Specify study, enrollment, and visit settings.</p>
Value	Indicates the value set for each subject setting.
Last Modified	The date when each setting was configured.
Last Modified User	User name of the user who performed the latest change (typically a study manager).
Visit Settings	Description
Visit Type	Displays the type of visit: Screening, Randomization, Dispensation Non-Dispensation, Option, Withdrawal or Study Completion.
Site Enters Dates	Displays if a site user can enter a date for a specific visit type.
Site Edits Visit Dates	Displays if a site user can edit a date for a specific visit type.
Visit Can be Skipped	Displays if a visit can be skipped or not (Yes or N/A). Only applicable for dispensation and non-dispensation visits.
Visit Date Must Be On or After Randomization	Displays if the Visit Date Must Be On or after randomization (Yes, No, or N/A). Setting applicable only for the randomization visit type and it can only be set if a user just selects the setting Site Edits Visit Dates in Study Settings.
Visit Date Must On or After Dispensation	Displays if the Visit Date Must Be On or after dispensation (Yes, No, or N/A). Setting only applicable for dispensation visits and it can only be set if a user selects the Site Edits Visit Dates setting in Study Settings.
Send Visit Notification	Displays in which cases the visit notification is sent: Success, Success and Error, Error only.

Supply Settings	Description
Setting	Name of the setting configured in the study, such as: <ul style="list-style-type: none"> Inventory Schedule Settings Inventory Settings Shipment Settings For more details on what supply settings you can configure and display in the Study Design report, see Specify supply settings.
Value	Indicates the value set for each subject setting.
Last Modified	The date when each setting was configured.
Last Modified User	User name of the user who performed the latest change (typically a clinical supply manager).

Locally Sourced Kit Settings	Description
Kit Type	Kit type of each kit selected to be locally sourced.
Locally Sourced Countries	Indicates the countries selected for the kit types to be sourced from.
Sourced by Site Countries	Indicates the country of the sites selected whose kits can be locally sourced.
Last Modified	The date when each setting was configured.
Last Modified User	User name of the user who performed the latest change.

Source Data Verification	Description
Setting	Name of the setting configured in the study, such as: <ul style="list-style-type: none"> Allow SDV in Study Amount of SDV Allow SDV Overrides
Value	Indicates the value set for each setting.
Last Modified	The date when each setting was configured.
Last Modified User	Email address of the user who performed the latest change.
Source Data Verification Strategy	Name of the Source Data Verification strategy.
Subject Count	Number of subjects included in the Source Data Verification strategy: Initial Subjects and Remaining Subjects.
SDV Type	Type of Source Data Verification: All Questions or Critical Questions.
Last Modified	The date when each SDV strategy was configured.
Last Modified User	User name of the user who performed the latest change for the SDV strategy.

Signature Configuration	Description
Title	The title of the signature configuration, for example, Adverse Event Signature.
Required By	The role(s) required for the signature configuration.
Signature Text	The affidavit description selected for the signature configuration.
Required On	Indicates the type of signature configuration.

Signature Configuration	Description
Required Form(s)	The name of the required form.
Required Visit(s)	The name of the required visit.
Required on Selected Visits	Indicates which selected visits a signature is required on.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;">  Note: This only applies to form level configurations. This field populates as N/A for visit level configurations. </div>
Trigger by Question	Indicates the question and value(s) and whether or not a response to a question or form value prompts a signature request.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;">  Note: This field is populated with N/A for visits. </div>
Trigger by Response	Indicates the question answer that prompts a signature request.
Target	Indicates the target date for the signature.
Email Notification	Indicates whether assigned users will receive an email notification on signature activity.
Date Created	Indicates the date the signature configuration was created.
Created By	The email address of the user who created the signature configuration.
Last Updated Date	The date in which the configuration was last modified.
Updated By	User name of the user who last modified the configuration.

Study Enrollment report

In this report, you view details about enrollment for a study.

Details in the report include the following:

- The open or closed status for enrollment for a study, site, country, and cohort.
- For each location, the number of screened, screened failed, randomized, withdrawn and complete subjects, as well as the screening and randomization limit.
- For each cohort, the number of randomized subjects, as well as the randomization limit.
- The total number of subjects that have been randomized in the study.

- The number of subjects that have been enrolled from another study.

This report is particularly useful if you're a member of the study management team. You can run this report whenever you want to see the total enrollment for a given group. The report is an easy way to see count information across multiple groups.

Modes


Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user assigned the *Run the Enrollment Report* permission can generate this report.

Filters

Filter	Description
Include Audit Trail	Choose one of the following: <ul style="list-style-type: none"> • Yes to see the current values plus all historical changes to them. • No to see only the current value.
Audit Trail Date Range	Choose a date range for the report. The report will include only the sites and depots that were updated during the date range.
File Type	Choose the output type for the report: <ul style="list-style-type: none"> • HTML • PDF • XLSX

 **Note:**

For the **XLSX** format, each section of the report has its own sheet.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study
Include Audit Trail	Setting that indicates if you included audit trails in your report or not
Report Generated By	User name of the user who generated this report

Initial fields	Description
Create Date	UTC time and date of the current generated report
Audit Trail Date Range	Period of time indicated to show the audit trail

Fields in General Enrollment	Description
Group	Displays the enrollment level: Study Total or Site
Enrollment	Indicates whether the enrollment is opened or closed (Opened or Closed)
Screening Limit	Numbers of subjects that can be screened in a study
Screened Subjects	Number of subjects in a state of New, Screened, and Screen Failed
Screen Failed Subjects	Number of subjects with a state of screen failed
Randomization Limit	Number of subjects that can be randomized in a study
Randomized Subjects	Total number of subjects that have ever been randomized in a study, including those subjects with a status of Withdrawn or Complete
Enrolled Subjects	Number of subjects that were enrolled from another study
Completed Subjects	Number of subjects with a state of Complete
Withdrawn Subjects	Number of subjects with a state of Withdrawn
Notification %	Percentage value as to when a notification can be triggered for a specific level

Fields in General Enrollment Audit Trail	Description
Group	Displays the enrollment level: Study Total or Site
Enrollment	Indicates whether the enrollment is opened or closed (Opened or Closed)
Screening Limit	Number of subjects that can be screened in the study or site
Randomization Limit	Number of subjects that can be randomized in a study or site
Notification %	Percentage value as to when a notification can be triggered for a specific level
Last Modified	Date of the most recent changes performed by a user
Last Modified By	User name of the user who made the latest change

Fields in Screening and Randomization by Site	Description
Site Name	A site's name
Site ID	A site's ID
Screening Limit	Numbers of subjects that can be screened in a study
Screened Subjects	Number of subjects in a state of Screened
Screen Failed Subjects	Number of subjects with a state of screen failed
Randomization Limit	Number of subjects that can be randomized in a study

Fields in Screening and Randomization by Site	Description
Randomized Subjects	Total number of subjects that have ever been randomized in a study, including those subjects with a status of Withdrawn or Complete
Enrolled Subjects	Number of subjects that were enrolled from another study
Completed Subjects	Number of subjects with a state of Complete
Withdrawn Subjects	Number of subjects with a state of Withdrawn
Last Modified By	User name of the user who last performed the last change.

Fields in Cohort Enrollment	Description
Cohorts	Cohorts included in the study
Enrollment Randomization Limit	Number of subjects that can be randomized for each cohort
Randomized Subjects	Total number of subjects that have ever been randomized in each cohort
Notification %	Percentage value as to when a notification can be triggered for a specific level
Last Modified	Date of the most recent changes performed by a user
Last Modified By	User name of the user who made the latest change

Fields in Country Enrollment	Description
Countries	Country where subjects are enrolled in the study
Enrollment	Indicates whether enrollment is opened or closed (Opened or Closed values)
Screening Limit	Number of subjects that can be screened in the study, country, or countries
Screened Subjects	Number of subjects with a state of screened
Screen Failed Subjects	Number of subjects with a state of screen failed
Randomization Limit	Number of subjects that can be randomized in a study, country, or countries
Randomized Subjects	Total number of subjects that have ever been randomized in a study, including those subjects with a status of Withdrawn or Complete
Enrolled Subjects	Number of subjects that were enrolled from another study
Completed Subjects	Number of subjects with a state of Complete
Withdrawn Subjects	Number of subjects with a state of Withdrawn
Notification %	Percentage value as to when a notification can be triggered for a specific level

Fields in Country Enrollment Audit Trail	Description
Country	Country where subjects are enrolled in the study
Enrollment	Indicates whether enrollment is opened or closed (Opened or Closed values)
Screening Limit	Number of subjects that can be screened in the study

Fields in Country Enrollment Audit Trail	Description
Randomization Limit	Number of subjects that can be randomized in a study
Notification %	Percentage value as to when a notification can be triggered for a specific level
Last Modified	Date of the most recent changes performed by a user
Last Modified By	User name of the user who made the latest change

Study Roles report (by study)

In this report, you view information on all study roles created for a specific study that you're assigned to. The report includes information on predefined study roles created by Oracle, as well as data on retired study roles.

If you're a user administrator or a sponsor user who needs to view data on study created at a study level, then this is the report you'll typically generate. On the Home page, click the **Reports** tab to find the report, and run it any time during the duration of a study.

If you run the report for multiple studies, data for each study will be displayed in a separate table that includes the columns described below, in the **Field Descriptions** section.

Modes

Available in all modes: Study Design

Permission required to run the report

Only study-level users who are assigned the *Run the Study Roles Report* permission to the specific study can generate this report. Typically, these users might be:

- User administrator
- Clinical Research Administrator (CRA)
- Production Admin
- Site Administrator
- View Only for Unblinded Support Users

If you want to run the report at a global level, the name changes to *Study Roles Report By Study* and you will need a global role assigned to you.

Filters

Filter	Description
Study Names	Choose a study to run the report for. Leave the field blank to run the report for all studies.
File Type	Choose the output type for the report: HTML or PDF.

Field descriptions

**Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Column name	Descriptions
Customer Name	A customer's name used to purchase the cloud subscription
Study Names	Name of the study or studies selected as a filtering option for the report
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of the current generated report
Study Role Name	Name of the study role name as entered by a user administrator
Permissions	Permissions a user administrator included in the respective study role
Data Classification	Data classifications a user administrator included in the respective user role.
Status	Status of a study role: can be Active or Retired
Last Modified By	User name of the user who last modified a study role
Last Modified	UTC time and date of the latest update for a study role

Subject Data for CTMS report

In this report, you view all subject data at multiple sites within your study. This report is designed specifically for studies that need to send subject information to their clinical trial management system. Only a study team member with the required user roles can run and download this report.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Subject Data for CTMS Report* permission can generate this report.

Prerequisites for running this report

- **Visit IDs should only contain letters and numbers:** To make sure visit IDs are mapped to subjects' data for this report, visit IDs must always be written using numbers and letters only.
- **Demography forms should be standard:**
 - A demography form should always be associated with 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: subject's initials, their date of birth, their gender, and the 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.

Filters

Table 2-1 Filters table

Filter	Description
File Type	Select TXT as the output type for the report.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Field	Description
SITE	A site's ID as entered by the site manager when they created the site
VSITE	The ID of the site where the visit took place
SYSKEY	Subject's GUID
SUBJECT	Subject ID
RANDNO	The subject's randomization number
VISIT	Name of the visit from study design
VISITNO	Visit ID
EVENTDTC	The visit's start date
INITIALS	Subject's initials
BRTHDTC	Subject's day of birth
DOBMON	Subject's month of birth
DOBYR	Subject's year of birth
SEX	Subject's gender
INFCNDTC	Date of the informed consent
SCRNDTC	Date when the subject was screened
SCRNFDTTC	Date when the subject was screen failed
RANDDTC	Date when the subject was randomized
TERMDTC	Date when the subject was withdrawn from the study
COMPDTTC	Date when the subject completed the study
SCRFALRN	Reason the subject was screen failed
WDRWRN	Reason the subject was withdrawn from the study
OTHRN	Other reason for subject withdrawal

 **Note:**

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.

Subject Data report

In this report, you view all data collected on every form in the study, including the study version that the data was collected on.

 **Note:**

If your study is designed with unscheduled visits, this report also contains information about the data captured for subjects during such a visit.

The report includes audit information on several levels:

- For every question, you can see who entered the data and whether any changes were made to it, including the date and time of any changes.
- For every visit, you'll see one row for every time something happens in a visit, such as when a new form is started and saved.

There are no standard data points in this report, and that's because form design in Oracle Clinical One Platform is flexible: You can collect whatever data points that you want in a study. For instance, if you want the report to include information about a subject's date of birth, you must include a DOB question on a form, or the data point won't be included in the report.

The following information appears in the report header:

- Name of the report
- Name of your organization and the study
- Mode the report was run for
- User who ran the report and the date and time the report was run

The body of the report contains one entry for each time a site user enters or updates a value, along with the following information for the data point that was collected:

- Study version for which the data was collected
- Site that the data was collected at
- Subject ID and subject number for whom the data was collected
- Date the data was entered
- Visit, form, and question the data was collected for
- Value entered by the site user
- Unit of measure on the question, or N/A if not relevant
- Reason for change and a comment, if a value was updated; or N/A if not relevant

 **Note:**

If the verified information collected on a repeating form is deleted, two records are added under the **Reason for change** column of the report:

- The first will reflect **DELETE REPEATING FORM**.
- The second will reflect **N/A**.

Under the **Reason for change** column of the report, the first record will reflect **DELETE REPEATING FORM**. The second record will reflect **N/A** under the same column.

- Validation error on the question, or N/A if not relevant
- User who entered the data

 **Note:**

Hidden questions are included in the report only if the user generating the report has the permissions to view or edit hidden data.

Modes



Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Subject Data Report* permission can generate this report.

Filters

Filter	Description
Study Version	Choose a study version to include only data collected for that study version, or choose All to include data collected in all study versions.
User Name	Choose a user to include only the changes made by that user, or leave the filter blank to include changes made by all users.
Location	Choose a site or depot to include only the data collected at the location, or leave the filter blank to include changes at all locations.

Filter	Description
Subject Number	Choose a subject to include only the data collected for the subject, or leave the filter blank to include data for all subjects.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>If a subject is removed from a study and its subject number is subsequently reused, then there will be two entries for that subject within the report.</p> </div>
Visit Title	Choose a visit to include only data collected during that visit or leave it blank to include data collected in all visits.
Form Title	Choose a form to see only data collected with that form or leave it blank to include data collected for all forms included in a visit or in a study version.
Question label	Select a question label to see the data collected for that question or leave it blank to view data that was collected for all questions included in the form you previously selected.
File Type	Choose the output type for the report: CSV, HTML, or PDF.
Include/ Exclude cleared Data	Choose to include or exclude cleared data from the Subject Data Report.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>Default permissions are set to exclude the data.</p> </div>

Field descriptions

 **Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription

Initial fields	Description
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study
Study version	The number of the study version for which the subject data was collected
Form Title	Name of the form you selected to include in the report
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of the current generated report
Visit Title	Name of the visit you selected to include in the report

Fields in every subject's section	Description
Study Version	Study design version for the visit
Site	A site's name
Subject ID	A subject's GUID in the system
Screening Number	The number assigned to a subject after screening or enrollment.



Note:

This matches the Subject Number column unless you are Replacing the Subject Number with the Randomization Number.

Subject Number	User-friendly subject identifier
Lab ID	A lab's GUID in the system
Lab Name	A lab's name
Entry	UTC time and date of when the subject was first added into the system
Visit/Event Title	Name of the visit from study design. It includes branch visits and unscheduled visits and events
Visit/Event Instance	Displays every instance of an unscheduled visit or cycled branch visit for a subject
Form Title	Name of the form from study design
Repeating Form Number	A unique sequence number that is automatically assigned to a repeating form. This column also displays the unique sequence number of a two-section form instance, as well as the sequence number of a lab form.
Question Label	Name of the question from study design

Fields in every subject's section	Description
Type of Change	Indicates whether a question was created, modified, signed (at the form, visit, or subject level), unsigned, verified, unverified, locked, unlocked, or frozen by a lead site user or Clinical Research Associate (CRA)
Value	Data entered, including calculated values, drop-down answer options, as well as answers for a question with check boxes or radio buttons
Unit of Measure	Value from study design when a question is designed as a number type of question
Reason for Change	Indicates a reason for changes in a subject's data. Populated by drop-down list
Reason for Change Comment	Required comment in a reason for change if 'Other' is selected Populated as Rule Execution for calculated values
Validation Error	Populated if the form field has validation failure due to rule execution. For example, age is outside the allowed range
User Name	User name of the user responsible for this transaction

Subject Dispensation report

In this report, you view dispensation information for a subject at a site.

The report lists the kits with dosing instructions that were dispensed to a subject during a visit in the study. The same data can also be found in the [Kit Dispensation report](#).

Pharmacists or unblinded site users can also see Unblinded Pharmacist kits in this report.

Modes

Available in all 3 modes: Testing, Training, and Production

Roles that can run the report

Any user that's assigned the *Run the Kit Dispensation Report* permission can generate this report.

Subject Events report

In this report, you view all actions that have occurred to each subject, all in a single location.

The report also includes subjects' randomization numbers and the numbers of the kits that were dispensed to them (this information isn't unblinding because this data is available to blinded users in the user interface).

This report is a good way to see what's happening with each subject, including their current visit. Note that it will include events and visits that were dynamically added to a subject's schedule. Filtering makes this report even more useful, letting you find exactly what you need. You have several options for filtering:

- Like any other report, you can filter the type of data that you want included in the report. For example, you can include only code breaks or screen failures that have occurred in a study.

- You can also run this report as a CSV file and then use column-level filters to see only the data that you care about.

This report includes a full history of a subject, so expect lots of details, including multiple lines for each subject. For every event, you'll see one line for every time something happens, such as when a visit is started or completed and when a visit date is changed.

This report can also be customized by adding more data records in it. For more details, see [Add custom fields to a report](#).



Note:

Hidden questions are included in the report only if the user generating the report has the permissions to view or edit hidden data.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Subject Events Report* permission can generate this report.

Filters

Filter	Description
Study Version	Choose a study version to include only actions that occurred in that study version, or choose All to include events that occurred in all study versions.
Location	Choose a site or depot to include only the actions that occurred at the location, or leave the filter blank to include actions for all locations.
Current Subject Number	Choose a subject to include only the actions that occurred to the subject, or leave the filter blank to include actions for all subjects.
Event Type	Choose the event type, such as Visit Started, to include only actions in those events, or leave the filter blank to include actions for all event types.



Note:

If a subject is removed from a study and its subject number is subsequently reused, then there will be two entries for that subject number within the report.

Filter	Description
File Type	Choose the output type for the report: <ul style="list-style-type: none"> • CSV • HTML • PDF

 **Note:**

We recommend choosing CSV, so that you can narrow your view of the data.

Field descriptions

 **Note:**

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data before going live with your study.
Location	The site or depot you previously selected to be included in the report.
Report Generated By	User name of the user who generated this report.
Created Date	UTC time and date of the current generated report.
Event Type	The event type you previously selected to be included in the report.
Subject Number	The number of the subject you previously selected to be included in the report.

Indicates the unscheduled visit's number or branch visit instance

Fields for a subject's events	Description
Study Version	Study design version for the visit.
Site	A site's name.
Country	A site's country.
Subject ID	A subject's ID. Included as part of the report for integrated data purposes.
Current Subject Number	Indicates a subject's current subject number at a site.

Fields for a subject's events	Description
Previous Subject Number	Indicates a subject's previous subject number at a site. If no subject number update was performed, this column indicates N/A.
Screening Number	This matches the value in the Current Subject Number column unless the Screening Number is changed.
Event Type	Indicates the data collection status of the event, such as: <ul style="list-style-type: none">• New Subject• Visit Started• Visit Completed• Screened• Screen Failed• Randomized• Signed (Visit Level Signature or Subject Level Signature)• Unsigned• Verified• Unverified• Code Break• Locked• Unlocked• Visit Date Entered• Visit Date Cleared• Subject Number Changed• Undo Add Subject
Visit/Event Title	Name of visit or branch visit from Study Design. May be N/A if the event is a subject action such as screen failure, locking, randomization, code break, and withdrawal.
Visit/Event Instance	Indicates the unscheduled visit number or the branch visit instance for a subject.
Visit/Event Status	Indicates whether a visit's status is: <ul style="list-style-type: none">• NOT_STARTED: A placeholder status for in-between visits.• NEW: The visit has not been started.• INPROGRESS: Any field for a visit is complete without any validation errors, or data has been partially entered for that visit.• COMPLETE: All required fields for a visit are complete with no validation errors.• COMPLETE_ERR: "Complete with errors," all required fields for a visit are complete, or contains a validation error.• INCOMPLETE: If any of the fields are marked as <i>Null</i> for a completed visit.• INCOMPLETE_ERR: "Incomplete with errors," a field for a completed visit is marked as <i>Null</i>, or one of the fields contains a validation error.• SKIPPED: The visit has been marked as <i>Skipped</i>.• UNDO_SKIP: When the visit has been marked as <i>Undo Skip</i>.• N/A: No visit data is applicable.

Fields for a subject's events	Description
Visit/Event Date	Date of the event entered by the user.
Date	UTC date and time of a subject's event specified in the Event Type column.
Dispensed Date	Reflects the date when a kit was replaced.
User Comment	Required comment in reason for change if 'Other' is selected.
Reason	Indicates reason for selected actions. For example, Manual Screen Fail, Code Break, or Withdraw.



Note:

This field will not populate for replacements kits.

Randomization Number	Indicates a subject's randomization number if assigned in the event.
Replaced Kit Number	Indicates the numbers of kits which have been replaced.
Dispensation Kit Number	Indicates a replacement kit's dispensation number.
Transfer Original Site	Site a subject is transferred from.



Note:

After updating any subject data, allow the system a 15-minute buffer time to load existing commands before making any other changes to subject data or related reports.

Fields for a subject's events	Description
Transfer New Site	Site a subject is transferred to.
Transfer New Subject Number	The number of the subject after the transfer.
User Name	User name of the user responsible for the transaction.
Undo Add Subject	Indicates the subject has been removed from the study.

 **Note:**

Before transferring a subject, clear out all data inputs that connect to the subject's former site (for example, subject data or event-related reports). If you make edits after transferring the subject to a new site, the edits will show in the new site.

Subject Queries report

In this report, you view query information.

This report offers useful information for several users:

- CRAs can see open queries for a site that they monitor, so they can encourage timely responses from the site.
- Data managers can see open queries as they prepare for site closeout activities, and make sure that all data is revised. Data managers can also see open queries based on a visit date, so they can prepare interim analyses for certain periods of time during the study.
- Site managers can review the history of queries for their site, so they can resolve any open queries.
- In general, the entire study team can use this report to analyze trends that may reveal issues.
For instance, if CRAs are querying the same data point across all sites, changes might need to be made; like editing a question or its hint, or even revisiting the training strategy for the form.

 **Note:**

Queries open on hidden items are included in the report only if the user generating the report has the permissions to view or edit hidden data.

Modes

Available in all 3 modes: Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Subject Query Report* permission can generate this report.

Filters

Filter	Description
Locations	Choose a site to include only the queries raised at the location, or leave the filter blank to include queries for all locations.
Subjects	Choose one or more subjects to include only the queries raised for the subjects, or leave the filter blank to include queries for all subjects. If you filter your report by subject, you see only the site that the subject is at.
Last Query State	Choose a query status to include only data collected for queries in that state.
Query Age	Choose an age range for the queries in the report. The report will include only queries within the specified age range.
Include Audit Trail	Choose Yes to see the current values plus all historical changes to them; choose No to see only the current value.
File Type	Choose the output type for the report: CSV, HTML, or PDF.



Note:

If a subject is removed from a study and its subject number is subsequently reused, then there will be two entries for that subject number within the report.

Field descriptions



Note:

- Fields that don't have any corresponding values are marked as N/A in the report.
- The fields that become available in a report depend on the filter selection. Not every field is available for every report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report. For example, you may run a report in Testing mode to verify the data of your sites before going live with your study
Locations	Sites included in the report, according to the filter selection.
Last Query State	The query status you selected to be included in the report
Query Age	Indicates age of a query included in the report based on the date when they were created
User Name	User name of the user who generated this report
Date Created	UTC time and date when this report was run
Subjects	The number of the subject for whom the queries were raised
Include Audit Trail	Indicates whether audit trail is included or not in this report

Fields displayed for each site with associated subject and queries	Description
Site	The site where the queries were raised.
Subject ID	The number of the subject for whom the queries were raised.
Query Age Age of Query	A query's age listed in days.
Assigned to	The user role for which this query is assigned to and email details when the rule indicates email notifications.
Last Query State	<i>Only for report with No audit trail included.</i> A query's current state can be either: <ul style="list-style-type: none"> • Candidate • Opened • Closed • Answered • Deleted
Query State	<i>Only for report with audit trail included.</i> The query state at the time of each query update.
Last Query Comment	<i>Only for report with No audit trail included.</i> Comment entered by user the last time a query was updated.
Query Comment	<i>Only for report with audit trail included.</i> The comment entered at the time of each query update.
Value	Entered value that initiated the query.
Unit of Measure	Data from the defined form.
Visit/Event	Name of the visit that contains the query

Fields displayed for each site with associated subject and queries	Description
Visit/Event Instance	An unscheduled visit's number or branch visit instance that contains the query
Form	Indicates the name of the form that contains the query. For a two-section form, also indicates the number of the two-section form instance. For example: "Physical Examination 1".
Repeating Section Number	Indicates the number of a repeating form instance where a query is raised, for both a two-section form and a regular repeating form.
Question	Label of the question that contains the query.
Created By	The ID of the user who created the query.
Created By Role	The study role of the user who created the query.
Last Modified By	User name of the user who last modified a query.
Last Transaction Date	The date and time in UTC (DD-MM-YYYY HH:MM) when the last transaction occurred.
Query State	Lists the states of a query throughout time.
Last Updated on Site	<i>Only for report with audit trail included.</i> Site to which the subject is assigned to at the time the query was updated. Value only changes with transferred subjects.
Last Modified Date	<i>Only for report with audit trail included.</i> UTC date and time (DD-MM-YYYY HH:MM:SS) of the query update.

Subject Visits (Blinded) report

In this report you view blinded details about each subject's visits and their treatments. With this report you get a complete view of each subject's visit scheduled, including completed visits and projected appointments.

The Subject Visit report is available for both blinded and unblinded studies. The details included in each report differ according to the permissions assigned to the user that runs the report.

With this report you get a complete view of each subject's visit schedule, including completed visits and projected appointments. Additionally, for unblinded studies, the report offers details about the subject's treatment, such as Kit ID, Kit description, and the anticipated number of kits to be dispensed in future visits.

The report is available in both CSV and PDF formats.


Modes

Available in all 3 modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Subject Visit Report* permission can generate this report.

Filters

Filter	Description
Projected Window Dates	See all projected window dates within an interval of time.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;">  Note: The results do not include dispensation dates. </div>
Visit Type	Choose one of the following: <ul style="list-style-type: none"> • All to include all visits in a study. • Completed Only to only include a subject's completed visits in the report.
Site	Choose a site to include only the visits that took place at that specific location or leave it blank to include data for all sites.
Subject	Choose one or more subjects to include only visits for these specific subjects or leave it blank to receive visit data for all subjects included in the study.
Subject Status	Choose one of the following: <ul style="list-style-type: none"> • Active to only include data related to active subjects in a study (typically, these are subjects who have been randomized in a study). • All Subjects to include data related to all subjects in a study, no matter their state.
File Type	Choose the output type for the report: <ul style="list-style-type: none"> • CSV • HTML • PDF

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report.
Visit Type	The type of visits you selected for this report. Can be All or Completed Only.
Report generated by	User name of the user who generated this report.
Created Date	UTC time and date of when this report was run.
Site	The site you selected for this report.
Subject	The subjects you selected for this report.

Initial fields	Description
Subject Status	Indicates the type of subject you selected for this report, whether active or not.
Fields displayed for every selected site and subject	Description
Dispensed Date	Reflects the date when a kit was replaced.
Visit Title	A visit's title as entered by a study designer.
Unscheduled Visit Number	Number of the unscheduled visit a subject attended.
Visit Start Date	Date stamp of a visit's start date.
Projected Visit Date	Date of the upcoming visit type for a subject.
Kit Number	Numbers of kits dispensed to a subject during a visit. The number of locally sourced kits displays if applicable.
Kit Replacement	Reflects replacement kit numbers.
Last Modified By	User name of the user who last performed this transaction.
Reason	Indicates reason for selected actions, for example: Lost, Damaged, Not Dispensed to Subject.

**Note:**

This field will not populate for replacement kits.

Related Topics

-

Subject Visits (Unblinded) report

This report offers details about the subject's visits and treatment, such as kit ID, kit description, and the anticipated number of kits to be dispensed in future visits.


Modes

Available in all 3 modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Unblinded Subject Visit Schedule Report* permission can generate this report.

Filters

Filter	Description
Projected Window Dates	See all projected window dates within an interval of time.
	<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;">  Note: The results do not include dispensation dates. </div>
Visit Type	Choose one of the following: <ul style="list-style-type: none"> • All to include all visits in a study. • Completed Only to only include a subject's completed visits in the report.
Site	Choose a site to include only the visits that took place at that specific location or leave it blank to include data for all sites.
Subject	Choose one or more subjects to include only visits for these specific subjects or leave it blank to see visit data for all subjects included in the study.
Subject Status	Choose one of the following: <ul style="list-style-type: none"> • Active to only include data related to active subjects in a study (typically, these are subjects who have been randomized in a study). • All Subjects to include data related to all subjects in a study, no matter their state.
File Type	Choose the output type for the report: <ul style="list-style-type: none"> • CSV • HTML • PDF

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran the report.
Visit Type	The type of visits you selected for this report. Can be All or Completed Only .
Report generated by	User name of the user who generated the report.

Initial fields	Description
Created Date	UTC time and date of when this report was run.
Site	The site you selected for this report.
Subject	The subjects you selected for this report.
Subject Status	Indicates the type of subject you selected for this report, whether active or not.
<hr/>	
Fields displayed for every selected site and subject	Description
Dispensed Date	Reflects the date when a kit was replaced.
Subject ID	The number of the subject for whom the visit details are displayed.
Randomization Number	A subject's assigned randomization number. Displayed only in the section header.
Treatment Arm	A subject's treatment arm. Displayed only in the section header.
Visit Title	A visit's title as entered by a study designer.
Unscheduled Visit Number	Number of the unscheduled visit a subject attended.
Visit Start Date	Date stamp of a visit's start date.
Projected Visit Date	Date of the upcoming visit type for a subject.
Kit Number	Numbers of kits dispensed to a subject during a visit. The number of locally sourced kits displays if applicable.
Kit Replacement	Reflects replacement kit numbers.
Kit Type ID	Indicates ID of the dispensed kit type.
Kit Description	A dispensed kit's description as entered by a study designer.
Quantity	Amount of dispensed kits. The quantity of locally sourced kits to be dispensed displays if applicable.
Reason	Indicates reason for selected actions, for example: Lost, Damaged, Not Dispensed to Subject.
<hr/>	
Last Modified By	User name of the user who last performed this transaction.

**Note:**

This field will not populate for replacement kits.

Titration Summary report

In this report, you view at a glance all visits for each subject, along with the titration details for each visit. This report is useful for blinded users who need to verify dispensation and titration data at a site for one or multiple subjects.

Modes

Available in all 3 modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Titration Summary Report* permission can generate this report.

Filters

Filter	Description
Site	Choose a site to include only the visits that took place at that specific location or leave it blank to include data for all sites.
Subject	Choose one or more subjects to include only visits for these specific subjects or leave it blank to receive visit data for all subjects included in the study.
File Type	Choose the output for the report: CSV, HTML, or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of when this report was run
Site	The site you selected for this report
Subject	The subjects you selected for this report

Fields about titration data in a study	Description
Visit	A visit's name as completed by a site user
Titration	Kit type titration associated with a visit

Fields about titration data in a study	Description
Unscheduled Visit Number	An unscheduled visit's number during which dose changes were performed
Title of Dose Level	Dose level title assigned to each blinded kit type titration
Kit Number	Numbers of kits used in titrations and number of locally sourced kits if applicable.
Duration from Last Dose Change	Number of days from a subject's last dose change
Dispensation Date	Date stamp of when the last dispensation occurred
Projected Dispensation Date	Date of the upcoming dispensation visit
Last Modified By	User name of the user who last performed this transaction

Titration Summary (Unblinded) report

In this report, you view titration details for all subjects and visits at a site or at multiple sites. This report is useful for unblinded users who want to verify dispensation and titration data at a site, as well as treatment arm information.

Modes

Available in all 3 modes: Testing, Training, and Production.

Permission required to run the report

Any user who's assigned the *Run the Unblinded Titration Summary Report* permission can generate this report.

Filters

Filter	Description
Site	Select a specific site to only include visits and titration data for that specific location or leave it blank to include visits and titration data for all sites in a study.
Treatment Arm	Choose a treatment arm to only include the visits during which a specific treatment arm was assigned to subjects or leave it blank to include data for all treatment arms.
Subject	Choose one or more subjects to only include visits for these specific subjects or leave it blank to receive visit data for all subjects included in the study.
File Type	Choose the output for the report: CSV, HTML, or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription.
Study Name	A study's ID as entered by the study manager when they created the study.
Mode	The mode in which you ran this report.
Report Generated By	User name of the user who generated this report.
Created Date	UTC time and date of when this report was run.
Site	The site you selected for this report.
Subject	The subjects you selected for this report.
Treatment Arm	The treatment arms you selected for this report.
<hr/>	
Fields about titration data in a study	Description
Subject	<i>This data point is displayed in a report's header.</i> The subject's number.
Treatment Arm	<i>This data point is displayed in a report's header.</i> The treatment arm the subject is on.
Visit	A visit's name as completed by a site user.
Titration	Kit type titration associated with a visit.
Unscheduled Visit Number	An unscheduled visit's number during which dose changes were performed.
Title of Dose Level	Dose level title assigned to each blinded kit type titration.
Kit Number	Kit numbers used in titrations, as well as their descriptions. Includes calculated dose level description and locally sourced number if applicable.
Duration from Last Dose Change	Number of days from a subject's last dose change.
Dispensation Date	Date stamp of when the last dispensation occurred.
Projected Dispensation Date	Date of the upcoming dispensation visit.
Last Modified By	User name of the user who last performed this transaction.
<hr/>	
Titration Settings	Description
Maximum Dose Changes	Indicates the maximum number of dose changes for a subject. Can display the limit for total titrations or for up and down titrations separately, depending on the study design configuration.
Minimum Time Between Dose Changes	Indicates the minimum time allowed between dose changes. Can display the limit for total titrations or for up and down titrations separately, depending on the study design configuration.

Titration Settings	Description
Dispense when on Highest Dose and Site Wants Higher Dose	Indicates whether a site user is allowed to dispense when a subject requests a higher dose but they're already on the highest dose. <ul style="list-style-type: none"> Yes means to keep a subject on their current dose level when the subject is already on the highest dose and the site asks to titrate up. No means to prevent dispensation when the subject is already on the highest dose and the site asks to titrate up. The subject remains in the study, and if subject decides to maintain their current dose, dispensation can still occur.
Message for Site Users	Indicates the custom message to display at dispensation when an up titration request occurs and the subject is already on the highest dose.
Dispense when on Lowest Dose and Site Wants Lower Dose	Indicates whether a site user is allowed to dispense when a subject requests a lower dose but they're already on the lowest dose. <ul style="list-style-type: none"> Yes means to keep a subject on their current dose level when the subject is already on the lowest dose and the site asks to titrate down. No means to prevent dispensation when the subject is already on the lowest dose and the site asks to titrate down.
Message for Site Users	Indicates the custom message to display at dispensation when a down titration request occurs and the subject is already on the lowest dose.
Titration Exceptions	Description
Titration Exception Type	Indicates whether the exception is applied to an up titration or a down titration.
Starting Dose Level Description	Indicates the description of the starting dose for the titration to which an exception is applied. Includes the calculated dose level description if applicable.
Minimum Time Between Dose Changes	Indicates the minimum time allowed between dose changes as an exception to the standard time in the titration settings (see table above).
Ending Dose Level Description	Indicates the description of the ending dose for the titration to which an exception is applied. Includes the calculated dose level description, if applicable.

User Assignment reports

User Assignment reports can help you identify and resolve issues related to user management, as well as give you valuable data on study access at your organization.

Some of the use cases for running these reports include:

Troubleshooting

For instance, if work is falling behind schedule, these reports could help you identify a reason. You can see the last time each user signed in and determine whether their end date for study access has passed, or whether someone has updated their roles so that they no longer have access. Similarly, if a user reports that they no longer can do an action that they could do before, you can run this report to see if their access has changed over time.

Collecting information

Both site and sponsor users will likely want to run the report of their choice at the beginning of the study so they can see who has access to the site data and at the end of the study so they can see everyone who signed in and had access at any point during the study conduct period.

- [User Assignment report](#)
Much like the User Assignment by Site report, you can run the User Assignment report only for the organizations that you're assigned to.
- [User Assignment Across Studies report](#)
This report displays the study roles and permissions assigned to users across studies.
- [User Assignment by Site report](#)
This report contains the same data as the User Assignment report, but organized differently. You can only run this report for the organizations that you are assigned to.

User Assignment report

Much like the User Assignment by Site report, you can run the User Assignment report only for the organizations that you're assigned to.



Note:

The **User Assignment report** is available as a CSV file and is therefore more useful to users who want to sort and filter the data, such as sponsor users. Want to learn more about the User Assignment by Site report? See [User Assignment by Site report](#).

The User Assignment report contains the following details:

- Each user's roles
- The date the user was provisioned, plus their end date, if it was specified
- The last time the user signed in
- All changes that have been made to the user, only if historical information is included

Modes

Available for all 4 modes: Testing, Training, and Production., and Draft mode.

Permission required to run the report

Any user who's assigned the *Run the User Assignment Report* permission can generate the User Assignment report.

Filters

Filter	Description
Location Type	Select Site to include user assignment information for sites only, select Depots to include information for depots only, or All for both.

Filter	Description
Location	Choose a site or depot to include assignment details for users at that location only or leave the filter blank to include assignment details for all locations.
User Name	Choose one or more users to include assignment information for or leave the filter blank to include assignment information for all users.
Last Modified By	Choose one or more users to see only the users that they last modified or leave the filter blank to include users that anyone last modified.
Permissions	Select Exclude Permissions or Include Permissions to exclude or include permissions included in a user's assigned study roles.
Data Type	Select Current Data to see a user's current assignments. Select Historical Data to see every change that has been made to a user.
File Type	Select the output type for the report: CSV, HTML, or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report.
Location Type	Displays values such as Site, Depot, or both.
Data Type	Indicates whether the generated report contains historical data, current data, or both.
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of when this report was run
Permissions	Indicates one of the two values, depending on what you selected when you generated the report: <ul style="list-style-type: none"> • Include Permissions • Exclude Permissions

Fields for users assigned to a location	Description
User Name	Indicates the specified user's name.
First Name	Indicates a user's first name as entered by a user administrator when they created their user account.
Last Name	Indicates a user's last name as entered by a user administrator when they created their user account.

Fields for users assigned to a location	Description
Site ID	Indicates a site's ID as entered by a global user when they created the institution at a global level.
Study Role	The study role that is assigned to the user.
Roles	This column used to indicate the roles associated to a user before study roles were introduced. Typically, this column displays N/A. In a future release, this column will become deprecated and be removed.
Permissions	If included, permissions are listed in this column for a specified user. If excluded, the column only displays a value of "Excluded".
Organization	Indicates the associated institution or vendor that a user is assigned to. The field displays the Site ID, as well as the ShortOrg ID.
State	Indicates the county or province associated with a user.
Country	Indicates the user's associated country.
Effective Start Date	Displays the date of when the user could sign into the study.
Effective End Date	Displays either "No End Date" or the date entered to terminate a user's access.
Last Login	Indicates a user's last login session into Oracle Clinical One Platform.
Status	A user's status in the system (Active or Inactive)
Last Modified By	User name of the user who last modified a user's assignments
Last Modified	UTC time and date of when the last transaction was performed by a user
Comment	Comment entered when uploading users in Oracle Clinical One Platform. If no comment is specified, the field displays N/A. For more information, see About uploading & assigning users in bulk.

Related Topics

- [User Assignment reports](#)
User Assignment reports can help you identify and resolve issues related to user management, as well as give you valuable data on study access at your organization.

User Assignment Across Studies report

This report displays the study roles and permissions assigned to users across studies.



Note:

Do you need to run reports for a specific study or site? Learn more about the [User Assignment report](#) and the [User Assignment by Site report](#).

The User Assignment Across Studies report contains the following details:

- User's names and their assigned study roles
- The date a user was provisioned or their end date, if it was specified
- A user's status helping you determine which users should be removed across multiple studies

Modes

Available in all modes: Study Design, Testing, Training, and Production.

Permission required to run the report

There is no specific permission that is required to run this report. Only users who are assigned the Global User Manager and the Study Creator global roles can generate this report.

Table 2-2 Filters


Filters	Description
User name	Choose an individual user or multiple users.
	<div style="border: 1px solid #0070c0; padding: 10px; background-color: #e6f2ff;">  Note: The filter does not allow the selection of all users. </div>
Study Mode	Choose one or all study modes for which you want to run this report: Study Design, Testing, Training, or Production.
Include Permissions	Select Yes to show the permissions assigned to users in one or multiple study roles across studies that they are a part of. Select No to exclude these permissions from the report. By default, this setting is set to No .
Include Decommissioned Studies	Select Yes to include study roles from decommissioned and inactive studies. Select No (default) to exclude data from these studies. By default, this setting is set to No .
File Type	Select the output type for the report: CSV, HTML, or PDF.

Table 2-3 Field descriptions

Fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
User Name	Displays the names of the users that you selected to include in this report.
Include Permissions	Displays Yes or No, depending on your setting configuration.
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of when this report was run
Study Mode	The study mode to which the user is assigned. For example, you may run a report for Testing mode to verify a user's assignment details for that specific study mode.

Table 2-3 (Cont.) Field descriptions

Fields	Description
Include Decommissioned Studies	Displays Yes or No, depending on your setting configuration.
User Name	Indicates the specified user's name.
Study Name	A study's ID as entered by the study manager when they created the study
Study Mode	Indicates the study mode associated with the user's assigned study role. For example, the same user may have different study roles assigned to them for each study mode. User A may be assigned the Study Designer (template) study role in Study Design mode and the Study Manager study role in Testing mode.
Study Role	The name of the study role as entered by a user administrator.
Permissions	If included, permissions are listed in this column for a specified user. If excluded, the column only displays a value of "Excluded".
Start Date	The date the user was first assigned the role.
End Date	Displays either "No End Date" or the date entered to terminate a user's access.
Status	The user's status at the time the report is run for example, New or Active.
	<div data-bbox="1143 1077 1192 1119" data-label="Image"></div> <p>Note:</p> <p>Currently, the only status showing is Active. If you want to identify users that are retired or deleted, this would not be displayed at the moment.</p>
Last Modified Date	UTC time and date of the latest update for a user's role assignment details.
Last Modified by	The user name of the user who last modified a user's role assignment details.

User Assignment by Site report

This report contains the same data as the User Assignment report, but organized differently. You can only run this report for the organizations that you are assigned to.

Note:

The **User Assignment by Site report** is available as an HTML and PDF file and therefore is more visually appealing and a bit easier to scan and review. This report is most useful for users who don't need to sort and filter data, such as CRAs and site users. Want to learn more about the User Assignment report? See [User Assignment report](#).

The User Assignment by Site report contains the following details:

- Each user's roles
- The date the user was provisioned, plus their end date, if it was specified
- The last time the user signed in
- All changes that have been made to the user only if historical information is included

Modes

Available for all 3 modes: Testing, Training, and Production. User Assignment is also available for the study design

Permission required to run the report

Any user who's assigned the *Run the User Assignment Report* permission can generate the User Assignment by Site report.

Filters

Filter	Description
Location Type	Select Site to include user assignment information for sites only, select Depots to include information for depots only, or All for both.
Location	Choose a site or depot to include only assignment details for users at the location or leave the filter blank to include assignment details for all locations.
User Name	Choose one or more users to include assignment information for or leave the filter blank to include assignment information for all users.
Last Modified By	Choose one or more users to see only the users that they last modified or leave the filter blank to include users that anyone last modified.
Permissions	Select Exclude Permissions or Include Permissions to exclude or include permissions included in a user's assigned study roles.
Data Type	Select Current Data to see a user's current assignments. Select Historical Data to see every change that has been made to a user.

Filter	Description
File Type	Select the output type for the report: HTML, or PDF.

Field descriptions



Note:

Fields that don't have any corresponding values are marked as N/A in the report.

Initial fields	Description
Customer Name	A customer's name used to purchase the cloud subscription
Study Name	A study's ID as entered by the study manager when they created the study
Mode	The mode in which you ran this report.
Location Type	Displays values such as Site, Depot, or both.
Data Type	Indicates whether the generated report contains historical data, current data, or both.
Report Generated By	User name of the user who generated this report
Created Date	UTC time and date of when this report was run
Permissions	Indicates one of the two values, depending on what you selected when you generated the report: <ul style="list-style-type: none"> • Include Permissions • Exclude Permissions

Fields for users assigned to a location	Description
User Name	Indicates the specified user's name.
First Name	Indicates a user's first name as entered by a user administrator when they created their user account.
Last Name	Indicates a user's last name as entered by a user administrator when they created their user account.
Study Role	The study role that is assigned to the user
Roles	This column used to indicate the roles associated to a user before study roles were introduced. Typically, this column displays N/A. In a future release, this column will become deprecated and be removed.
Permissions	If included, permissions are listed in this column for a specified user. If excluded, the column only displays a value of "Excluded".
Effective Start Date	Displays the date of when the user could sign into the study.
Effective End Date	Displays either "No End Date" or the date entered to terminate a user's access.
Last Login	Indicates a user's last login session into Oracle Clinical One Platform.
Status	A user's status in the system (Active or Inactive)

Fields for users assigned to a location	Description
Last Modified by	User name of the user who last performed this transaction
Last Modified	UTC time and date of when the last transaction was performed by a user
Comment	Comment entered when uploading users in Oracle Clinical One Platform. If no comment is specified, the field displays N/A. For more information, see About uploading & assigning users in bulk.

Related Topics

- [User Assignment reports](#)
User Assignment reports can help you identify and resolve issues related to user management, as well as give you valuable data on study access at your organization.

User Upload Error report

This report contains errors encountered when importing the User Upload Template.

For information about the **User Upload Template**, see About creating user accounts using the upload template.

Modes

Available in 3 modes: Testing, Training, and Production.

Permission required to run the report

Users assigned to a role that includes the *Upload Users in Bulk* permission can run this report.

Types

A system report is generated automatically after each import. The report can also be generated manually at any time.

- System-generated
 - Automatically generated after each import if errors are identified in the import file.
 - This is not a cumulative report; it contains errors encountered for each batch processed.
 - Errors can be addressed directly in the report, which can then be imported.
- Manually-generated
 - It can be generated manually at any time.
 - Includes errors encountered over the last seven (7) days.
 - A study-level notification appears when the report is ready.
 - An email notification is also sent with the subject; User Upload Error Report is ready in Clinical One.

How to use the report

1. After importing the **User Upload Template** or the **User Upload Error report**, look for the Bulk User Upload email notification.
 - The **User Uploaded** row indicates the number of users successfully created.
 - The **User with error** row, if one (1) or greater, means you have import errors to address.
2. Go to the **Download Reports** side panel for the User Upload Error report and download the system-generated report.
3. Make corrections directly in the report, then import it. For import steps, see step 6. in Create user accounts using the upload template.
4. The report can be manually generated at any time to view errors encountered over the last seven (7) days. Errors can also be corrected in the file, which can then be imported.



Tip:

The recommended best practice is to use the system-generated report to correct import issues for each batch and generate it manually to view a history of import issues.

Report filters for manually-generated reports.

Filter	Description
Date Range	The report output includes import errors encountered during the range specified. Errors are retained for seven (7) days unless addressed.
File Type	XLSM



Tip:

If you need import information for an import processed on the 15th, use the range from the 14th to the 16th.

Report output fields for system and manually generated reports

Header fields	Description
Customer Name	The customer name used to purchase the cloud subscription.
Study Name	The study ID entered by the study manager when the study was created.
Mode	The mode the report was run in, either Testing, Training, or Production.
Report Generated By	<ul style="list-style-type: none"> • System-generated displays System. • Manually-generated displays the user name of the person who generated the report.

Header fields	Description
Created Date	The date and time, in UTC, when the report was created.
Date Range	The date range entered when the report was run.

 **Note:**

Only included in user-generated reports.

Column name	Description
First Name	First name of the user.
Last Name	Last name of the user.
Email	Email address of the user.
User Name	User name assigned to the user.
Start Date	The first day the user can access the study.
End Date	The last day the user can access the study.
Role	The name of the study role assigned to the user.

 **Tip:**

To populate the drop-down click **Enable Content** then go to the Study Roles tab and click **Validate Roles**.

Site IDs	The site or sites the user was assigned to.
Depot IDs	The depot or depots the user was assigned to.
Comment	Comments entered by the user, in the user interface, while processing the import file.
Uploaded by	The user name of the person who imported the user upload template.
Uploaded at	The date and time, in UTC, when the user upload template was imported.
Error Message	Details about the error.

3

Oracle Clinical One Platform data extracts

- [About data extracts](#)
Data managers, statisticians, and other sponsor users can extract cumulative study data for data analysis or regulatory reporting for the study that they are working in.
- [Run a Subject Data Extract](#)
While the Subject Data Extract is running, you can navigate away from the Reports & Archives page and do more work in the study.
- [Download a Subject Data Extract](#)
You get a notification when the Subject Data Extract is available to download.
- [Data extract descriptions](#)

About data extracts

Data managers, statisticians, and other sponsor users can extract cumulative study data for data analysis or regulatory reporting for the study that they are working in.

In Oracle Clinical One Platform, there are different ways of extracting data, depending on its purpose.

You can run the Subject Data Extract to extract specific and cumulative subject data. Or you can extract data in an ODM-XML format to get other types of data such as admin data or a study's metadata to either store, analyze, or submit in other systems.

Run a Subject Data Extract

While the Subject Data Extract is running, you can navigate away from the Reports & Archives page and do more work in the study.



Note:

As part of a study version change, if an existing question is hidden and classified, that question will be hidden for new subjects in the UI so it will not be populated for new subjects in the Subject Data Extract. However, the question will continue to be included for all subjects in the Subject Data Extract since the data is shown in an aggregated manner. If you don't want that specific field (corresponding to a question hidden and classified as an Advanced Study Version Change) to be included in the Subject Data Extract for all subjects, you must work with your study designer to apply the update as an Advanced Study Version Change, specifying the hidden and data classified characteristics to the question for the earliest study version in which the question is included.

1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).
2. On the **Reports** tab, select the Subject Data Extract.

3. On the right, make sure **Report Settings** is expanded, and fill in the fields. To view tips for completing a field, click into the field or choose an option.
4. Click **Run Report**.

Related Topics

- [About data extracts](#)
Data managers, statisticians, and other sponsor users can extract cumulative study data for data analysis or regulatory reporting for the study that they are working in.
- [Download a Subject Data Extract](#)
You get a notification when the Subject Data Extract is available to download.

Download a Subject Data Extract

You get a notification when the Subject Data Extract is available to download.



Note:

All dates in reports are in the UTC (Coordinated Universal Time) time zone, which corresponds to the Greenwich Mean Time zone.

1. Navigate to the Reports & Archives tab. For step-by-step instructions, see [Access the Reports & Archives page](#).
2. In the lower right, expand **Download Reports** and locate the version of the Subject Data Extract that you want to view.



Tip:

The timestamp below each report tells you when it was run.

Related Topics

- [About data extracts](#)
Data managers, statisticians, and other sponsor users can extract cumulative study data for data analysis or regulatory reporting for the study that they are working in.
- [Run a Subject Data Extract](#)
While the Subject Data Extract is running, you can navigate away from the Reports & Archives page and do more work in the study.

Data extract descriptions

- [ODM-XML extract](#)
Sponsor users can extract study data, admin data, and metadata in an ODM-XML format to either store, analyze, or submit it to other systems.
- [Subject Data Extract](#)
Data managers and statisticians can extract cumulative subject data for data analysis or regulatory reporting of a given study.

- [Subject Randomization Data Extract](#)
Extract cumulative data including randomization details, such as randomization number, associated treatment and stratification data. Blinded and unblinded extracts are available depending on your permissions.

ODM-XML extract

Sponsor users can extract study data, admin data, and metadata in an ODM-XML format to either store, analyze, or submit it to other systems.

Prerequisites

There are two prerequisites you must follow before you can run ODM-XML data extracts.

- Create the required users in Oracle Life Sciences IAMS in order to use the Oracle Clinical One Analytics ODM APIs. See [Create a user account in Oracle Health IAMS](#) in the *REST API for Clinical One Platform* user guide.
- Assign the **ODM Extract** study role to your users in Oracle Clinical One Platform. See [Assign a study role to a user in the Add Users Guide](#).

To learn more about the ODM Extract permissions, see [ODM Extract Permissions](#).

To learn more about ODM-XML data extracts, see [Generate ODM-XML data extracts](#).

Types of data that you can extract

Here's a list of specific data types that you can typically extract:

- **Subject data:** This includes visits, forms, items, but not queries.
- **Scope:** Transactional or snapshot.
 - Transactional data reflects incremental data changes with audit information.
 - Snapshot data reflects current data only.
- **Blind data:** Blinded or unblinded data.
- **Time range:** Data created or updated between two points of time.
- **Study mode:** Test, Training, or Production data.
- Data generated without Oracle Clinical One Platform extensions, conforming to the CDISC ODM-XML standard.

The data can additionally be partitioned and consumed using pagination parameters. The following parameters can be used:



Note:

Pagination parameters do not work if both *Sites* and *Users* are included in the API request.

- **offset:** Row number to start on. First page starts with 0.
- **limit:** Number of rows to return.

Subject Data Extract

Data managers and statisticians can extract cumulative subject data for data analysis or regulatory reporting of a given study.

The Subject Data Extract is particularly useful for improving the overall data collection process and making sure the study's data is of the best quality, as well as proving the study's efficacy through data analysis.

 **Note:**

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

Modes

Available for all 3 modes: Testing, Training, and Production.

Roles that can extract data

Any user that's assigned the *Run the Subject Data Extract* permission can generate this report. Users with this permission can only see the data that they're allowed to either view or edit, based on their access to classified data.

The Subject Data Extract can contain blinded or unblinded data, depending on your permissions within the study. Hidden questions are included in the report only if the user generating the report has the permissions to view or edit hidden data.

Output details

Here is a list of details on how data may be displayed in the Subject Data Extract:

- For any code lists you use in your study for answer options in forms, the codes will be displayed in the data extract, to follow the SDTM terminology.
- If a numeric value that contains leading zeros (0) is collected through a form, that numeric value is displayed without its leading zeros in the data that you extract in either a CPORT or XPORT format.
For example, if a site user collects a value of "0001.12345", the data extracted in a SAS format displays that value as "1.12345".
- Make sure you define SAS properties. If the SAS properties are not defined in a study's design, the form reference code is used instead and it is also displayed in the Subject Data Extract.
- For a two-section form, questions in the Questions Before the Table section and the Questions in the Table section are merged to offer you a consolidated view of what data to analyze.
- For a lab form, the Sample Collection Date and the Fasting questions are merged, as well, for the same reasons.
- Records of cleared forms are not included. This also applies to deleted repeating forms.

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.

- If you clear all elements in a form, the record is not included. Similarly, if you clear the data from the parent question of a dynamic form, which results in dynamic form being hidden, no record of that form will be included in the extract.
- If a site user does not answer a question or they apply a data flag to it, the corresponding field in the extract will be populated with a code specific to each data flag. The following codes can be displayed:
 - Not Applicable (NA): C48660
 - Not Done (ND): C49484
 - Unknown (UNK): C17998
 - Not Answered: -99999

 **Note:**

If all questions of a form have had the **Not Answered** flag applied, the form will not be included in the report.

- In the extract's columns, the code for every data flag is displayed in the QUESTIONLABEL_D column. Depending on a question's type, the code can also be displayed in the QUESTION LABEL column. The abbreviation (such as NA) is displayed in the QUESTIONLABEL_R column. For more details see Form item output mapping in data extracts.

Settings

Filter	Description
File Name	Select the appropriate name convention for your data extract. These naming conventions are only available for data extracted in a CSV format: <ul style="list-style-type: none"> • <Form Name> • <Study Name>_Form Name>_<Time stamp> • <Study Name>_<Form Name> • <Form Name>_<Time stamp>
Site	Choose one or more sites that you're assigned to. This drop-down includes sites in all states: New, Active, Retired.
File Type	Choose the output type for the report: Transport (XPORT) , CPORT , CSV , or sas7bdat . <ul style="list-style-type: none"> • A CSV or SAS file is generated for each form designed in the study. Each question or item in each form will contain four corresponding columns as described in the <i>Field descriptions</i> section below. • If generated in a SAS format, such as Transport (XPORT) or CPORT, the data extract will consist of a ZIP file containing a SAS proprietary dataset for each form with the SAS Label and Variable for each data element within a form. • A sas7bdat extract is generated in a ZIP file format. • If you only need to view data in a Subject Data Extract, then we recommend you extract data in a CSV format for a more flexible and faster user experience.

Field descriptions

Key Column	SAS Label	Description
TENANTID	Tenant Identifier	Indicates the organization identifier.
STUDYID	Study Identifier	A study ID as specified by the study manager when they created the study.
COUNTRY	Country of Investigator Site	A site's country as specified by the site manager when they created the sites in Oracle Clinical One Platform.
SITEID	Site Identifier	Indicates the site's ID.
INVID	Investigator Identifier (DEA Number)	A principal investigator's ID as specified by the site manager when they created the sites in Oracle Clinical One Platform.
INVNAM	Investigator First and Last Name	A principal investigator's name as specified by the site manager when they created the sites in Oracle Clinical One Platform.
USUBJID	Unique Subject ID (GUID)	Unique subject ID across all studies for all applications or submissions involving the product.

Key Column	SAS Label	Description
SCRNID	Screening Number	The number assigned to a subject after screening or enrollment.

 **Note:**

This matches the SUBJECT column unless you are replacing the Subject Number with the Randomization Number.

SUBJID	Subject Identifier (Subject Number)	Indicates the unique subject number within the study.
VISITNUM	Visit Identifier	Indicates a visit's ID as specified by the study designer.
VISIT	Visit Title	Indicates a visit or event title as specified by the study designer.
UNSCHED	Unscheduled Visit Instance Number	Indicates the unscheduled visit instance number as designed by the study designer.
SVSTDTC	Visit Start Date (Start Date/Time of Visit)	Indicates a visit's start date, represented in ISO 8601 character format.
LABID	Lab ID	The Lab ID.

Key Column	SAS Label	Description
NAM	Lab Name	The Lab name.
DOMAIN	Form Reference Code	Indicates the form's reference code as a two-character abbreviation.
REPEATNUMBER	Row number in a repeating form.	For different types of forms, this column displays data in the following ways: <ul style="list-style-type: none"> For one-section (flat) forms, these fields are not populated. For repeating forms, this column is populated with the number of repeating form instances used in a study. For lab forms and two-section forms, this column is populated with the instance number of each lab form.
ENTERED BY	The user who initially entered data into the form.	Indicates the user name of the user who initially entered data into the form or answered a question.
ENTERED DATE	The date when the user entered data into the form. Date is UTC Timezone.	The UTC time and date of when the user entered data into the form or answered a question, represented in ISO 8601 character format.
LAST CHANGED BY	The latest user or system user who modified any form item.	Indicates the user name of the latest user to have modified any questions on the form. Queries are not taken into account as form updates.
LAST CHANGED DATE	The latest date of any form item that is modified. Date is UTC Timezone.	The UTC time and date of when a question was last modified, represented in ISO 8601 character format.
QUESTION LABEL	The answer to the question label.	Indicates the answer to a question as entered by a site user.
QUESTION LABEL_R	The question label's raw value.	Indicates the raw value: alphanumeric value as entered in Oracle Clinical One Platform with no conversions. This includes data entry flags. For more details see Form item output mapping in data extracts.

Key Column	SAS Label	Description
QUESTIONLABEL_F	The question label's data type.	Indicates the formatted value: value as entered in Oracle Clinical One Platform converted to the question data type as per form design. For more details see Form item output mapping in data extracts.

 **Note:**

Incomplete date / time data will not be exported under this column, but will still be available under QUESTIONLABEL_R. This means that all date / time data collected

Key Column	SAS Label	Description
QUESTIONLABEL_D	The question label's data type for the answer.	Indicates the decoded raw value, with additional considerations according to data type. If the question has a code value, it is populated in this field. For more details see Form item output mapping in data extracts.

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Key Column	SAS Label	Description
DeletedQn	Deleted Questions	If a form item was deleted in a previous version of the study, but data had been collected for it, this data will be displayed under this column.
SOURCEFORMID	Source Form ID	Indicates the ID of the source form, that is the form which contains the question that launches a form association.
SOURCEITEMID	Source Item ID	Indicates the source item ID. The source item is the question/item that launches a form association.
RVISITNUM	Related Visit ID	Indicates the ID of the visit that contains the form with which the source form is related/linked.
RVISIT	Related Visit Title	Indicates the name of the visit that contains the form with which the source form is related/linked.

 **Note:**

The SAS Label of the deleted form item will be displayed as D<GUI D>, using the deleted form's GUID.

Key Column	SAS Label	Description
RVISITINST	Related Unscheduled/Cycle Instance	Indicates the instance number of the unscheduled visit or cycle visit that contains the form with which the source form is related/linked.
RSVSTDTC	Related Visit Start Date	Indicates the start date of the visit that contains the form with which the source form is related/linked.
RELID	Related Record ID	Indicates the ID of the repeating form instance with which the source form is related/linked.
RDOMAIN	Related Form Name	Indicates the name of the form with which the source form is related/linked.
RFORMID	Related Form ID	Indicates the name of the form with which the source form is related/linked.
RREPEATNUMBER	Related Repeat Number	Indicates the number of the repeating form instance with which the source form is linked.
RSREPEATID	Related Repeating Section Unique Identifier	Indicated the instance number of the flat section with which the source form is linked.
RSREPEATNUMBER	Related row number in a repeating section	Indicated the instance number of the section with which the source form is linked.
REPEATNUMBER	Row number in a repeating form	In case of a two-section form or a lab form, this number indicates the instance ID of a two-section form. The same ID is displayed for the Questions Before the Table section and the Questions in the Table section. As the SAS Label indicates, this also represents the row number for a repeating row.
SREPEATID	Repeating Section Unique Identifier	This is a unique number assigned to the Questions in the Table section of a two-section form, including a lab form.
SREPEATNUMBER	Row number in a repeating section	This is a row's unique number (whether located in a lab form or a two-section form). This number is unique for every section (in a two-section form), form, and event for a subject.

Related Topics

- What is the difference between an XPORT and CPORT file format?
- Why do I have to define SAS properties?

Subject Randomization Data Extract

Extract cumulative data including randomization details, such as randomization number, associated treatment and stratification data. Blinded and unblinded extracts are available depending on your permissions.

Modes

Available for all 3 modes: Testing, Training, and Production.

Roles that can extract data

Any user that's assigned the *Run the Subject Randomization Data Extract Report* permission can generate this report. Users with this permission can only see the data that they're allowed to view, based on their access to classified data.

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

WARNING:

If you generate this extract as an unblinded user, you must be careful when sharing to protect other users blinding.

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

Hidden questions are included in the report only if the user generating the report has the permissions to view or edit hidden data.

Output details

Here is a list of details on how data may be displayed in the Subject Randomization Data Extract:

- This report includes only records of randomized subjects.

If the extract is generated before the first subject is randomized, an empty dataset is created that includes all fields except for the stratification factors. Stratification factors are added to the dataset when the first subject is randomized. To view this data you need to generate a new extract.

- Only values that were used for a given subject as stratification factors at the time of randomization are populated for the subject. This means that, even if the site updates this data for a subject after randomization, the values that were actually used to determine randomization are retrieved.
- Whenever a subject is re-randomized, a second record is created for the same subject in the report.

 **Note:**

For manual updates to a subject's randomization details (randomization number and treatment arm), no new record is created and the original data is displayed.

- If a subject is re-randomized and no new randomization number is assigned, the second record for the subject displays empty fields for Randomization Number, Treatment Arm, and Block ID.
- If a numeric value that contains leading zeros (0) is collected through a form, that numeric value is displayed without its leading zeros in the data that you extract in either a CPORT, XPORT or sas7bdat format.
For example, if a site user collects a value of "0001.12345", the data extracted in a SAS format displays that value as "1.12345".
- Make sure you define SAS properties. If the SAS properties are not defined in a study's design, the form reference code and question label are used instead.

 **Note:**

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](#).²

Settings

Filter	Description
File Name	Select the appropriate name convention for your data extract. These naming conventions are only available for data extracted in a CSV format: <ul style="list-style-type: none"> • <Study Name>_File Name>_<Time stamp> • <Study Name>_<File Name> • <File Name>_<Time stamp> • <File Name>
Site	Choose one or more sites that you're assigned to. This drop-down includes sites in all states: New, Active, Retired.

² 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.

Filter	Description
File Type	<p>Choose the output type for the report: Transport (XPORT), CPORT, CSV, or sas7bdat.</p> <ul style="list-style-type: none"> A CSV or SAS file is generated for each form designed in the study. Each question or item in each form will contain four corresponding columns as described in the <i>Field descriptions</i> section below. If generated in a SAS format, such as Transport (XPORT) or CPORT, the data extract will consist of a ZIP file containing a SAS proprietary dataset for each form with the SAS Label and Variable for each data element within a form. A sas7bdat extract is generated in a ZIP file format. If you only need to view data in a Subject Data Extract, then we recommend you extract data in a CSV format for a more flexible and faster user experience.

Field descriptions


Key Column	SAS Label	Description
TENANTID	Tenant Identifier	Indicates the organization identifier.
STUDYID	Study Identifier	A study ID as specified by the study manager when they created the study.
COUNTRY	Country of Investigator Site	A site's country as specified by the site manager when they created the sites in Oracle Clinical One Platform.
SITEID	Site Identifier	Indicates the site's ID.
INVID	Investigator Identifier (DEA Number)	<i>This field is usually blank.</i> A principal investigator's ID as specified by the site manager when they created the sites in Oracle Clinical One Platform.
INVNAM	Investigator First and Last Name	A principal investigator's name in the format: <Last Name>, <First Name>.
USUBJID	Unique Subject ID (GUID)	Unique subject ID across all studies for all applications or submissions involving the product.
SUBJID	Subject Identifier (Subject Number)	Indicates the unique subject number within the study.
SCRNID	Screening Number	The number assigned to a subject after screening or enrollment.
VISITNUM	Visit Identifier	Indicates a visit's ID for the visit where randomization event occurred.
VISIT	Visit Title	Indicates the title for the visit where randomization event occurred, as specified by the study designer.




Note:

This matches the SUBJID column unless you are Replacing the Subject Number with the Randomization Number.

Key Column	SAS Label	Description
UNSCHEd	Unscheduled/Cycle Visit Instance Number	Indicates the unscheduled visit instance number, and cycle number for cycle visits, as designed by the study designer.
SVSTDTc	Visit Start Date (Start Date/Time of Visit)	Indicates the randomization visit's start date, represented in ISO 8601 character format.
DOMAIN	Form Reference Code (Source Form)	Indicates the source form's reference code. This value, for the source dataset of this data extract, is always <i>RAND_SYS</i> .
ENTEREDBY	Initial user to enter data into the Visit/Stratification	Indicates the user name of the user who first entered any stratification data or who started the randomization visit, whichever happens first. In case of re-randomization, only the newest randomization event is considered.
ENTEREDDT	Initial date data entered into the Visit/Stratification	The UTC time and date of when the user first entered any stratification data or started the randomization visit, whichever happens first. This date is represented in ISO 8601 character format (<i>YYYY-MM-DDTHH:MM:SSZ</i>). In case of re-randomization, only the newest randomization event is considered.
LASTCHANGEDBY	Last user to modify data prior to Randomization	Indicates the user name of the latest user to have modified any stratification factor value or randomization visit data prior to randomization. Queries are not taken into account as updates. In case of re-randomization, only the newest randomization event is considered.
LASTCHANGEDDATE	Last date data modified prior to Randomization	The UTC time and date of when a stratification factor value or randomization visit data was last modified, prior to randomization. Represented in ISO 8601 character format (<i>YYYY-MM-DDTHH:MM:SSZ</i>).
DSSTDAT	Randomization Date	The UTC time and date of when the subject was randomized, represented in ISO 8601 character format (<i>YYYY-MM-DDTHH:MM:SSZ</i>). In case of re-randomization, only the newest randomization event is considered.
SUBJDOB	Subject Date of Birth	Indicates the subject's date of birth, as entered by the user including unknown elements. This field is populated with the value from the question identified with the Date of Birth Subject Tag, as per design. If the tag is not used in the study or there are multiple fields collecting a subject's date of birth, this field is blank. The raw (<i>_R</i>), formatted (<i>_F</i>) and decoded (<i>_D</i>) values are also available as part of this extract. For more details see Form item output mapping in data extracts.
SUBJDOB_R	Subject Date of Birth	Indicates the raw value for the subject's date of birth: as entered, in alphanumeric format (no date format). For more details see Form item output mapping in data extracts.

Key Column	SAS Label	Description
SUBJDOB_F	Subject Date of Birth	Indicates the formatted value for the subject's date of birth: as a complete date or date/time using the format specified in the form's design in Oracle Clinical One Platform. For more details see Form item output mapping in data extracts.
SUBJDOB_D	Subject Date of Birth	Indicates the decoded value for the subject's date of birth: using an ISO 8601 date format (<i>YYYY-MM-DDTHH:MM:SSZ</i>), managing partial and full datetime values (unknown elements are omitted). For more details see Form item output mapping in data extracts.
RANDID	Randomization Number	Indicates the randomization number assigned to the subject.
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note:</p> <p>In the case of re-randomization, if a treatment arm is already mapped, a new randomization number isn't assigned to the subject and the randomization information is not updated.</p> </div>		
BLOCK	Block Number	Indicates the block number of randomization to which the subject is assigned. This field remains empty for blinded users.
COHORT	Cohort Label	Indicates the label for the cohort where the subject belongs. This value is <code>null</code> for a minimization randomization.
STRATUM	STRATUM GROUP	Indicates the stratum group where the subject belongs. This value is <code>null</code> for a minimization randomization.
TREATARM	Treatment Arm	Indicates the treatment arm that is assigned to the subject. This field remains empty for blinded users.

Key Column	SAS Label	Description
Stratification factors	Label as defined for the form item.	Lists the stratification factors data. A stratification factor is any form question identified in the randomization design as a stratum factor. Site, region and country data are not included. The values for the stratum factors, defined in any version for the given mode, are listed in separate columns for each, considering the following: <ul style="list-style-type: none"> • Four columns are added for each stratum factor: the item itself, the raw (_R), formatted (_F) and decoded (_D) values. Differences between them depend on the answer's data type. For more details, see Form item output mapping in data extracts. • Only values that were used for a given subject as stratification factors at the time of randomization are populated for the subject. • If stratification factors are not specified, no stratification factors will be listed. • In case of re-randomization, these fields are blank for the newly created record. • For the stratification factors collected in repeating forms or in forms present in more than one instance prior to randomization, the stratum factors are not included in the extract. • In Testing mode, if a stratification factor is removed from the design after a subject has been randomized, that question is not included in the extract.

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 **Note:**

This is not applicable to Production mode as questions cannot be deleted from an approved version.

Key Column	SAS Label	Description
	herandomization · These columns ' titles are dynamically	

Key Column	SAS Label	Description
	e t c h e d b a s e d o n h o w t h e S A S V a r i a b l e i s d e f i n e d f o r e a c h s t r a t i f i c a	

Key Column	SAS Label	Description
	t i o n f a c t o r a t t h e r f o r m l e v e l .	

4

Oracle CRF Submit archives and reports

- [About archives and reports](#)
Sponsors and site users can generate and download study archives and reports for mid-study data analysis and to meet end-of-study regulatory submission requirements.
- [Email and in-application notifications](#)
Notify sponsor and site users about the status of their archive and report requests, ensuring they complete related follow-up activities like downloading and confirming requests and reports.
- [Generate an archive or report](#)
Learn how to generate an archive or report.
- [Download and Confirm an archive or report request](#)
Learn how to download archive and report requests and provide confirmation when requested.
- [About Electronic Trial Master File \(eTMF\)](#)
Use this feature to send Archival PDF (sponsor), Archival PDF (site), and Custom PDF archive requests to the Oracle sFTP server, where they can be programmatically retrieved for import into an eTMF system.

About archives and reports

Sponsors and site users can generate and download study archives and reports for mid-study data analysis and to meet end-of-study regulatory submission requirements.

To get started, Access the Reports & Archives page.

- The Oracle Clinical One Platform user interface allows users to generate and download archives and reports. For a complete list, see Available archive types and reports.
- Oracle allocates 1000 GB of storage server space for each customer, which is shared across all studies. You can configure notifications to inform specific users when storage server capacity reaches 75%. For more information, see Email and in-application notifications.

Note:

You can delete requests manually to free up space. You can also reach out to your Oracle point of contact to request additional storage space.

- Users can generate certain archive types and have the output delivered to the Oracle sFTP server, where you can programmatically transfer them to an electronic trial master file (eTMF) system. For more information, see About eTMF.

Email and in-application notifications

Notify sponsor and site users about the status of their archive and report requests, ensuring they complete related follow-up activities like downloading and confirming requests and reports.

Email and in-application notifications can be customized to notify Sponsor and Site users about the status of PDF and report requests and inform Sponsor users about site-level PDF request, download, and confirmation activities. The system can even notify sponsor users if the storage limit is reaching capacity. For more information about viewing in-application notifications, see View notifications.

Modes

This feature is available in Testing and Production modes only.

Review the table below to familiarize yourself with each notification.

Table 4-1 Notification name, details, and required permissions

Notification name	Notification details	Required permissions to receive the notification
Request available for download	<ul style="list-style-type: none"> Sponsor and site users receive this notification when a request they generated has been completed successfully and is ready for download. Site users also receive this notification when a request generated by a sponsor user is shared with sites and is ready for download. 	<p>For site users</p> <ul style="list-style-type: none"> Run Archival PDFs for your site(s) (Site) Download Archival PDFs and Audit Reports (Site) <p>For sponsor users</p> <ul style="list-style-type: none"> Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation
Request failure	Sponsor and site users receive this notification when a request they generated has failed to complete successfully.	<ul style="list-style-type: none"> Run Archival PDFs for your site(s) (Site) Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation
Request submitted by site user	Sponsor users receive this notification when a site user has generated a new request for a site to which they are both assigned.	<ul style="list-style-type: none"> Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation
Request shared with site downloaded	The sponsor user who generated the request receives this notification when a request shared with a site has been downloaded by the site.	<ul style="list-style-type: none"> Run and download Site Confirmation and Download Log audit reports
Request confirmed by site	The sponsor user who generated the request receives this notification when a request shared with a site has been confirmed by the site.	<ul style="list-style-type: none"> Run and download Site Confirmation and Download Log audit reports

Table 4-1 (Cont.) Notification name, details, and required permissions

Notification name	Notification details	Required permissions to receive the notification
Storage limit has exceeded	All sponsor users assigned to the study whose request surpasses the 75% storage threshold receive this notification.	N/A Sponsor users with access to Oracle CRF Submit receive this notification.

 **No
te:**

Oracle allocates 1000 GB of storage server space for each customer, which is shared across all studies.

Required permissions

Users belonging to a study role that includes the *Manage Archives Settings* permission can access the **Archives Settings** tab under Study Settings to do the following.

- Define the Default Email address.
- Enable and disable each notification.
- Determine the recipients for each notification.
- Customize the default notification body text.

Configure notifications and customize the notification body text

Here's how to enable a notification, define the default email address, determine the recipients, and customize the notification body text.

1. Start by opening the Study Settings.
2. Click on the **Archives Settings** tab.
3. Select the mode to work in (Production or Testing).
4. Enter a **Default Email Address**. Notifications are sent to this address when the **Default Email** option is selected as a recipient.
5. Use the arrow to the left of each notification category (Request Status, Site Monitoring, and Miscellaneous) to expand the section to view the notifications.
6. Use the toggle to the left of each notification to enable and disable it. The toggle is blue when a notification is active.

 **Note:**

The Storage limit has exceeded notification, under Miscellaneous, is enabled by default and cannot be disabled.

7. Click the arrow on the far right of an active notification to expand it, then select the recipients.

 **Note:**

In-application notifications are not created if **Default Email** is the only recipient selected.

8. To customize the notification body text, click the pencil icon to the right of **Code-list: <notification name>**.
9. You are taken to the **Code List** tab. Select ArchivesNotificationBody from **Clinical One Default Code List**.
10. Click the pencil icon in the upper-right corner.
11. Click in the **Label** cell to edit the content.

 **Tip:**

Copy and past the default text before making any changes. That way, you can restore the default text if needed.

12. Click **Save**.

Generate an archive or report

Learn how to generate an archive or report.

1. Navigate to the **Reports & Archives** tab.

For step-by-step instructions, see [Access the Reports & Archives page](#).







2. On the **Archives** tab, select the archive or report.
3. On the right, make sure **Settings** is expanded, and fill in the fields.

For more information about each archive and report and their settings, see Available archive types and reports.

4. Click **Run Report**.
5. Expand the **Download Archives** side panel.

A **Download** link is made available after processing completes. For more information see, Download an archive or report.

Table 4-2 Available actions on the Download Archives side panel

Icon	Description
	Pause a request with a status of Generating.
	Resume a request with a status of Paused.
	Cancel a request with a status of Generating or Paused. Cancelled requests appear under Download Archives until the request is deleted.
	Delete a completed, cancelled, or failed request.
	Reload Archives status retrieves updated request processing details for all requests with a status of Generating.
 Retry	Retry attempts to re-process failed files. Files that generated successfully are not be included in the retry attempt.

- [Available archive types and reports](#)
Learn more about each archive type, report, and its settings.

Available archive types and reports

Learn more about each archive type, report, and its settings.

- [Submission PDF](#)
Users assigned to a sponsor study role typically use this archive type for submission to the FDA and other regulatory agencies at the conclusion of a study. The information is automatically compiled and formatted according to the regulators' requirements.
- [Archival PDF \(for sponsor users\)](#)
Users assigned to a sponsor study role typically use this archive type for mid-study data analysis or to generate a final archive of study data. This makes the data available for auditors, sponsors, sites, and regulatory agencies.
- [Archival PDF \(for site users\)](#)
Users assigned to a site study role typically use this archive type for mid-study data analysis or to generate a final archive of study data. This makes the data available for auditors, sponsors, sites, and regulatory agencies.

- **Blank Form PDF**
Generate this type of archive to view a set of blank forms with active controls for each study version. The output contains no subject data.
- **Custom PDF**
This archive type gives users assigned to a sponsor study role access to all of the settings available in Oracle CRF Submit, letting them control what to include in the output.
- **Kit Chain of Custody (Blinded) report**
Some organizations require the sponsor and sites to archive the Kit Chain of Custody (Blinded) report. Still, not all organizations grant site access to the standard report, located under the **Reports** tab, and the standard report cannot be shared with sites.
- **Download Log report**
Users assigned to a sponsor study role can generate this report (CSV only) to view a history of all archive downloads performed by sponsor and site users in the Oracle Clinical One Platform user interface.
- **Site Confirmation report (for site and sponsor users)**
Sponsor and site users can generate this report (CSV or PDF) to view an audit history of confirmation actions performed by site users.

Submission PDF

Users assigned to a sponsor study role typically use this archive type for submission to the FDA and other regulatory agencies at the conclusion of a study. The information is automatically compiled and formatted according to the regulators' requirements.

Subject data in the output files match the data the user making the request can see in the user interface.

The request output ZIP file contains the following:

- A folder for each site containing PDFs for each subject.

Note:

Subject transfer history files (.prth files) are also included for transferred subjects.

- A set of blank PDFs containing active controls for each study version.
- A table of contents PDF.
- A request settings PDF outlining the settings used to generate the archive.

Modes




Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions

Users assigned to a sponsor study role that includes the following permission can generate this archive.

- *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*

Filters

Setting	Details
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
As of Date	<ul style="list-style-type: none"> Select Now (default) to include all data from the beginning of your study until the date displayed. Choose Select Date/Time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>The date entered must be after the date when the first study version was created.</p> </div>
Included in Report	<ul style="list-style-type: none"> Select All Subjects (default) to include data for all enrolled subjects in the request output. Choose Select Subjects to include data for a selection of enrolled subjects in the request output. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>If a subject number was changed, the As of Date determines what value is presented in the drop-down.</p> </div> <ul style="list-style-type: none"> Choose Select Sites to include data for a selection of sites and their subjects in the request output. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>You see the following when sites included in the archive have no subjects.</p> <ul style="list-style-type: none"> When hovering over the Request Settings icon to the left of the request name on the Download Archives side panel, you see all sites included in the archive, even those without subjects. The Zip file includes folders for only those sites with subjects. Also, the Table of Contents and the Request Settings PDF, included in the zip file, only include sites with subjects. </div>

Setting	Details
Page size	<ul style="list-style-type: none"> • Letter (default) 8-1/2" by 11" • A4 European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> • Select Casebook (default) to show all forms in every visit. • Select Unique Forms to show one of each blank form in every visit.
Header Text	<ul style="list-style-type: none"> • Enter up to 90 characters to appear at the top of each page. • The study name is the default.
Footer Text	<ul style="list-style-type: none"> • Enter up to 30 characters to appear at the bottom of each page. • **Confidential** is the default.
Advanced settings - Include RTSM data	<ul style="list-style-type: none"> • Select Yes to include subject RTSM data elements in site-level archives. • Select No (default) to exclude subject RTSM data. <p>For more information, see <i>When an Archives request includes RTSM data</i> below.</p>
Advanced settings - PDF security	<p>The security settings for this request type are set to No and are locked by default.</p> <ul style="list-style-type: none"> • The Prevent Form Changes setting controls the ability to create and apply a password to the PDF files generated by a request. • The Prevent Form Comments Changes and Prevent Context Extracts and Copying settings control the ability to add comments, annotations, and to copy PDF content. <p>When all three are set to No, users can add comments and annotations and copy PDF content without needing a password.</p>

When an Archives request includes RTSM data

The following Randomization and Dispensation details are included in subject PDFs when the setting **Include RTSM Data** is set to **Yes**. This advanced setting is available for Submission, Archival (Site and Sponsor), and Custom archive requests.

Randomization details

Subject PDFs include a **Subject History** section, which refers exclusively to Randomization events.

Note:

This section is unrelated to the Subject History right-side panel in the user interface, which includes details for events like screened and withdrawn, which are not included in the Subject History section of subject PDFs.

Table 4-3 The Subject History section in subject PDFs includes:

Action	Details
Randomized	<ul style="list-style-type: none"> • Randomization Date • Randomization Number

Dispensation details

Subject PDFs also include a **Visit History** section when Include RTSM Data is set to Yes.

Table 4-4 The Visit History section in subject PDFs includes:

Action	Details
Kit Dispensation	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • User
Kit Dispensation (Calculation)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Calculation • User
Kit Dispensation (Titration)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Titration • User
Replacement	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Replacement Kit • User
Dose Hold	<ul style="list-style-type: none"> • Date • Kit Description • User

Additional information

- Kits marked Not Dispensed to Subject are not included in the output.
- Before running your final extract, update your permissions to ensure unblinded pharmacist kit types and kit descriptions for blinded studies are included in the output.

Archival PDF (for sponsor users)

Users assigned to a sponsor study role typically use this archive type for mid-study data analysis or to generate a final archive of study data. This makes the data available for auditors, sponsors, sites, and regulatory agencies.

Subject data in the output files match the data the user generating the archive can see in the user interface.

The archive output ZIP file contains the following:

- A folder for each site containing PDFs for each subject. Subject transfer history files (.prth files) are also included for transferred subjects;
- A set of blank PDFs containing active controls for each study version;
- A table of contents PDF;
- A request settings PDF outlining the settings used to generate the archive.

Note:

The archive does not contain any associations between repeating forms assigned to different visits or form types, or associations between a repeating form and a standard form.

Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions

Users assigned to a sponsor study role that includes the following permission can generate this archive.





- *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*



Filters

Setting	Details
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
As of Date	<ul style="list-style-type: none"> • Select Now (default) to include all data from the beginning of your study until the date displayed. • Choose Select Date/Time to enter a specific date.

Note:

The date entered must be after the date when the first study version was created.

Setting	Details
Share with Sites	<ul style="list-style-type: none"> Select Yes (default) if you want the PDFs made available for download by site users. Select No if site users do not need to download the request.
Confirm Site Downloads	<ul style="list-style-type: none"> Select Yes (default) if you want site users to confirm downloading the archives shared with them. Select No if you do not require confirmation from site users.
	<div data-bbox="355 441 805 617" style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note: Only displayed if Share with Sites is Yes.</p> </div>
Included in Report	<ul style="list-style-type: none"> Select All Subjects (default) to include data for all enrolled subjects in the request output. Choose Select Subjects to include data for a selection of enrolled subjects in the request output.
	<div data-bbox="355 724 805 926" style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note: The Select Subjects option is only displayed if Share with Sites is No.</p> </div>
	<div data-bbox="867 814 1468 1016" style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note: If a subject number was changed, the As of Date determines what value is presented in the drop-down.</p> </div>
	<ul style="list-style-type: none"> Choose Select Sites to include data for a selection of sites and their subjects in the request output.
	<div data-bbox="867 1115 1468 1585" style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note: You see the when sites included in the archive have no subjects.</p> <ul style="list-style-type: none"> When hovering over the Request Settings icon to the left of the request name on the Download Archives side panel, you see all sites included in the archive, even those without subjects. The Zip file includes folders for only those sites with subjects. Also, the Table of Contents and the Request Settings PDF, included in the zip file, only include sites with subjects. </div>
Page Size	<ul style="list-style-type: none"> Letter (default) 8-1/2" by 11" A4 European letter size: 210 x 297 mm
Include Blank Forms	<ul style="list-style-type: none"> Select Yes (default) to include blank forms in the PDF output. Select No if blank forms are not needed.

Setting	Details
Blank Form Format	<ul style="list-style-type: none"> Select Casebook (default) to show all forms in every visit. Select Unique Forms to show one of each blank form in every visit. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: Only displayed if Include Blank Forms is Yes.</p> </div>
Header Text	<ul style="list-style-type: none"> Enter up to 90 characters to appear at the top of each page. The study name is the default.
Footer Text	<ul style="list-style-type: none"> Enter up to 30 characters to appear at the bottom of each page. **Confidential** is the default.
Advanced Settings - Include RTSM data	<ul style="list-style-type: none"> Select Yes to include subject RTSM data elements in site-level archives. Select No (default) to exclude subject RTSM data. <p>For more information, see <i>When an Archives request includes RTSM data</i> below.</p>
Advanced Settings - Allow archives to be stored in Oracle sFTP	<ul style="list-style-type: none"> Select Yes to send an archive to the Oracle sFTP server. Requests can then be programatically transferred to an eTMF system. Select No (default) if you do not need to send an archive to the Oracle sFTP server. <p>Before enabling this setting, see About eTMF .</p>
Advanced Settings - PDF security	<ul style="list-style-type: none"> The Prevent Form Changes setting controls the ability to create and apply a password to the PDF files generated by a request. <div style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: The setting defaults to Yes for this request type, and a password is created but cannot be retrieved.</p> </div> <ul style="list-style-type: none"> The Prevent Form Comments Changes and Prevent Content Extracts and Copying settings, which default to No, control the ability to add comments and annotations and to copy PDF content. Change to Yes if you'd like to prevent users from adding comments and annotations and copying PDF content.

When an Archives request includes RTSM data

The following Randomization and Dispensation details are included in subject PDFs when the setting **Include RTSM Data** is set to **Yes**. This advanced setting is available for Submission, Archival (Site and Sponsor), and Custom archive requests.

Randomization details

Subject PDFs include a **Subject History** section, which refers exclusively to Randomization events.

 **Note:**

This section is unrelated to the Subject History right-side panel in the user interface, which includes details for events like screened and withdrawn, which are not included in the Subject History section of subject PDFs.

Table 4-5 The Subject History section in subject PDFs includes:

Action	Details
Randomized	<ul style="list-style-type: none"> • Randomization Date • Randomization Number

Dispensation details

Subject PDFs also include a **Visit History** section when Include RTSM Data is set to Yes.

Table 4-6 The Visit History section in subject PDFs includes:

Action	Details
Kit Dispensation	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • User
Kit Dispensation (Calculation)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Calculation • User
Kit Dispensation (Titration)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Titration • User
Replacement	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Replacement Kit • User
Dose Hold	<ul style="list-style-type: none"> • Date • Kit Description • User

Additional information

- Kits marked Not Dispensed to Subject are not included in the output.
- Before running your final extract, update your permissions to ensure unblinded pharmacist kit types and kit descriptions for blinded studies are included in the output.

Archival PDF (for site users)

Users assigned to a site study role typically use this archive type for mid-study data analysis or to generate a final archive of study data. This makes the data available for auditors, sponsors, sites, and regulatory agencies.

Subject data in the output files match the data the user generating the archive can see in the user interface.

The archive output ZIP file contains the following:

- A folder for each site containing PDFs for each subject.

Note:

Subject transfer history files (.prth files) are also included for transferred subjects.

- A set of blank PDFs containing active controls for each study version.
- A table of contents PDF.
- A request settings PDF outlining the settings used to generate the archive.

Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions




Users assigned to a site study role that includes the following permissions can generate this archive.


- *Confirm download of Archival PDFs and content*
- *Download Archival PDFs, and Audit Reports*
- *Run Archival PDFs for your site(s)*

Setting	Details
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
As of Date	<ul style="list-style-type: none"> • Select Now (default) to include all data from the beginning of your study until the date displayed. • Choose Select Date/Time to enter a specific date.

Note:

The date entered must be after the date when the first study version was created.

Setting	Details
Included in Report	<ul style="list-style-type: none"> Select All Subjects (default) to include data for all enrolled subjects in the request output. Choose Select Subjects to include data for a selection of enrolled subjects in the request output.
	<p> Note:</p> <p>If a subject number was changed, the As of Date determines what value is presented in the drop-down.</p>
	<ul style="list-style-type: none"> Choose Select Sites to include data for a selection of sites and their subjects in the request output.
	<p> Note:</p> <p>You see the following when sites included in the archive have no subjects.</p> <ul style="list-style-type: none"> When hovering over the Request Settings icon to the left of the request name on the Download Archives side panel, you see all sites included in the archive, even those without subjects. The Zip file includes folders for only those sites with subjects. Also, the Table of Contents and the Request Settings PDF, included in the zip file, only include sites with subjects.
Page Size	<ul style="list-style-type: none"> Letter (default) 8-1/2" by 11" A4 European letter size: 210 x 297 mm
Include Blank Forms	<ul style="list-style-type: none"> Select Yes (default) to include blank forms in the PDF output. Select No if blank forms are not needed.
Blank Form Format	<ul style="list-style-type: none"> Select Casebook (default) to show all forms in every visit. Select Unique Forms to show one of each blank form in every visit.
	<p> Note:</p> <p>Only displayed if Include Blank Forms is set to Yes.</p>
Header Text	<ul style="list-style-type: none"> Enter up to 90 characters to appear at the top of each page. The study name is the default.
Footer Text	<ul style="list-style-type: none"> Enter up to 30 characters to appear at the bottom of each page. **Confidential** is the default.

Setting	Details
Advanced Settings - Include RTSM data	<ul style="list-style-type: none"> Select Yes to include subject RTSM data elements in site-level archives. Select No (default) to exclude subject RTSM data. <p>For more information, see <i>When an Archives request includes RTSM data</i> below.</p>
Advanced Settings - Allow archives to be stored in Oracle sFTP	<ul style="list-style-type: none"> Select Yes to send an archive to the Oracle sFTP server. Requests can then be programatically transferred to an eTMF system. Select No if you do not need to send an archive to the Oracle sFTP server. <p>Before enabling this setting, see About eTMF .</p>
Advanced Settings - PDF security	<ul style="list-style-type: none"> The Prevent Form Changes setting controls the ability to create and apply a password to the PDF files generated by a request. <div style="border: 1px solid #0070C0; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>The setting defaults to Yes for this request type, and a password is created but cannot be retrieved.</p> </div> <ul style="list-style-type: none"> The Prevent Form Comments Changes and Prevent Content Extracts and Copying settings, which default to No, control the ability to add comments and annotations and to copy PDF content. Change to Yes if you'd like to prevent users from adding comments and annotations and copying PDF content.

When an Archives request includes RTSM data

The following Randomization and Dispensation details are included in subject PDFs when the setting **Include RTSM Data** is set to **Yes**. This advanced setting is available for Submission, Archival (Site and Sponsor), and Custom archive requests.

Randomization details

Subject PDFs include a **Subject History** section, which refers exclusively to Randomization events.

 **Note:**

This section is unrelated to the Subject History right-side panel in the user interface, which includes details for events like screened and withdrawn, which are not included in the Subject History section of subject PDFs.

Table 4-7 The Subject History section in subject PDFs includes:

Action	Details
Randomized	<ul style="list-style-type: none"> Randomization Date Randomization Number

Dispensation details

Subject PDFs also include a **Visit History** section when Include RTSM Data is set to Yes.

Table 4-8 The Visit History section in subject PDFs includes:

Action	Details
Kit Dispensation	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • User
Kit Dispensation (Calculation)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Calculation • User
Kit Dispensation (Titration)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Titration • User
Replacement	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Replacement Kit • User
Dose Hold	<ul style="list-style-type: none"> • Date • Kit Description • User

Additional information

- Kits marked Not Dispensed to Subject are not included in the output.
- Before running your final extract, update your permissions to ensure unblinded pharmacist kit types and kit descriptions for blinded studies are included in the output.

Blank Form PDF

Generate this type of archive to view a set of blank forms with active controls for each study version. The output contains no subject data.

The archive output ZIP file contains the following:

- A set of blank PDFs containing active controls for each study version.
- A request settings PDF outlining the settings used to generate the archive.


Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions

Users assigned to a sponsor study role that includes the following permissions can generate this archive.

- *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*

Setting	Details
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
As of Date	<ul style="list-style-type: none"> • Select Now (default) to include all data from the beginning of your study until the date displayed. • Choose Select Date/Time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note:</p> <p>The date entered must be after the date when the first study version was created.</p> </div>
Page Size	<ul style="list-style-type: none"> • Letter (default) 8-1/2" by 11" • A4 European letter size: 210 x 297 mm
Blank Form Format	<ul style="list-style-type: none"> • Select Casebook (default) to show all forms in every visit. • Select Unique Forms to show one of each blank form in every visit.
Study Versions	<ul style="list-style-type: none"> • Select All Versions (default) to include blank forms from all study versions. • Choose Select Versions to include blank forms from specific study versions.
Header Text	<ul style="list-style-type: none"> • Enter up to 90 characters to appear at the top of each page. • The study name is the default.
Footer Text	<ul style="list-style-type: none"> • Enter up to 30 characters to appear at the bottom of each page. • **Confidential** is the default.
Advanced settings - PDF security	<p>The security settings for this request type are set to No and are locked by default.</p> <ul style="list-style-type: none"> • The Prevent Form Changes setting controls the ability to create and apply a password to the PDF files generated by a request. • The Prevent Form Comments Changes and Prevent Context Extracts and Copying settings control the ability to add comments, annotations, and to copy PDF content. <p>When all three are set to No, users can add comments and annotations and copy PDF content without needing a password.</p>

Custom PDF

This archive type gives users assigned to a sponsor study role access to all of the settings available in Oracle CRF Submit, letting them control what to include in the output.

The archive output ZIP file contains the following:

- A folder for each site containing PDFs for each subject. Subject transfer history files (.prth files) are also included for transferred subjects;
- A set of blank PDFs containing active controls for each study version;
- A table of contents PDF;
- A request settings PDF outlining the settings used to generate the archive;

Modes


Available only in Testing and Production mode. To get started, Access the Reports & Archives page.





Required permissions



Users assigned to a sponsor study role that includes the following permission can generate this archive.




- *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*

Filters

Setting	Details
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
As of Date	<ul style="list-style-type: none"> • Select Now (default) to include all data from the beginning of your study until the date displayed. • Choose Select Date/Time to enter a specific date. <div style="border: 1px solid #0070C0; padding: 10px; margin-top: 10px;"> <p> Note: The date entered must be after the date when the first study version was created.</p> </div>
Share with Sites	<ul style="list-style-type: none"> • Select Yes if you want the PDFs made available for download by site users. • Select No (default) if site users do not need to download the request.

Setting	Details
<p>Confirm Site Downloads</p> <div data-bbox="565 310 906 514" style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: Only displayed if Share with sites is Yes.</p> </div>	<ul style="list-style-type: none"> • Select Yes (default) if you want site users to confirm downloading the archives shared with them. • Select No if you do not require confirmation from site users.
<p>Included in Report</p> <div data-bbox="565 625 906 850" style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: The Select Subjects option is only displayed if Share with Sites is No.</p> </div>	<ul style="list-style-type: none"> • Select All Subjects (default) to include data for all enrolled subjects in the request output. • Choose Select Subjects to include data for a selection of enrolled subjects in the request output. <div data-bbox="971 741 1471 976" style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: If a subject number was changed, the As of Date determines what value is presented in the drop-down.</p> </div> <ul style="list-style-type: none"> • Choose Select Sites to include data for a selection of sites and their subjects in the request output. <div data-bbox="971 1098 1471 1686" style="border: 1px solid #0070C0; padding: 5px; margin-top: 10px;"> <p> Note: You see the following when sites included in the archive have no subjects.</p> <ul style="list-style-type: none"> – When hovering over the Request Settings icon to the left of the request name on the Download Archives side panel, you see all sites included in the archive, even those without subjects. – The Zip file includes folders for only those sites with subjects. Also, the Table of Contents and the Request Settings PDF, included in the zip file, only include sites with subjects. </div>
<p>Page Size</p>	<ul style="list-style-type: none"> • Letter (default) 8-1/2" by 11" • A4 European letter size: 210 x 297 mm
<p>Include Blank Forms</p>	<ul style="list-style-type: none"> • Select Yes to include blank forms in the PDF output. • Select No (default) if blank forms are not needed.

Setting	Details
Blank Form Format <div style="border: 1px solid #0070c0; padding: 10px; margin-top: 10px;">  Note: Only displayed if Include Blank Forms is Yes. </div>	<ul style="list-style-type: none"> Select Casebook (default) to show all forms in every visit. Select Unique Forms to show one of each blank form in every visit.
Study Versions <div style="border: 1px solid #0070c0; padding: 10px; margin-top: 10px;">  Note: Only displayed if Include Blank Forms is Yes. </div>	<ul style="list-style-type: none"> Select All Versions (default) to include blank forms from all study versions. Choose Select Versions to include blank forms from specific study versions.
Header Text	<ul style="list-style-type: none"> Enter up to 90 characters to appear at the top of each page. The study name is the default.
Footer Text	<ul style="list-style-type: none"> Enter up to 30 characters to appear at the bottom of each page. **Confidential** is the default.
Advanced Settings - Display in Archive Header	Select the items to appear at the top of every page in the PDF file. <ul style="list-style-type: none"> Form Version: Select Yes (default) or No Visit Name and Number: Select Yes (default) or No Site Name and Number: Select Yes (default) or No Sponsor Name: Select Yes or No (default) Protocol Name: Select Yes or No (default)
Advanced Settings - Data Inclusion and Format	<ul style="list-style-type: none"> Include Study Name in the Subject File Name: Select Yes (default) or No Forms to Include: All forms are included by default Visits to Include: All visits are included by default Include RTSM Data: Select Yes to include randomization and dispensing information for subjects at your sites. For additional details about this setting, see <i>When an Archives request includes RTSM data</i> below. The default is No. Include Bookmark Prefixes: Select Yes or No(default) Audit Trail Location: Select After each form (default) or End of PDF. Generate TOC (table of contents): select Yes (default) or No

Setting	Details
Advanced Settings - Security	<ul style="list-style-type: none"> Prevent Form Changes: Select Yes to require a password to make changes to the PDF. No is the default. <div data-bbox="974 373 1468 632" style="border: 1px solid #0070C0; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>When Yes is selected, the Password and Confirm Password fields dynamically appear. Passwords entered are not saved and cannot be retrieved by Oracle.</p> </div> <ul style="list-style-type: none"> Prevent Form Comment Changes: Defaults to No. Select Yes to prevent comments and annotations from being added to the output PDF without the password. <div data-bbox="974 787 1468 957" style="border: 1px solid #0070C0; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>The option is only active if Prevent Form Changes is Yes.</p> </div> <ul style="list-style-type: none"> Prevent Content Extracts and Copying: Defaults to No. Select Yes to prevent contents being copied from the output PDF without the password. <div data-bbox="974 1117 1468 1291" style="border: 1px solid #0070C0; padding: 10px; margin: 10px 0;"> <p> Note:</p> <p>This option is only active if Prevent Form Changes is Yes.</p> </div>
Advanced Settings - Allow archives to be stored in Oracle sFTP	<ul style="list-style-type: none"> Select Yes to send an archive to the Oracle sFTP server. Requests can then be programatically transferred to an eTMF system. Select No (default) if you do not need to send an archive to the Oracle sFTP server. <p>Before enabling this setting, see About eTMF .</p>

When an Archives request includes RTSM data

The following Randomization and Dispensation details are included in subject PDFs when the setting **Include RTSM Data** is set to **Yes**. This advanced setting is available for Submission, Archival (Site and Sponsor), and Custom archive requests.

Randomization details

Subject PDFs include a **Subject History** section, which refers exclusively to Randomization events.

 **Note:**

This section is unrelated to the Subject History right-side panel in the user interface, which includes details for events like screened and withdrawn, which are not included in the Subject History section of subject PDFs.

Table 4-9 The Subject History section in subject PDFs includes:

Action	Details
Randomized	<ul style="list-style-type: none"> • Randomization Date • Randomization Number

Dispensation details

Subject PDFs also include a **Visit History** section when Include RTSM Data is set to Yes.

Table 4-10 The Visit History section in subject PDFs includes:

Action	Details
Kit Dispensation	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • User
Kit Dispensation (Calculation)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Calculation • User
Kit Dispensation (Titration)	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Titration • User
Replacement	<ul style="list-style-type: none"> • Date • Kit Number • Kit Description • Kit Status • Replacement Kit • User
Dose Hold	<ul style="list-style-type: none"> • Date • Kit Description • User

Additional information

- Kits marked Not Dispensed to Subject are not included in the output.
- Before running your final extract, update your permissions to ensure unblinded pharmacist kit types and kit descriptions for blinded studies are included in the output.

Kit Chain of Custody (Blinded) report

Some organizations require the sponsor and sites to archive the Kit Chain of Custody (Blinded) report. Still, not all organizations grant site access to the standard report, located under the **Reports** tab, and the standard report cannot be shared with sites.

The same report, with different settings, located under the **Archives** tab, can be shared with sites. The settings for each report are different but the output is the same, as the content is pulled from the same database tables.

For more information about the standard report, including output details (for both), see the standard Kit Chain of Custody (Blinded) report.

The report 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

Once generated, the report is available for site download under the **Download Archives** side panel.

Download and confirmation (optional) details are captured in the Download Log report and the Site Confirmation report.

Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions


Users assigned to a sponsor study role that includes the following permission can generate this report.

- *Run the Blinded Chain of Custody Report*

Table 4-11 Kit Chain of Custody (Blinded) report settings

Settings	Description
Name	Enter a unique name (alphanumeric characters only) that does not exceed 64 characters.
Include Audit Trail	<ul style="list-style-type: none"> • Select Yes (default) to see the current kit status plus all historical changes to them. • Select No to see only the current Kit status.

Table 4-11 (Cont.) Kit Chain of Custody (Blinded) report settings

Settings	Description
Transaction Date	Select a date range for the report. The report will include only kits with status changes during the date range.
<div style="border: 1px solid #0070C0; padding: 10px; background-color: #E6F2FF;"> <p> Note: Only displays if Include Audit Trail is set to Yes.</p> </div>	
Share with Sites	This setting is defaulted to Yes and cannot be changed, as the intent of this report is to be shared with the sites.
Confirm Site Downloads	<ul style="list-style-type: none"> • Select Yes (default) if you want site users to confirm downloading the report shared with them. • Select No if you do not require confirmation from site users.
Location	<ul style="list-style-type: none"> • Select one or more sites or depots to include only the kits at the location in the report. • Leave it set to All to include kit types at all locations.

Download Log report

Users assigned to a sponsor study role can generate this report (CSV only) to view a history of all archive downloads performed by sponsor and site users in the Oracle Clinical One Platform user interface.

Requests downloaded from the Oracle sFTP server are not included in this report. For more information, see About eTMF.

A final version of this report is included in the pluggable database (PDB) package that is provided to the customer during the study decommission process. For more information, see Decommission a production study.

Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions

Users assigned to a sponsor study role that includes the following permissions can generate this report.

- *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*

Site Confirmation report (for site and sponsor users)

Sponsor and site users can generate this report (CSV or PDF) to view an audit history of confirmation actions performed by site users.

Sponsor users can share the Archival PDF (for sponsor users), Custom PDF, and the Kit Chain of Custody (Blinded) report with site users and request that they confirm they have downloaded and reviewed the content.

This report includes the confirmation date and time, the user name of the person who performs the action, and the status (Confirmed and Not Confirmed) of each archive shared with sites where confirmation is requested.

- For sponsor users, the report includes confirmation details for all sites in a study, but site users can only see details for their assigned sites.
- Requests shared with sites and later deleted by the sponsor appear in the report with the status of Not Confirmed.
- The pluggable database (PDB) package, provided to the customer during the study decommission process, includes a final version of this report. For more information, see Decommission a production study.

Modes

Available only in Testing and Production mode. To get started, Access the Reports & Archives page.

Required permissions

Users assigned to one of the following permissions can generate this report.

- **Sponsor users:** *Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation*
- **Site users:** *Confirm download of Archival PDFs and content (Site)*

Download and Confirm an archive or report request

Learn how to download archive and report requests and provide confirmation when requested.

Users receive a notification when an archive or report is ready to be downloaded. For more information, see In-application and Email Notifications.



Note:

The Download Log contains an audit history for each archive and report downloaded. The report does not include details for archives or reports manually downloaded from the Oracle sFTP server. For more information about the ability to deliver archives to the sFTP server, see About eTMF.

1. Access the Reports & Archives page.
2. Click the **Archives** tab, then click on the archive or report type you want to download.
3. Expand the **Download Archives** side panel, locate the archive or report, and click **Download**.

Site users assigned to a study role that includes the permission *Confirm download of Archival PDFs and content* see a pop-up reminder if the sponsor user who generated the request requires site confirmation. After clicking **OK**, a **Confirm** link appears under **Download**.

 **Note:**

If multiple users at a site download a request without confirming it, the pop-up reminder appears until the confirmation process is complete.

4. If confirmation is required, click **Confirm** in the **Download Archives** side panel. The **Confirm Download** widow opens.
5. Read the confirmation text, check **I agree to the terms above**, and then click **Confirm**. The Confirmed date is displayed.

 **Note:**

The Site Confirmation report includes all site confirmation actions.

About Electronic Trial Master File (eTMF)

Use this feature to send Archival PDF (sponsor), Archival PDF (site), and Custom PDF archive requests to the Oracle sFTP server, where they can be programmatically retrieved for import into an eTMF system.

About eTMF

- The primary purpose of this feature is to allow you to programmatically transfer archives from the Oracle sFTP server to your eTMF system.
- In order to maintain data integrity for your study, it is suggested that study users are not granted access to the sFTP folder.
 - Content delivered to the sFTP server includes all data the user who created the archive request can see in a study. In some cases, viewing this data could result in unblinding if the wrong user were to download and view it.
 - Manual downloads from the sFTP server are not tracked in the Download Log or Site Confirmation report.

eTMF setting and archive retention

- The setting, **Allow archives to be stored in Oracle sFTP**, is available for the following archive types:
 - Archival PDF (for sponsor users)
 - Archival PDF (for site users)
 - Custom PDF
- When the setting **Allow archives to be stored in Oracle sFTP** is set to **Yes**, archives are delivered to the sFTP server and are available in the Oracle Clinical One Platform user interface. When set to **No**, archives are only available in the user interface.
- Deleting an archive from one location (sFTP or the user interface) does not delete it from the other.
- Archives are automatically deleted from the sFTP server after 60 days and from the user interface after 120 days.

Named sFTP account details

The username and password of this account are used to access the Oracle sFTP server to retrieve requests programmatically. The email address, first name, and last name of an individual need to be included in the request to create this account.

WARNING:

Archives include all of the data the user who created the request can see in a study. The person associated with the named sFTP account can access the sFTP server and manually download requests. This could result in unblinding if the request contains data that the sFTP user should not have access to.

Request a named sFTP account

Follow these steps to create a request for a named sFTP account.

1. Log into [Oracle Life Sciences Support Cloud](#).
2. Click **Create Request** in the upper-right corner, then select **Change Request**.
3. Click the **Maintain an application** tile.
4. Click the **Request user access** tile, then complete the following fields.
 - **Summary:** Requesting the creation of an sFTP named account and sFTP folder access.

Note:

If you want to grant permission to an existing sFTP account, enter *Please grant folder access to an existing sFTP user*.

- **Severity:** Medium
- **Description:** Grant <enter first name, last name, and email> Read Only access to the sFTP directory defined in this request.

Note:

To grant access to an existing sFTP account, enter *Grant <enter username> Read Only access to the sFTP directory defined in this request*.

- **Category:** Change-Cloud Infrastructure > Infrastructure Services > SFTP > User > Add

Note:

Select **Change** in place off **Add** to for an existing sFTP account.

- **Customer:** Select your company's name
- **Product:** CRF Submit

- **Business Service:** CRF Submit-customer name
- **Environment:** Prod/Live
- **Implementation Window:** Make a selection
- **Action:** Leave set to **No value**
- **sFTP:** Leave the check box unchecked and enter */clients/<enter tenant name>.crfs/* as the path. Requests for any study using eTMF associated with the tenant entered are deposited at this path.
- **Date Required:** Enter a date

Error handling

If errors are encountered while copying files to the sFTP server, the request is marked as Failed in the user interface, and the reason captured (in the FailureReport.txt file) is *Request output could not be copied to the sFTP location*.

 **Note:**

An archive can still be downloaded in the user interface even if an error is encountered copying files to the sFTP server.

5

Troubleshoot

- [Browse the Known Issues List](#)
When you are running into issues related to any of the Oracle Clinical One Platform standard reports, extracts, or archives, make sure you browse the Known Issues List.
- [Plus and minus characters cannot be displayed in a CSV file](#)
When generating reports, note that the plus (+) and minus (-) characters are not properly displayed in reports that are generated in CSV format. This applies to reports generated by both site and sponsor users. While this issue does not cause any data loss for your study, it does prevent you from properly viewing your study's collected data.
- [What are the limitations on SAS variables, data set names, and labels?](#)
You can avoid issues with your data extracts in Oracle Clinical One Platform by following certain guidelines when creating SAS elements.
- [What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?](#)
Follow these steps to render multi-byte characters, including Chinese characters, in Microsoft Excel.

Browse the Known Issues List

When you are running into issues related to any of the Oracle Clinical One Platform standard reports, extracts, or archives, make sure you browse the Known Issues List.

The Known Issues List can be found on My Oracle Support (MOS). For more information, see the [Known Issues List](#).

Plus and minus characters cannot be displayed in a CSV file

When generating reports, note that the plus (+) and minus (-) characters are not properly displayed in reports that are generated in CSV format. This applies to reports generated by both site and sponsor users. While this issue does not cause any data loss for your study, it does prevent you from properly viewing your study's collected data.

This issue is caused by the way certain characters are processed in Microsoft Excel. Whenever a data string starts with the plus character (+) or the minus character (-), Microsoft Excel attempts to apply a calculation formula in that specific cell.

If a site user enters any of these two characters in a field, when you attempt to generate a report in a CSV format and open that file in Microsoft Excel, the data for that field will not be correctly processed by Microsoft Excel.

What are the limitations on SAS variables, data set names, and labels?

You can avoid issues with your data extracts in Oracle Clinical One Platform by following certain guidelines when creating SAS elements.

SAS variables

- When creating variables, do not use the names of special SAS automatic variables (for example, `_N_` and `_ERROR_`) or special variable list names (for example, `_CHARACTER_`, `_NUMERIC_`, and `_ALL_`).
- The maximum length of a variable is 32 bytes.
- The first character must be an English letter (A–Z, a–z) or an underscore (`_`). Subsequent characters can be letters, numeric digits (0, 1, . . . , 9), or underscores.
- The name cannot contain blank spaces or special characters except for an underscore.
- You can use uppercase or lowercase letters.
- The name can contain mixed–case letters.

Note:

SAS stores and writes the variable name in the same case that is used in the first reference to the variable. However, when SAS processes variable names, SAS internally converts it to uppercase. You cannot, therefore, use the same variable name with a different combination of upper and lowercase letters to represent different variables. For example, `cat`, `Cat`, and `CAT` all represent the same variable.

- Trailing blanks are ignored. The name alignment is left-justified.

SAS data set names and file names

- When creating SAS data sets, do not use these names: `_NULL_`, `_DATA_`, `_LAST_`.
- The maximum length of a data set name is 32 bytes.
- The first character must be an English letter (A–Z, a–z) or an underscore (`_`). Subsequent characters can be letters, numeric digits (0, 1, . . . , 9), or underscores.
- The name cannot contain blank spaces or special characters except for an underscore.
- You can use uppercase or lowercase letters.
- The name can contain mixed-case letters.

Note:

SAS internally converts the member name to uppercase. Do not use the same member name with a different combination of uppercase and lowercase letters to represent different variables. For example, `customer`, `Customer`, and `CUSTOMER` all represent the same member name. How the name on the disk appears is determined by the operating environment.

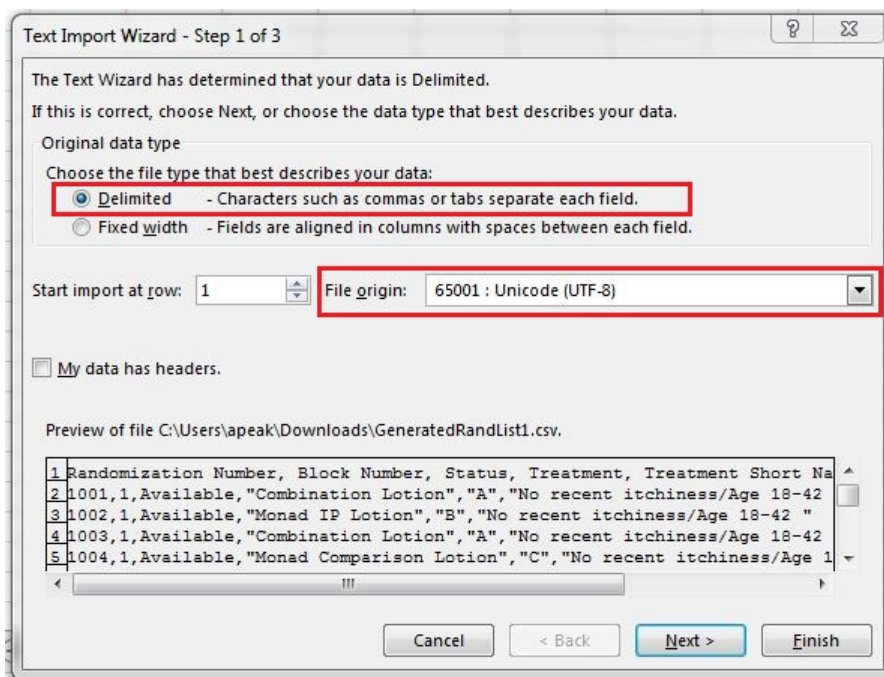
SAS labels

- The maximum length is 256 bytes.

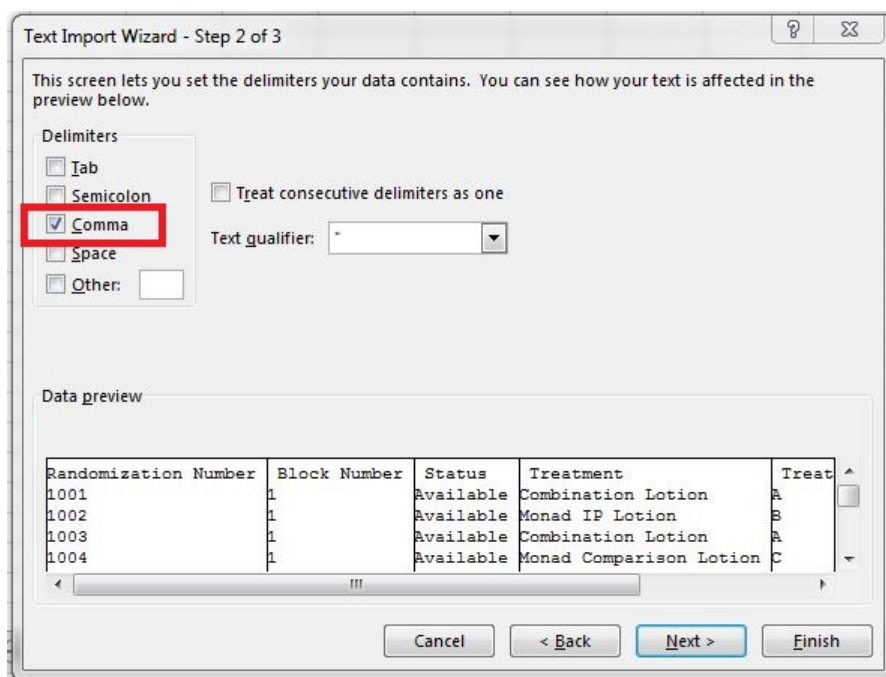
What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?

Follow these steps to render multi-byte characters, including Chinese characters, in Microsoft Excel.

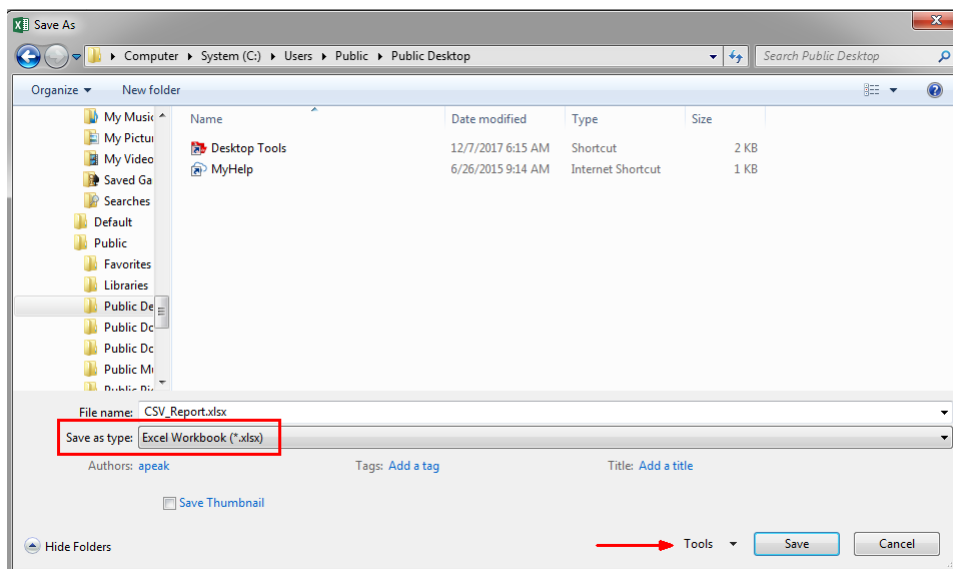
1. Open Microsoft Excel.
2. On the **Data** tab, in the Get External Data section on the left, click **From Text**.
3. Navigate to the saved report file, select it, and click **Import**.
4. In the Text Import Wizard dialog box, select the **Delimited** file type, and then from the **File origin** drop-down, select **65001: Unicode (UTF-8)**.



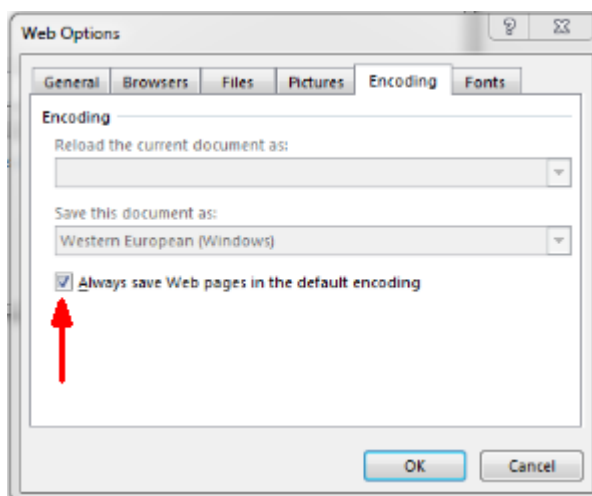
5. Click **Next**.
6. In the Delimiters section, select **Comma**.



- Click **Finish**.
- The Import Data dialog box appears.
- Click **New Worksheet**, and then click **OK**.
 - On the **File** tab, click **Save As**, and select a location for your file.
 - Enter a name for the report in **File name**, and from the **Save as type** drop-down, choose **Excel Workbook (*.xlsx)**.



- From the **Tools** drop-down, select **Web Options**.
- Along the top, select the **Encoding** tab, and from the **Save this document as** drop-down, select **Unicode (UTF-8)**.
- Select **Always save Web pages in the default encoding** button, and then click **OK** and then **Save**.



6

Revision History

Table 6-1 Revision history

Date	Part number	Description
01-July-2024	F91499-06	<ul style="list-style-type: none">Included updates related to the new Subject Randomization Data Extract in the following topics:<ul style="list-style-type: none">– Subject Randomization Data Extract
31-May-2024	F91499-05	Renamed the Replaced Kit ID column title to Replaced Kit Number, as well as updated the description of that column. See the Subject Events report .
21-May-2024	F91499-04	Section 2 Standard reports and section 3 Data extracts were renamed making it easier for users to differentiate between Oracle Clinical One Platform reports, data extracts, and Oracle CRF Submit archives and reports.
10-May 2024	F91499-03	Details about what gets included in Oracle CRF Submit archives when sites have no subjects was added to the following: <ul style="list-style-type: none">• Submission PDF• Archival PDF (for sponsor users)• Archival PDF (for site users)• Custom PDF
06-May-2024	F91499-02	Content about the increase in Oracle CRF Submit storage server allocation from 100 GB to 1000 GB was added to the following: <ul style="list-style-type: none">• About archives and reports• Email and in-application notifications
02-May-2024	F91499-01	Original version of this document.