Oracle® Health Sciences Clinical One Platform

Reporting Guide

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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.

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 achive 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.

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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.

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)
- 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 Health 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:**
>
> Reach out to your Customer Success Manager (CSM) or Oracle Project Manager if you have questions about creating Change Requests.

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.

Video

- 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.
- 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.

- 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.
- 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.
- 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.
- 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 (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.

- 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.
- Subject Dispensation report
  In this report, you view dispensation information for a subject at a site.
- 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 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 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 visits for each subject, along with titration details for each of these visits. 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 and User Assignment by Site report
  These reports contain the same data organized differently. You can run each report only for the locations that you are assigned to. In both reports, you view details about users, organized by the site or depot they're associated with.
- User Upload Error report
  This report contains error details for issues encountered during upload. After reviewing the errors, make corrections in the upload file and re import.

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.

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
Question	Indicates a question's title, as well as the question's hint, 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), and many more
Validations	A question's validation rules or rules related to dynamic questions and forms
Advanced	A question's advanced properties such as SAS variables, SAS Labels, Lab Normals Tag, Data Classifications, Source Data Verification

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

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, Testing, Training, and Production

Permission required to run the report

Any user who's assigned the *Run the Study Roles Report* permission 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

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

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 an 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 **Note:** This field appears only for Predictive Resupplies.
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.
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: • 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: – 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
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

Fields in Depot Addresses Information	Description
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)

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.
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

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.

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
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
Site Name	A site's name as entered by the site manager when they created the site

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
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), and Dispensed
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
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

Fields in Kit section	Description
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

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.

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.
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

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
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), and Dispensed
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
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

Fields in Kit section	Description
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

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	(Available only if you select a subject) Choose a visit to include only the kits dispensed during the visit.
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
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
Location	The location you selected for audit history, either a site or depot

Fields in the table header	Description
Site ID	The site's ID as entered by the site manager when they created the site

Fields in the table header	Description
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	Description
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 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
Reason for Change	Where applicable, a user indicates a reason for change. Not all state changes require this additional comment
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.

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
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
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 What statuses can kits have? 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.

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.
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
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
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 What statuses can kits have? 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.

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
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 (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, or PDF.
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
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

Initial fields	Description
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.

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 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.
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
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

Fields displayed for every selected form title	Description
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.

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.
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: 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
Report generated by	User name of the user who generated the report
Created date	UTC time and date of when this report was run

Initial fields	Description
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
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
Shipment Type	A shipment can be Initial, Resupply, or 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

Note:

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.

Fields displayed for every order	Description
Temperature Monitor Status	The status of a temperature monitor included in a shipment. For example, the temperature monitor status might be: • **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. **Note:** If your study does not allow for temperature excursions, this column will display as N/A.
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
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

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: It's 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

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
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	The allowed duration of a visit
Last Modified	Last time the visit was modified in any way
Last Modified User	Email address 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

Branches	Description
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
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	Email address 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	Email address 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
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)
Answer Type	The type of answer chosen for each question
List of Values	Answer options shown for a drop-down question, or a question with checkboxes or radio buttons. Also displays the code and description of code list items, if code lists are used for questions with multiple options for an answer
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

Forms	Description
Properties	Properties applied to a question: • 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
Character Limit	Indicates whether there's a character limit, typically for a text or number question
Format	Specifies the format details for each question: • 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	Email address of the user who performed the latest change (typically a study designer)

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.

Kits	Description
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
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	Email address of the user who performed the latest change (typically a study designer

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)

Calculated Doses	Description
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 traction

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
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

Kit Dispensation	Description
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)

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.

Randomizations	Description
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	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	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

Generated Randomization List	Description
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	Name of the setting configured in the study, such as: • Allow Subjects to be Manually Added • Allow Site to Select Subject Number • Include Hyphen Between Site and Subject Numbers • Leading Zeros in Subject Number • Subject Number Format • First Subject Number • Subject Numbering • Withdraw Subjects After Code Break • Limit Screened Subjects For more details on what subject settings you can configure and display in the Study Design report, see Specify study, visit, limit, and cohort settings .
Value	Indicates the value set for each subject setting
Last Modified	The date when each setting was configured
Last Modified User	Email address 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 Settings	Description
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: • 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	Email address of the user who performed the latest change (typically a clinical supply manager)

Source Data Verification	Description
Setting	Name of the setting configured in the study, such as: • 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	Email address of the user who performed the latest change for the SDV strategy

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 ever been randomized in the study.
- The number of subjects that were 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 who's assigned the *Run the Enrollment Report* permission can generate this report.

Filters

Filter	Description
Include Audit Trail	Choose Yes to see the current values plus all historical changes to them; choose 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: 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 before going live with your study
Include Audit Trail	Setting that indicates if you included audit trails in your report or not

Initial fields	Description
Report Generated By	Username of the user who generated this report
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 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
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	Username of the user who made the latest 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

Fields in Cohort Enrollment	Description
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	Username 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
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	Username of the user who made the latest change

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 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
- 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.
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.
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.

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
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
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
Type of Change	Indicates whether a question was created, modified, signed, unsigned, verified, unverified, or frozen by a lead site user or Clinical Research Associate (CRA)

Fields in every subject's section	Description
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 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
SCRNFDTC	Date when the subject was screen failed
RANDDTC	Date when the subject was randomized
TERMDTC	Date when the subject was withdrawn from the study
COMPDTC	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 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. Do 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.
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.
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.

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

Initial fields	Description
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
Subject Number	User-friendly subject identifier
Event Type	Indicates the data collection status of the event, such as: New Subject, Visit Started, Visit Completed, Screened, Randomized, Signed, Unsigned, Verified, Unverified, Code Break, etc.
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, 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 New, In Progress, Complete or N/A
Visit/Event Date	Date of the scheduled visit
Date	UTC date and time of a subject's event specified in the Event Type column
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
Randomization Number	Indicates a subject's randomization number if assigned in the event
Dispensation Kit Number	Indicates a kit's dispensation number if assigned in the event
Transfer Original Site	Site a subject is transferred from
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

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.
- Lastly, the study team can see whether any trends reveal issues.
  For instance, if CRAs are querying the same data point across all sites, changes might need to be made. For instance, you might need to edit a question or its hint, update an edit check on a question, or revisit 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.
Visits	Choose one or more visits to include only the queries raised for the visits, or leave the filter blank to include queries for all visits.
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.

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
Locations	The site were the queries were raised
Action Target	The user role for assigned to this query and email details when the rule indicates email notifications.
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 were the queries were raised
Subject ID	The number of the subject for whom the queries were raised
Age of Query	A query's age listed in years
Last Query State	A query's current state can be either Candidate, Opened, Closed, Answered, or Deleted
Visit/Event	Name of the visit that contains the query
Visit/Event Instance	An unscheduled visit's number or branch visit instance that contains the query
Repeating Form 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.

Fields displayed for each site with associated subject and queries	Description
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"
Question	Label of the question that contains the query
Query State	Lists the states of a query throughout time
Query Comment	Comment entered by user every time a query is updated
Value	Entered value that initiated the query
Unit of Measure	Data from the defined form
Last Updated on Site	Value only changes with transferred subjects
Last Modified By	User name of the user who last modified a query
Last Modified Date/Time	UTC date and time (DD-MM-YYYY HH:MM:SS) of the latest query update
User Name	The user who requested the last transaction. This is displayed when the Audit Trail filter is set to **No**.
Last Transaction Date	The date and time in UTC (DD-MM-YYYY HH:MM) when the last transaction ocurred. This is displayed when the Audit Trail filter is set to **No**.

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
Visit Type	Choose **All** to include all visits in a study or **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 **Active** to only include data related to active subjects in a study (typically, these are subjects who have been randomized in a study). Choose **All Subjects** to include data related to all subjects in a study, no matter what their state they're in.
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.

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
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
Visit Title	A visit's title as entered by a study designer
Unscheduled Visit Number	Number of the unscheduled visit a subject attended

Fields displayed for every selected site and subject	Description
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
Last Modified By	User name of the user who last performed this transaction

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
Visit Type	Choose **All** to include all visits in a study or **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 **Active** to only include data related to active subjects in a study (typically, these are subjects who have been randomized in a study). Choose **All Subjects** to include data related to all subjects in a study, no matter what their state they're in.
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.

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
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.

Fields displayed for every selected site and subject	Description
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
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
Last Modified By	User name of the user who last performed this transaction

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 Numbers	Numbers of kits used in titrations
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 visits for each subject, along with titration details for each of these visits. 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	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.
Treatment Arm	Choose a treatment arm to include only 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 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
Treatment Arm	The treatment arms you selected for this report

Fields about titration data in a study	Description
Subject	The subject's ID (displayed in the header)
Treatment Arm	The treatment arm the subject is on (displayed in the header)
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 Numbers	Numbers of kits used in titrations
Kit Numbers - Descriptions	Kit numbers used in titrations, as well as their descriptions
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

User Assignment and User Assignment by Site report

These reports contain the same data organized differently. You can run each report only for the locations that you are assigned to. In both reports, you view details about users, organized by the site or depot they're associated with.

Details include:

- 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
- If you include historical information, all changes that have been made to the user

There are a number of use cases for running these reports:

- 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.

Which report is better for you? Here are some guidelines to help you choose:

- **User Assignment by Site** is available in HTML and PDF 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.
- **User Assignment** 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.

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 and User Assignment by Site reports.

Filters

Filter	Description
Location Type	Choose whether to include user assignment information for sites, depots, or 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.

Filter	Description
Data Type	Choose **Current Data** to see the users' current assignments. Choose **Historical Data** to see every change that has been made to the user.
File Type	Choose the output type for the report: • For the User Assignment report: CSV, HTML, or PDF • For the User Assignment By Site 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 rant his report
Location Type	Type of location as selected by user who generated the 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
Data Type	Indicates whether the generated report contains historical or current data
Trainee User Name/ User Name	User Assignment report indicates the selected user's name. User Assignment by Site report indicates the selected trainee's user name.
Location	The location you selected for audit history, either a site or depot
Last Modified By	User name of the user who last modified a user's assignments

Fields for users assigned to a study or site	Description
User Name	User assigned to the study
Study Role	The study role that is assigned to the user
Roles	Currently can have one or more roles assigned to provide appropriate access
Organization	A site the user is assigned to (available for User Assignment report only)
State	The state defined for a site or depot (available for User Assignment report only)
Country	The country defined for a site or depot (available for User Assignment report only)
Effective Start Date	When the user could sign into the study

Fields for users assigned to a study or site	Description
Effective End Date	Either No End Date or the date entered to terminate a user's access
Last Login	Date user last signed in 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 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. For more information, review About uploading & assigning users in bulk

User Upload Error report

This report contains error details for issues encountered during upload. After reviewing the errors, make corrections in the upload file and re import.

For additional information about creating user accounts in Oracle Clinical One Platform review, About creating user accounts using the upload template

This report is available in CSV format only.

Modes

Available for the following modes: Production, and Training.

Permission required to run the report

Any user who's assigned the *Upload Users in Bulk* permission can generate this report.

Filters

Filter	Description
Date Range	Select a **From** and **To** date range for the report output.
File Type	This report is only available in CSV file output.

Field Descriptions

Initial fields	Description
Customer Name	The 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 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.

Fields in this report	Description
First Name	First name of the user created.
Last Name	Last name of the user created.
Email	Email address of the user created.
User Name	User name assigned to the user created.
Start Date	The date included in the import file indicating the first day the user can access the study.
End Date	The date included in the import file indicating the last day the account will be active.
Role	The name of the study role assigned to the user.
Sites	The site or list of sites the user was assigned to.
Depots	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 was imported.
Error Message	A list of any error's encountered for each user.

Note:

This field is not part of the import template, it is included in the user interface and is completed during the import process.

3

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.

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.

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 now extract cumulative subject data for data analysis or regulatory reporting for the study that they're working in.

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 Health 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*.
- Assign the **ODM Extract** study role to your users in Oracle Clinical One Platform. See Assign a study role to a user in the *Health Sciences Clinical One Platform Add Users*.

To learn more about the ODM Extract permissions, see ODM Extract Permissions.

To learn more about ODM-XML data extracts, see Perform 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.
- **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 now extract cumulative subject data for data analysis or regulatory reporting for the study that they're working in.

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. Additionally, 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.

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.

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]

> **Note:**
>
> 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".

Modes

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

Roles that can extract data

Any user that's assigned the *Run the Blinded Subject Data Extract* permission can generate this report. Users with this permission 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.

Filters

- If generated as CSV, the data extract will consist of a ZIP archive containing a CSV file for each form designed in your study.
- 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 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 *Field descriptions* section below.
- 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, since a CSV file can be opened in a variety of applications.

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: • <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.

[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.

Filter	Description
File Type	Choose the output type for the report: Transport (XPORT), CPORT, CSV, or sas7bdat.

Field descriptions

> **Note:**
>
> All forms will be included in an extract even if no data is entered (null). Extracts in a CSV file format will only include populated forms.

Here is a list of particularities on how data may be 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.
- 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

  In the extract's columns, the code for every answer option 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.

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

Key Column	SAS Label	Description
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
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
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 regular forms, these fields are not populated. For repeating forms, this column is populated with the number of repeating form instances used in a study.
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
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
DELETED	The deleted repeating form flag.	This flag, with values (Y/N), indicates if the repeating form has been deleted. This column will show **N** if the repeating form shows current data or if the form is not a repeating form. A deleted repeating form will show **Y**

Key Column	SAS Label	Description
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 a question's raw value as entered by a site user
QUESTIONLABEL_F	The question label's data type.	Indicates a question's answered converted to the respective question data type (character, number, date or time)
QUESTIONLABEL_D	The question label's data type for the answer.	Indicates a question's answer type, such as alphanumeric, text, or date based on the SDTM terminology. For example, if a question uses code lists for answer options, the code for the answer type selected by a site user will appear on this column. For more details on how to create and use code lists, see Create a code list and Add a code list to a question.
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
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

Key Column	SAS Label	Description
RREPEATNUMBER	Related Repeat Number	Indicates the number of the repeating form instance with which the source form is linked.
REPEATNUMBER	Row number in a repeating form	In case of a two-section 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.
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?

4

Oracle CRF Submit archives and reports

Oracle CRF Submit archives and reports

Oracle CRF Submit archives and reports are available for download on the Oracle Clinical One Platform. Sponsor and site users can generate and download archives and reports from Oracle CRF Submit for mid-study reviews and end-of-study requirements.

Generate an Oracle CRF Submit archive or report

While an archive or report is generating, you can navigate away from the Reports & Archives page and do more work in the study.

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 that you want to generate.
3. On the right, make sure **Settings** is expanded, and fill in the fields. For more information on settings, review the related links below.
4. Click **Run Report**.

Table 4-1 Available actions

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 will appear under Download Archives until the request is deleted.

Table 4-1 (Cont.) Available actions

Icon	Description
	**Delete** a completed, cancelled, or failed request.
	**Refresh** will retrieve an updated percentage complete (% Complete) for all requests with a status of Generating. Users can also click **Refresh to update**.
	**Retry** will attempt to re-process failed files. Files that generated successfully will not be included in the retry attempt.

Related Topics

- Download an Oracle CRF Submit archive or report
  You get a notification when the archive or report is available to download.
- Submission PDF settings
- Archival PDF (for sponsor users) settings
- Archival PDF (for site users) settings
- Blank PDF settings
- Custom PDF settings

Download an Oracle CRF Submit archive or report

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

1. Navigate to the Reports & Archives tab. For step-by-step instructions, see Access the Reports & Archives page.
2. Click the **Archives** tab.
3. In the lower right, expand **Download Archives** and locate the report that you want to view.
4. Click **Download** for the report that you want to download.

Related Topics

- Oracle CRF Submit archives and reports
  Oracle CRF Submit archives and reports are available for download on the Oracle Clinical One Platform. Sponsor and site users can generate and download archives and reports from Oracle CRF Submit for mid-study reviews and end-of-study requirements.
- Generate an Oracle CRF Submit archive or report
  While an archive or report is generating, you can navigate away from the Reports & Archives page and do more work in the study.

Oracle CRF Submit archives and reports

Topics within this category include descriptions of every Oracle CRF Submit archive and report generated from within Oracle Clinical One Platform.

- Submission PDF
  This archive contains data that is available and visible to the user who creates the request for the Submission PDF. The archive also contains audit trails and is included in submissions to FDA and other regulatory authorities at the conclusion of a clinical trial. The information is automatically compiled and formatted according to the regulators' requirements.
- Archival PDF (for sponsor users)
  This PDF consists of an archive of all of the data that is available and visible to the user who creates the request for an Archival PDF.
- Archival PDF (for site users)
  This PDF consists of an archive of all of the data that is available and visible to the user who created the request for the Archival PDF.
- Blank Form PDF
  This PDF consists of an archive of only blank forms within a study.
- Custom PDF
  The Custom PDF request type gives you access to all settings available in Oracle CRF Submit, letting you control what study data to include in the output.
- Download Log report
  This report contains a log of all the electronic downloads performed by sponsor and site users at all sites in a study. The log is saved in a CSV format and is available to users even after study decommission.
- Site Confirmation report
  This report consists of tabular data on the site confirmations processed in the system.

Submission PDF

This archive contains data that is available and visible to the user who creates the request for the Submission PDF. The archive also contains audit trails and is included in submissions to FDA and other regulatory authorities at the conclusion of a clinical trial. The information is automatically compiled and formatted according to the regulators' requirements.

Only sponsor users with the required user roles can generate and download this archive.

The Submission PDF is a ZIP file that includes the following:

- A folder for each site included in the request with a set of PDFs per subject within each site folder, including prth (i.e. subject record transfer history) files, if a subject is ever transferred out or in to a site.
- Table of contents
- Blank PDFs with active controls
- Request Settings PDF.

Modes

Available only in Testing and Production mode

Roles that can generate this PDF

Any user that's assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate this archive.

Filters

Setting	Description
Name	The name of the Submission PDF is required and must be unique.
As of Date	Select **Now** or enter a date range. The data includes all available information at the current date and time or up to the date and time you enter.
Included in Report	Select the following options: • **All Subjects** (default) to include all enrolled subjects into the study as part of the archive • **Select Subjects** to include a selection of subjects enrolled into the study as part of the archive • **Select Sites** to include a selection of sites and their subjects as part of the archive that you want to share with sites
Page size	Choose **Letter** (default) or **A4** for the page size of your PDF archive.
Blank Form Format	Choose **Unique Forms** to show one of each blank form in every visit. Or choose **Casebook** (default) to show all forms in every visit.
Header Text	Enter between 1 and 90 characters that appear at the top of each page in the Blank Form PDF. If you do not enter any text, the study's name is displayed by default.
Footer Text	Enter up to 30 characters that appear in the footer of each page in the Blank Form PDF. If you do not enter any text, the standard ***Confidential*** text is displayed.

Setting	Description
Advanced	Click **Advanced** to see the following settings and how they are configured. **Note:** You cannot modify any of these three settings. • **Prevent Form Changes**: By default, this setting is set to **No**. This means that a sponsor user can make any changes to the Submission PDF without requiring a password. • **Prevent Form Comments**: By default, this setting is set to **No**. This means that a sponsor user can add comments or any kind of annotations to the PDF archive without requiring a password. • **Prevent Content Extracts and Copying**: By default, this setting is set to **No**. This means that a sponsor user can copy the contents of the PDF archive without requiring a password.

Archival PDF (for sponsor users)

This PDF consists of an archive of all of the data that is available and visible to the user who creates the request for an Archival PDF.

Typically, this archive is generated mid-study or at the end of the study in order to safely store study archive data that you can later make available to auditors, sponsor users, site users, and other regulatory organizations. Sponsor users who are assigned the required roles can run this PDF, download it, and share it with site users. The Archival PDF can also be generated by site users with the appropriate role. Once made available, site users can download the Archival PDF and confirm the download.

The Archival PDF is a ZIP file that includes the following:

- A folder for each site included in the request with a set of PDFs per subject within each site folder, including prth (i.e. subject record transfer history) files, if a subject is ever transferred out or in to a site.
- Table of Contents
- Blank forms with active controls
- Request Settings PDF
- 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.

Roles that can generate this PDF

Any user that's assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate this archive.

Filters

Setting	Description
Name	The name of the Archival PDF is required and must be unique.
As of Date	Select **Now** or enter a date range. The data includes all available information at the current date and time or up to the date and time you enter.
Share with Sites	Choose **Yes** if you want to make the PDFs available for download by site users. Choose **No** if you don't want to let site users download these PDFs.
Confirm Site Downloads	This setting is displayed only if you choose to share the Archival PDF with sites. Choose **Yes** if you want site users to confirm downloading the archives you choose to share with them. Choose **No** if you do not require a confirmation from site users that they have downloaded the shared archives.
Included in Report	Select one of the following options: • **All Subjects** (default) to include all enrolled subjects into the study as part of the archive • **Select Subjects** to include a selection of subjects enrolled into the study as part of the archive • **Select Sites** to include a selection of sites and their subjects as part of the archive that you want to share with sites
Page Size	Choose **Letter** (default) or **A4** for the page size of your PDF archive.
Include Blank Forms	Choose **Yes** (default) to include blank forms in your PDF output.
Blank Form Format	Choose **Unique Forms** to show one of each blank form in every visit. Or choose **Casebook** (default) to show all forms in every visit. **Note:** **Blank Form Format** only appears if **Include Blank Forms** is set to **Yes**

Setting	Description
Header Text	Enter between 1 and 90 characters that appear at the top of each page in the Archival PDF. If you do not enter any text, the study's name is displayed by default.
Footer Text	Enter up to 30 characters that appear in the footer of each page in the Archival PDF. If you do not enter any text, the standard **_Confidential_** text is displayed.
Advanced	Click **Advanced** to configure the following settings: • **Prevent Form Changes**: By default, this setting is set to **Yes**. You cannot change it to **No**. The password is randomly generated by the system and is not available. • **Prevent Form Comments**: Choose **No** to let a sponsor user add comments or any kind of annotations to the PDF archives. Choose **Yes** if you want to prevent a sponsor user from adding comments or any kind of annotations to the PDF archives, unless they enter the password of this document. By default, this setting is set to **No**. • **Prevent Content Extracts and Copying**: Choose **No** to let a sponsor user copy the contents of the PDF archives. Choose **Yes** to prevent a sponsor user from copying the contents of the PDF archives, unless they enter the password of this document. By default, this setting is set to **No**.

Archival PDF (for site users)

This PDF consists of an archive of all of the data that is available and visible to the user who created the request for the Archival PDF.

Typically, this archive is generated mid-study or at the end of the study in order to safely store study archive data that you can later make available to auditors, sponsor users, site users, and other regulatory organizations.

Site users who are assigned the required role can run this PDF and download it.

The Archival PDF contains the following information:

- A folder for each site included in the request with a set of PDFs per subject within each site folder
- Table of Contents
- Blank forms with active controls
- Request Settings PDF

Modes

Available only in Testing and Production mode.

Roles that can generate this PDF

Any user that's assigned the following permissions can generate this archive:

- Run Archival PDFs for your site(s)

- Confirm download of Archival PDFs and content
- Download Archival PDFs, and Audit Reports

Setting	Description
Name	The name of the Archival PDF is required and must be unique.
As of Date	Select **Now** or enter a date range. The data includes all available information at the current date and time or up to the date and time you enter.
Included in Report	Select one of the following options: • **All Subjects** (default) to include all enrolled subjects into the study as part of the archive • **Select Subjects** to include a selection of subjects enrolled into the study as part of the archive • **Select Sites** to include a selection of sites and their subjects as part of the archive that you want to share with sites
Page Size	Choose **Letter** (default) or **A4** for the page size of your PDF archive.
Include Blank Forms	Choose **Yes** (default) to include blank forms in your PDF output.
Blank Form Format	Choose **Unique Forms** to show one of each blank form in every visit. Or choose **Casebook** (default) to show all forms in every visit.

Note:

Blank Form Format only appears if **Include Blank Forms** is set to **Yes**

Blank Form PDF

This PDF consists of an archive of only blank forms within a study.

Modes

Available only in Testing and Production mode.

Roles that can generate this PDF

Any user that's assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate this archive.

Setting	Description
Name	The name of the Blank Form PDF is required and must be unique.

Setting	Description
As of Date	Select **Now** or enter a date range. The data includes all available information at the current date and time or up to the date and time you enter.
Page Size	Choose **Letter** (default) or **A4** for the page size of your PDF archive.
Blank Form Format	Choose **Unique Forms** to show one of each blank form in every visit. Or choose **Casebook** (default) to show all forms in every visit.
Header Text	Enter between 1 and 90 characters that appear at the top of each page in the Blank Form PDF. If you do not enter any text, the study's name is displayed by default.
Footer Text	Enter up to 30 characters that appear in the footer of each page in the Blank Form PDF. If you do not enter any text, the standard ***Confidential*** text is displayed.
Advanced	Click **Advanced** to see the following settings and how they are configured. **Note:** You cannot modify any of these three settings. • **Prevent Form Changes**: By default, this setting is set to **No**. This means that a sponsor user can make any changes to the Blank Form PDF without the change requiring a password generated by the system. • **Prevent Form Comments**: By default, this setting is set to **No**. This means that a sponsor user can add comments or any kind of annotations to the PDF archive without requiring a password. • **Prevent Content Extracts and Copying**: By default, this setting is set to **No**. This means that a sponsor user can copy the contents of the PDF archive without requiring a password.

Custom PDF

The Custom PDF request type gives you access to all settings available in Oracle CRF Submit, letting you control what study data to include in the output.

Only sponsor users with the required user roles can generate and download this archive.

The Custom PDF ZIP file with the default name, <study name><date>.zip, includes the following.

- Blank PDFs with active controls.
- Subject PDFs containing clinical data for each subject included in the request.
- The Request Settings PDF.

Modes

Available in Testing and Production mode.

Roles that can generate this PDF

Any sponsor user assigned the *Run and Download all PDF request types and Audit Reports*, and *Enable Share with Sites and Site Confirmation* permissions can generate this archive.

Filters

Setting	Description
Name	Required and must be unique.
As of Date	Select **Now** (default) or enter a date range. The output will include all available information as of the current date and time (Now) or up to the date/time entered.
Share with Sites	Select **Yes**(default) if you want to make the PDFs available for download by site users.
Site Confirmation Required **Note:** Appears only when Share with sites is **Yes.**	Select **Yes** (default) if you require site users to confirm download of the custom PDFs.
Included in Report	Select one of the following. • **All Subjects** (default) to include all enrolled subjects for a study. • **Select Sites** to include all enrolled subjects in a study for specific sites. • **Select Subjects** to include a selection of enrolled subjects in a study.
Page Size	Select **Letter** (default) or **A4**.
Include Blank Forms	Select **Yes** (default) to include blank forms in the PDF output.
Study Versions **Note:** Appears only when Include Blank Forms is **Yes**.	Select **All** (default) to include all study versions, or select specific study versions to include in the PDF output.
Blank Form Format	Select **Casebook** (default) to include all forms in every visit or **Unique Forms** to include one of each form in every visit in the PDF output.

Setting	Description
Header Text	Enter up to 90 characters to appear at the top of each page of the Custom PDF output. If no text is entered, the study name is displayed by default.
Footer Text	Enter up to 30 characters to appear in the footer of each page of the Custom PDF output. If no text is entered **Confidential** is displayed by default.

Setting	Description
Advanced	**Display in the Archive Header** • Form Version; Yes (default) or No • Subject Initials; Yes (default) or No • Visit Name and Number; Yes (default) or No • Site Name and Number; Yes (default) or No • Sponsor Name; Yes or No (default) • Protocol Name; Yes or No (default) **Data Inclusion and Format** • Include Study Name in the Subject File Name; Yes (default) or No • Forms to Include; All forms included by default). • Visits to Include; All visits are included by default. • Include Bookmark Prefixes; Yes or No (default) • Audit Trail Location; After Each Form (default) or End of PDF **Security** • Prevent Form Changes: Select **Yes** to require a password to make changes to the PDF. Select **System-created : Hidden** to permanently prevent form changes to the PDF. Select **No** (default) to allow PDF to be modified. **Note:** When **Yes** is selected, the **Password** and **Confirm Password** fields will dynamically appear. Passwords entered are not saved in the database and cannot be retrieved by Oracle. • Prevent Form Comment Changes:Select **Yes** to prevent comments from being added to the output PDF using the same options as for Form Changes. Select **No** (default) to allow for PDF comments or annotations. • Prevent Content Extracts and Copying: Select **Yes** to prevent contents being copied from the output PDF using the same options as for Form Changes. Select **No** (default)to allow text to be copied.

Download Log report

This report contains a log of all the electronic downloads performed by sponsor and site users at all sites in a study. The log is saved in a CSV format and is available to users even after study decommission.

Modes

Available only in Testing and Production mode.

Roles that can generate this report

Any user that's assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate this archive.

Site Confirmation report

This report consists of tabular data on the site confirmations processed in the system.

If you chose to share the Archival PDF with the sites, and also requested their confirmation upon downloading the archives, then you might also need to run the Site Confirmation report to get data on the sites' activity.

If you generate archives for multiple sites and choose to share those archives with sites, as well as request their confirmation for downloading and reviewing, then a site user who has access to multiple sites must download multiple ZIP files, one for each site. A site user must confirm that they have downloaded and reviewed each ZIP file.

The Site Confirmation report is available to users after study decommission.

The Site Confirmation report contains confirmation data in a tabular format with the following columns:

- Request Name
- Request Type
- Published time (GMT)
- Site Name
- Confirmed By
- Confirmation Time (GMT)

Modes

Available only in Testing and Production mode.

Roles that can generate this report

Any user that's assigned the *Run and download all PDF request types and Audit reports. Enable Share with Sites and Site Confirmation* permission can generate this report.

Filters

Setting	Description
Name	The name of the Site Confirmattion report is required and must be unique.
File Type	Choose either CSV or PDF.

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.

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.

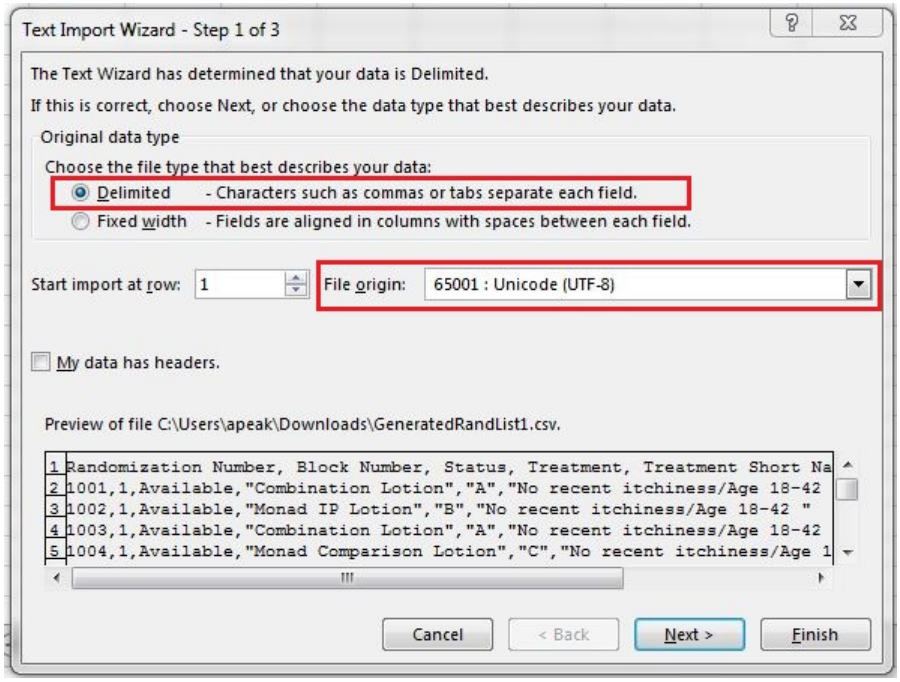
SAS labels

- The maximum length is 256 bytes.

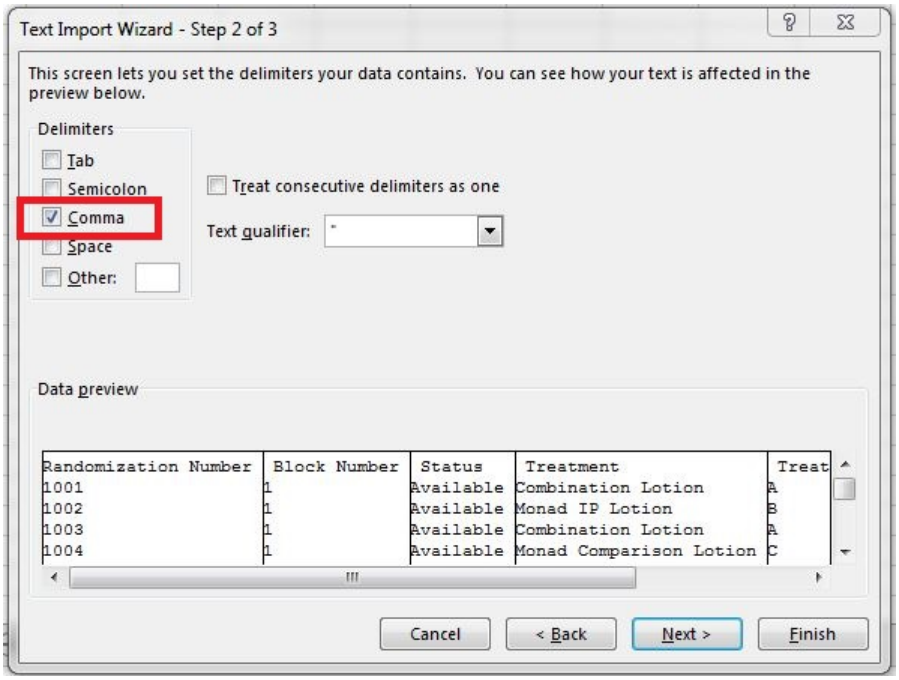
What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?

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**.



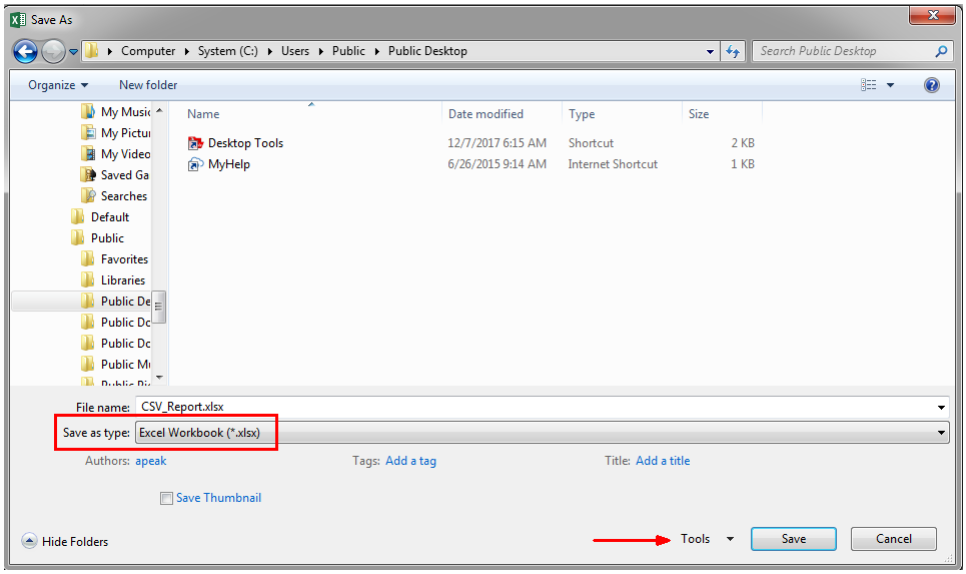
7. Click **Finish**.

   The Import Data dialog box appears.

8. Click **New Worksheet**, and then click **OK**.

9. On the **File** tab, click **Save As**, and select a location for your file.

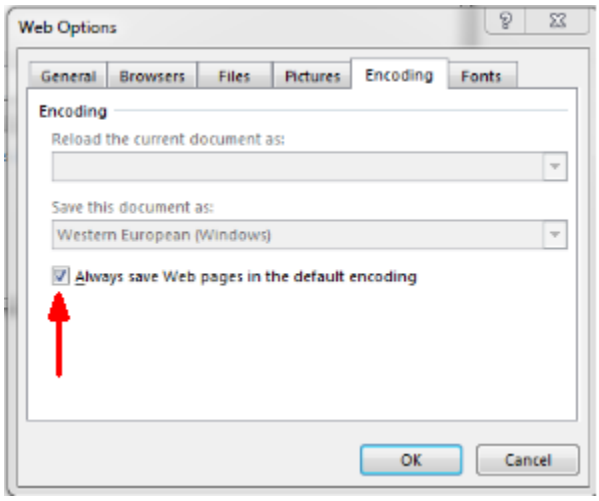
10. Enter a name for the report in **File name**, and from the **Save as type** drop-down, choose **Excel Workbook (*.xlsx)**.



11. From the **Tools** drop-down, select **Web Options**.

12. Along the top, select the **Encoding** tab, and from the **Save this document as** drop-down, select **Unicode (UTF-8)**.

13. Select **Always save Web pages in the default encoding** button, and then click **OK** and then **Save**.


Web Options
General
Browsers
Files
Pictures
Encoding
Fonts
Encoding
Reload the current document as:
Save this document as:
Western European (Windows)
Always save Web pages in the default encoding
OK
Cancel

6
Revision history

Table 6-1 Revision history

Date	Part number	Description
June 2022	F56745-01	Original version of the document.
June 2022	F56745-02	Updated the month of the publication.