Oracle® Life Sciences Clinical One Platform

Analytics User Guide

Release 25.1.1
G16753-04
March 2025

Oracle Life Sciences Clinical One Platform Analytics User Guide, Release 25.1.1

G16753-04

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Contents

Preface

This preface contains the following sections:

Documentation accessibility

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

Diversity and Inclusion

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

Related resources

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

Access to Oracle Support

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

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

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

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

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Get started with Oracle Clinical One Analytics

Oracle Clinical One Analytics is a powerful tool that empowers you to uncover new insights and make faster, more informed business decisions related to your studies managed in Oracle Clinical One Platform.

- About your access to Oracle Clinical One Analytics
  Users can have read-only or authoring access to Oracle Clinical One Analytics. In either case, to access Oracle Clinical One Analytics you must be assigned with the appropriate permissions and roles in Oracle Clinical One Platform.
- Browser requirements
- Open Oracle Clinical One Analytics
  Access Oracle Clinical One Analytics directly from Oracle Clinical One Platform.
- Navigate through Oracle Clinical One Analytics
  Learn what you can do once you access Oracle Clinical One Analytics.

About your access to Oracle Clinical One Analytics

Users can have read-only or authoring access to Oracle Clinical One Analytics. In either case, to access Oracle Clinical One Analytics you must be assigned with the appropriate permissions and roles in Oracle Clinical One Platform.

> **Note:**
>
> You must work with your organization's global user manager and study user administrator to make sure you have the associated roles and permissions required for your work.

- Read-only and authoring access in Oracle Clinical One Analytics
  Depending on your roles and permissions assigned in Oracle Clinical One Platform, you can get different types of access to Oracle Clinical One Analytics: read-only or authoring. The differences between these types of access and how they are granted dictate what you are allowed to do when working in Oracle Clinical One Analytics.
- Global roles for authoring access
  Authoring access is controlled by global roles. To have authoring access to Oracle Clinical One Analytics, you must be a global user in your organization assigned with the appropriate roles at the global level.
- Permissions to access Oracle Clinical One Analytics datasets
  Whether you need authoring or read-only access, you need to have specific study-level permissions to access a given dataset. Only with the proper access to run a specific dataset, you are able to use it or view it in any report in Oracle Clinical One Analytics.

Read-only and authoring access in Oracle Clinical One Analytics

Depending on your roles and permissions assigned in Oracle Clinical One Platform, you can get different types of access to Oracle Clinical One Analytics: read-only or authoring. The differences between these types of access and how they are granted dictate what you are allowed to do when working in Oracle Clinical One Analytics.

> **Note:**
>
> Regardless of the type of access you have, you can only access reports and dashboards that use the datasets for which you have access to. See Permissions to access Oracle Clinical One Analytics datasets.

Access type	Description	How access is granted
Read-only	Restricts users to only view and run existing reports and dashboards in Oracle Clinical One Analytics.	Read-only access is granted when you are added to a study, assigned with a study role that includes any of the study-level permissions associated with Oracle Clinical One Analytics datasets (without any of the Analytics authoring global roles). ***Note**: As soon as you get assigned with an Analytics authoring global role, your read-only access becomes authoring access.*
Authoring	Allows users to view, run, create, and modify new and existing reports and dashboards in Oracle Clinical One Analytics.	Access is granted when you are assigned a combination of global-level Analytics authoring roles and study-level permissions associated to Oracle Clinical One Analytics datasets. See Global roles for authoring access. Both global roles and study-level permissions are assigned in Oracle Clinical One Platform.

Global roles for authoring access

Authoring access is controlled by global roles. To have authoring access to Oracle Clinical One Analytics, you must be a global user in your organization assigned with the appropriate roles at the global level.

The Analytics authoring global roles are:

Global role	Description
Analytics: Data Visualizer Authoring	Provides complete authoring access to Oracle Clinical One Analytics, which allows you to: • Create and modify reports and dashboards in the Data Visualizer interface . • Access Oracle Business Intelligence (BI) Publisher functionality in the Oracle Analytics Classic View. ***Note**: This role includes the privileges from the* Analytics: BI Publisher Authoring *role. Users do not need to be assigned with both roles.*

Global role	Description
Analytics: BI Publisher Authoring	Provides access to Oracle BI Publisher functionality in the Oracle Analytics Classic View (accessed from the Oracle Clinical One Analytics portal). ***Note**: Oracle BI Publisher is mainly used to create pixel-perfect reports. For more information, see Create a pixel-perfect report using BI Publisher.*

For more details about global user management, reach out to your product administrator and refer to Add a global user in Oracle Clinical One Platform and Roles for global users.

Permissions to access Oracle Clinical One Analytics datasets

Whether you need authoring or read-only access, you need to have specific study-level permissions to access a given dataset. Only with the proper access to run a specific dataset, you are able to use it or view it in any report in Oracle Clinical One Analytics.

> **Note:**
>
> When using any dataset you only see the data for the studies that you have access to and sites that you are assigned to in each study.

The specific datasets which you can work with in Oracle Clinical One Analytics depend on your study role and the permissions it includes. The table below lists all datasets along with their respective permissions and the template study roles that include them.

> **Tip:**
>
> Access to datasets is not limited to template study roles. You can assign the appropriate permission to any custom study role you create within your study or organization.

Dataset	Associated permission	Template study roles
Blinded Kits Dataset	*Run the Blinded Kits Dataset*	• Clinical Supply Manager • View Only for Blinded Support Users • Study Manager
Blinded Subject Events Dataset	*Run the Blinded Subject Events Dataset*	• Clinical Supply Manager • CRA • Data Manager • Medical Monitor • Production Admin • Statistician • Study Manager • View Only for Unblinded Support Users

Dataset	Associated permission	Template study roles
Kits and Randomization Design Dataset	*Run the Kits and Randomization Design Dataset* **Note**: Available only for study design roles.	• Study Designer
Queries Dataset	*Run the Study Query Dataset*	• Clinical Supply Manager • CRA • Data Manager • Medical Monitor • Production Admin • Rules Designer • Statistician • Study Manager • View Only for Unblinded Support Users
Study Codelist dataset	*Run the Study Codelist Dataset* **Note**: Global level codelists data is only available to global users assigned with the *Code List Manager* or the *Oracle Admin* roles.	• Study Designer • View Study Design
Study Design Dataset	*Run the Data Collection Design Dataset* **Note**: Available only for study design roles.	• Study Designer
Subject Dataset	*Run the Subject Dataset*	• Clinical Supply Manager • CRA • Production Admin • Statistician • Study Manager • View Only for Unblinded Support Users
Subject Forms Dataset	*Run the Subject Forms Dataset*	• Clinical Supply Manager • CRA • Data Manager • Medical Monitor • Production Admin • Statistician • Study Manager • View Only for Unblinded Support Users
Subject Form Items Dataset	*Run the Subject Form Items Dataset*	• Clinical Supply Manager • Data Manager • Medical Monitor • Production Admin • Rules Designer • Statistician • Study Manager • View Only for Unblinded Support Users

Dataset	Associated permission	Template study roles
Unblinded Kits Dataset	*Run the Unblinded Kits Dataset*	• Clinical Supply Manager • Production Admin • Statistician • View Only for Unblinded Support Users
Unblinded Subject Events Dataset	*Run the Unblinded Subject Events Dataset*	• Clinical Supply Manager • View Only for Unblinded Support Users

All the permissions listed in the table above additionally grant access to the Dh Metrics dataset. There is no specific permission associated to this dataset.

Browser requirements

Browser and system requirements

Application	Device	Internet browser	Resolution
Oracle Clinical One Platform	Laptop or desktop	• **Google Chrome**: tested using version 127.0.6533.73 (Official Build) (64-bit). Version 119.0.6045.124 and later are supported. • **Microsoft Edge**: tested using version 126.0.2592.113 (Official build) (64-bit). Version 119.0.2151.58 and later are supported.	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers
Oracle Clinical One Analytics	Laptop or desktop	Oracle Analytics Serversupports Oracle Clinical One Analytics and it is supported in the following web browsers: • **Apple Safari** • **Google Chrome** • **Microsoft Edge** • **Mozilla Firefox** For more information see Certification - Supported Browsers.	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers

Open Oracle Clinical One Analytics

Access Oracle Clinical One Analytics directly from Oracle Clinical One Platform.

You can only access Oracle Clinical One Analytics if you have the right permissions assigned to your study role or if you have authoring global roles in Oracle Clinical One Platform. For more information see About your access to Oracle Clinical One Analytics.

> **Note:**
>
> You should always access Oracle Clinical One Analytics through the Oracle Clinical One Platform home page. Do not save or use direct links to Oracle Clinical One Analytics.

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

Video

1. On the Oracle Clinical One Platform Home page, click **Analytics** in the top-right.

   Can't see this button? Contact your Oracle point of contact or user administrator to check your permissions.

2. Navigate through Oracle Clinical One Analytics.

   The Oracle Clinical One Analytics opens directly in the Catalog page,where you can see saved workbooks (reports and dashboards) in personal and shared folders. See how to:

   - Create a workbook.
   - Find content in the homepage.
   - Access your data.

Related Topics

- Select a dataset to work with
  As an Oracle Clinical One Platform user, your data is available in Oracle Clinical One Analytics through predefined datasets of local subject area type. Choose one or more datasets to visualize related data.
- I step away and then can't work in Oracle Clinical One anymore
- Browser requirements
- Chat in real time with Oracle Support

Navigate through Oracle Clinical One Analytics

Learn what you can do once you access Oracle Clinical One Analytics.

When you access Oracle Clinical One Analytics through Oracle Clinical One Platform, you get redirected to the Catalog page. Other options are available through the main menu.

- Create a workbook
  Create a workbook to start visualizing and analyzing your data. Oracle Clinical One Analytics allows you to create a workbook directly from a dataset and from the top menu bar.

- Find content in the homepage
  From the homepage, you can access any workbook or dataset available to you.
- Access workbooks in your catalog
  Oracle Clinical One Analytics lets you save visualizations and analyses as workbooks to continue your work in different sessions. Through the Catalog page, you can access saved workbooks in personal and shared folders.
- Access your data
  Access available datasets from the Data page.

Create a workbook

Create a workbook to start visualizing and analyzing your data. Oracle Clinical One Analytics allows you to create a workbook directly from a dataset and from the top menu bar.

To create a workbook you must have authoring access to Oracle Clinical One Analytics. For more information see About your access to Oracle Clinical One Analytics.

1. **To create a workbook from the top menu bar:**
   a. Click **Create**.
   b. Select **Workbook**.

      You are prompted to add a dataset. You can do this now as listed below, or click **Cancel** to add it later (see Select a dataset to work with).
   c. Within the Add Dataset dialog, go to the **Subject Areas** tab.
   d. Select one of the available datasets and click **Add to Workbook**.
2. **To create a workbook starting from a dataset:**
   a. Access your data.
   b. Within the **Data** page, from the **Datasets** tab, locate the dataset to work with.

      See Select a dataset to work with.
   c. Click a dataset to open a new workbook with the given dataset loaded.

> **Note:**
>
> You can also use the actions button ( ) next to the dataset name, and select **Create workbook**. Both options have the same result.

The new workbook opens in the Visualize pane. If you created the workbook from a dataset, that dataset is automatically loaded into your workbook.
With an open workbook, you are ready to create reports and visualize and analyze your data:

- Select a dataset to work with
- Create and edit a data visualization
- Add multiple visualizations in a canvas.
- Create and apply filters.
- Organize visualizations in dashboards.
- Create stories.
- Export and share your work.

Find content in the homepage

From the homepage, you can access any workbook or dataset available to you.

When you access Oracle Clinical One Analytics through Oracle Clinical One Platform, you get redirected to the Catalog page. Other type of content is available through the main menu.

1. In Oracle Clinical One Analytics, click the menu icon ( ) located at the top left corner of the screen.

   A side menu expands.
2. Select **Home**.
3. Navigate through the homepage to find recent workbooks and available datasets.
   - Use the top search bar to find specific content.
   - Use the quick filters available under the search bar for a quick search:
     - **Workbooks and Reports**
     - **Data**
     - **Recent Datasets**
     - **Favorite Workbooks**
     - **Machine Learning**
4. Click a workbook or dataset to open or use the actions menu ( ) next to the element's name to see other options.

Access workbooks in your catalog

Oracle Clinical One Analytics lets you save visualizations and analyses as workbooks to continue your work in different sessions. Through the Catalog page, you can access saved workbooks in personal and shared folders.

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

Video

When you access Oracle Clinical One Analytics through Oracle Clinical One Platform, you get redirected to the Catalog page. You can access this page at any time from the main menu.

1. In Oracle Clinical One Analytics, click the menu icon ( ) located at the top left corner of the screen.

   A side menu expands.
2. Select **Catalog**.
3. In the top menu bar, navigate to the appropriate tab to access the location of the workbook you want to work with:
   - **My folders**
   - **Shared Folders**

> **Tip:**
>
> You can use the available Search and Sort By filters to easly locate your work.

4. Click the name of the workbook to open it.

   Other options are available from the actions menu ( ) next to the workbook title:

   - Open
   - Open in a New Tab
   - Inspect
   - Rename
   - Favorite
   - Export
   - Move to...
   - Duplicate
   - Delete

Access your data

Access available datasets from the Data page.

When you access Oracle Clinical One Analytics through Oracle Clinical One Platform, you get redirected to the Catalog page. Other type of content is available through the main menu.

To access available datasets you must have authoring access to Oracle Clinical One Analytics. For more information see About your access to Oracle Clinical One Analytics.

1. In Oracle Clinical One Analytics, click the menu icon ( ) located at the top left corner of the screen.

   A side menu expands.

2. Select **Data**.

   The Datasets tab displays the datasets available to you according to your permissions assigned in Oracle Clinical One Platform.

3. Access other data sources by navigating to different tabs:

   - **Datasets**
   - **Connections**
   - **Data Flows**
   - **Sequences**

See how to start a workbook from a dataset in Create a workbook.

2

Prepare data

Oracle Clinical One Analytics is synchronized with data from your studies in Oracle Clinical One Platform. Data is then available to you through predefined datasets, which you can use to create projects and visualize your data in many ways to make data-driven decisions and improve the data management processes at your organization.

> **Note:**
>
> Only the functionality documented in this user guide is supported. In your environment, other functionality may be available to you but has not been tested or is reserved for a future release. If you run into any issues, contact Life Sciences Support.

- How data is sent from Oracle Clinical One Platform to Oracle Clinical One Analytics
  Data in the Oracle Clinical One Analytics application is refreshed incrementally. The refresh processing occurs on saved data in the context of a visit, as data gets posted in Oracle Clinical One Platform. This means data can get refreshed even though the totality of the visit data entry is not yet completed.
- About datasets
  With datasets, you get a bespoke solution to visualizing the most relevant clinical data in your study. Visualizations then offer you the opportunity to analyze that data so it provides you with answers related to business-related and clinical questions.
- Select a dataset to work with
  As an Oracle Clinical One Platform user, your data is available in Oracle Clinical One Analytics through predefined datasets of local subject area type. Choose one or more datasets to visualize related data.
- Create calculated data elements
  Create calculated data elements to use in your visualizations in fields that take only measure data.
- Dataset descriptions

How data is sent from Oracle Clinical One Platform to Oracle Clinical One Analytics

Data in the Oracle Clinical One Analytics application is refreshed incrementally. The refresh processing occurs on saved data in the context of a visit, as data gets posted in Oracle Clinical One Platform. This means data can get refreshed even though the totality of the visit data entry is not yet completed.

> **Note:**
>
> For the Study Design dataset, data is sent when a study version is moved to Testing and data of a study version in draft mode can be manually published by clicking **Send to Analytics** in the draft mode dropdown.

View data hidden with data classifications

Some form items are hidden with data classifications, allowing just some users with the appropriate permissions to view them. Oracle Clinical One Analytics allows you to view these hidden form items as part of the Subject Form Items dataset and Queries dataset, according to those data classifications and your permissions in Oracle Clinical One Platform.

This means that, if any item has data classifications and you have the permissions to view it in Oracle Clinical One Platform, you will also be able to access it in Oracle Clinical One Analytics. On contrary, if according to your permissions these items are hidden to you in Oracle Clinical One Platform, they will be hidden as well in Oracle Clinical One Analytics.

About datasets

With datasets, you get a bespoke solution to visualizing the most relevant clinical data in your study. Visualizations then offer you the opportunity to analyze that data so it provides you with answers related to business-related and clinical questions.

Ultimately, with the right answers to your question you can make the best data-driven decisions. In Oracle Clinical One Analytics, you have a set of predefined datasets of subject local area type, that provide data from your studies in Oracle Clinical One Platform in sets by purpose of analysis. You can use this datasets to create custom reports or visualizations that you can then export in a variety of formats, such as CSV, PPT, PDF, and PNG. See Visualize data.

Besides the main actions that you can perform in Oracle Clinical One Analytics, there are numerous tips and tricks that you can use to better organize the data that you work with.

To read detailed instructions on the tasks available for you to perform in Oracle Clinical One Analytics, see the curated list of links in the **Related Topics** section below.

Related Topics

- Connect to Data Sources
- Connect to Your Data Using Datasets
- Enrich and Transform Data
- Create Datasets Using Data Flows

Select a dataset to work with

As an Oracle Clinical One Platform user, your data is available in Oracle Clinical One Analytics through predefined datasets of local subject area type. Choose one or more datasets to visualize related data.

The reason we have these different datasets is because each allows you to look through the changes based on a specific topic. Select the datasets that are relevant to your work and add them to your workbook to begin visualizing and analyzing data.

Once you selected a dataset to work with, make sure you have the appropriate access. For more information see About your access to Oracle Clinical One Analytics.

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

Video

1. Review the purpose of each dataset and select the most relevant to your work.

Dataset	Description
Blinded Kits dataset	Use it to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation, without viewing details that could potentially unblind users.
Blinded Subject Events Dataset	Use it to analyze and visualize data and audit history of events associated to individual subjects, without viewing details that could potentially unblind users.
Dh Metrics dataset	Use it to analyze when data was last refreshed in Oracle Clinical One Analytics and to monitor data reliability.
Kits and Randomization Design Dataset	Use it to analyze and visualize data regarding the metadata of kit definition, dispensation schedule and randomization definition for the study.
Queries Dataset	Use it to analyze and visualize details and audit history of query data.
Study Codelist dataset	Use it to analyze and visualize data regarding codelists at both study and global level, as well as current code configurations and changes made over time.
Study Design Dataset	Use it to analyze and visualize data regarding the metadata of visits, forms and items included in study versions and applied across study modes.
Subject Dataset	Use it to analyze and visualize subject level details and the audit history of a subject's data.
Subject Forms Dataset	Use it to analyze and visualize data and autdit history of forms associated to individual subjects.
Subject Form Items Dataset	Use it to analyze and visualize item-level data and the audit history of data entered for a question in a form for individual subjects.
Unblinded Kits Dataset	Use it to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation. This dataset includes information that could potentially unblind a user.
Unblinded Subject Events Dataset	Use it to analyze and visualize data and audit history of events associated to individual subjects. This dataset includes information that could potentially unblind a user.

> **Tip:**
>
> Browse Dataset descriptions if more details are needed.

2. Create a workbook in any of the the two options available:
   - From the top menu bar.
   - Starting from a dataset.
3. Add a dataset to your workbook:

> **Tip:**
>
> Even if you already added a dataset as part of the previous step, you can add as many datasets as you need and you can do it at any time while working on your workbook.

Option	Steps
From the Data Panel at the right of the screen	a. Make sure the **Data** tab () is selected in the Data Panel. b. Click on the plus icon () next to the search bar. c. Select **Add Dataset...**. d. In the Add Dataset dialog, navigate to the **Subject Areas** tab. e. Select a dataset to add and click **Add to Workbook**.
From the Prepare pane:	a. Click **Prepare** in the top menu bar. b. Click the plus icon (**+**) to add a dataset. c. In the Add Dataset dialog, navigate to the **Subject Areas** tab. d. Select a dataset to add and click **Add to Workbook**.

With an open workbook, you are ready to visualize and analize your data:

- Create and edit a data visualization
- Add multiple visualizations in a canvas.
- Create and apply filters.
- Organize visualizations in dashboards.
- Create stories.
- Export and share your work.

Create calculated data elements

Create calculated data elements to use in your visualizations in fields that take only measure data.

When building visualizations, some fields in the Grammar Panel only allow measure data, for example:

- Y-axis in two-dimensional graphs
- Size
- Tooltip
- Tile and Pie chart Values

Add calculations to your workbook to use as measure values to configure these fields.

You can also display claculated data elements in reports or tables and associate them with other sections in the Grammar Panel to customize a visualization, even if they are not restricted to measure data.

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

Video

1. Open a workbook:
   - Open an existing workbook as described inAccess workbooks in your catalog.
   - Create a workbook and add a dataset to work with
2. In the Data Panel, locate the *My Calculations* folder, right-click on it and select **Add calculation...**.

> **Tip:**
>
> You can also click on the plus icon () next to the search bar, then click **Add calculation...**.

3. In the New Calculation dialog, enter a name.
4. In the expression builder pane, compose and edit an expression.

> **Tip:**
>
> - You can search for functions and view their descriptions on the right column of the New Calculation dialog.
> - You can drag and drop a column from the data panel into the expression builder pane.
> - View and select autocomplete suggestions, for both functions and variables, as you type in the expression builder pane.

5. Click **Validate**.
6. Click **Save** if the expression was succesfully validated.

> **Note:**
>
> Click **Cancel** to go gack without saving.

Dataset descriptions

- Blinded Kits dataset
  Use this dataset to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation, without viewing details that could potentially unblind users.
- Blinded Subject Event dataset
  You can use the Blinded Subject Events dataset in Oracle Clinical One Analytics to analyze and visualize blinded data and audit history of events associated to each subject, including randomization and trials supply management (RTSM) related data.

- Dh Metrics dataset
  You can use Dh Metrics dataset to ensure that you're looking at the latest version of your study's data in the Oracle Clinical One Analytics.
- Kits and Randomization Design dataset
  You can use the Kits and Randomization Design dataset to analyze and visualize data in Oracle Clinical One Analytics regarding the metadata of kit definition, dispensation schedule and randomization definition for the study.
- Queries dataset
  You can use the Queries dataset to analyze and visualize details and audit history of query data.
- Study Codelist dataset
  You can use the Study Codelist dataset in Oracle Clinical One Analytics to analyze and visualize data regarding codelists at both study and global level, as well as current code configurations and changes made over time.
- Study Design dataset
  You can use the Study Design dataset data regarding the metadata of visits, forms and items included in study versions and applied across study versions and modes.
- Subject dataset
  You can use the Subject dataset to analyze and visualize subject level details and the audit history of a subject's data.
- Subject Form Items dataset
  You can use the Subject Form Items dataset in Oracle Clinical One Analytics to analyze and visualize item-level data and the audit history of data entered for a question in a form for individual subjects.
- Subject Forms dataset
  You can use the Subject Forms dataset in Oracle Clinical One Analytics to analyze and visualize data and autdit history of forms associated to individual subjects.
- Unblinded Kits dataset
  You can use the Unblinded Kits dataset to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation. This dataset includes information that could potentially unblind a user.
- Unblinded Subject Event dataset
  You can use the Unblinded Subject Events dataset in Oracle Clinical One Analytics to analyze and visualize data and audit history of events associated to individual subjects, including randomization and trials supply management (RTSM) related data.. This dataset includes information that could potentially unblind a user.

Blinded Kits dataset

Use this dataset to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation, without viewing details that could potentially unblind users.

In Oracle Clinical One Platform you can define kits to be **Blinded**, **Unblinded** (open label) or **Unblinded Pharmacist** for distribution. This dataset includes data about both blinded and unblinded kits, but omits details that may compromise the integrity of the study blind, such as treatment arm information. Data from unblinded pharmacist kits is not available in this dataset. To work with unblinded pharmacists kits and other unblinded data see Unblinded Kits dataset.

Modes

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

What type of data can I include in an blinded custom report or visualization?

With this dataset, you can get custom data such as:

- Blinded kit inventory status at all sites in a study.

> **Note:**
>
> Non-serialized kits are managed in bulk and only display the current status for a count of kits grouped in a lot. To track each kit individually, you need to use serialized kits.

- What kit numbers are included in a shipment and the shipment status.
- Randomization blinded details for all subjects in a study.
- Blinded lots status blinded data.
- Kit dispensation blinded data.

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse description of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event folder
- Randomization folder
- Lot folder
- Shipment folder
- Kits (Required) folder
- Audit folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-1 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-2 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.

Table 2-2 (Cont.) Data elements in the site folder

Data element	Description
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.

Table 2-2 (Cont.) Data elements in the site folder

Data element	Description
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_TYPE	Indicates the type of organization.

Country folder

This table describes the data elements included in the Country folder.

Table 2-3 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-4 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event folder

This table describes the data elements included in the event folder.

Table 2-5 Data elements in the event folder

Data element	Description
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.

Table 2-5 (Cont.) Data elements in the event folder

Data element	Description
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarly impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.

Table 2-5 (Cont.) Data elements in the event folder

Data element	Description
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Randomization folder

This table describes the data elements included in the Randomization folder.

Table 2-6 Data elements in the randomization folder

Data elements	Description
RAND_NUMBER	Indicates the randomization number assigned to each randomized subject in a study. ***Note**: If the **Blind Randomization Number** option in your study's settings is set to **Yes**, data for this field displays as **Blinded**. For more information, see Specify study, enrollment, and visits settings.*
RANDOMIZATION_DATE	Indicates the date on which a subject has been randomized in the study.
RND_STATUS	Indicates whether a subject has been randomized or not in a study. • If randomized, a subject's status must be updated to **Active**. • If a subject is not randomized, their status can be: – **New**: If they're newly enrolled in the study at the time that you are creating a report using this data element. – **Screened**: If they're screened in the study at the time that you are creating a report using this data element. – **Enrolled**: If they're enrolled in the study at the time that you are creating a report using this data element, but they have been screened in a different system outside of Oracle Clinical One Platform.

Lot folder

This table describes the data elements included in the Lot folder.

Table 2-7 Data elements in the lot folder

Data element	Description
BLINDED_LOT_TITLE	Indicates the unique name of a blinded lot, as specified by a clinical supply manager when they created the blinded lot.
BLINDED_LOT_SHORT_NAME	Indicates an alternative blinded lot label, as specified by the clinical supply manager when they created the blinded lot. A blinded lot short name can be used when multiple depots use the same lot and have different naming conventions. One depot can use the title of a blinded lot, whereas another depot can use the short name.

Table 2-7 (Cont.) Data elements in the lot folder

Data element	Description
BLINDED_LOT_DO_NOT_COUNT_DAYS	Indicates the number of days before the expiration date when the kit is no longer counted in a site's inventory, as specified by the clinical supply manager when they created the blinded lot.
BLINDED_LOT_DO_NOT_SHIP_DAYS	Indicates the number of days before the expiration date when a kit can no longer be shipped from a depot to a site, as specified by the clinical supply manager when they created the blinded lot.
BLINDED_LOT_EXPIRATION_DATE	Indicates the expiration date for the entire blinded lot, as specified by the clinical supply manager when they created the blinded lot.

Shipment folder

This table describes the data elements included in the Shipment folder.

Table 2-8 Data elements in the shipment folder

Data elements	Description
SHIPMENT_NAME	Indicates a shipment's full name.
SHIPMENT_STATUS	Indicates the status of a shipment, as updated by the system or by a user in the study: • Pending • In Transit • Received • Cancelled • Lost • Confirmed • Invalid • Pending Destruction • Received for Destruction • Destroyed
SHIPMENT_CREATED_DATE	Indicates the date a shipment was created, whether it is a: • **Manual shipment**: this is a shipment that is created by either a depot or sponsor user. The date during which the shipment was created in displayed in Coordinated Universal Time (UTC). • **Automatic shipment**: this is a shipment that is automatically created and sent based on the study's resupply strategy (as designed by the clinical supply manager) or based on a study's integration with a clinical depot facility (as designed by your Oracle point of contact). The date during which the shipment was created in displayed in Coordinated Universal Time (UTC).
SHIPMENT_DATE	Indicates a shipment's ship date, either automatically specified by an integration with the clinical depot facility or manually specified by someone from either the sponsor or depot.
SHIPMENT_RECEIPT_DATE	Indicates the date on which the shipment was received.
SHIPMENT_RECEIVED_BY	Indicates the user who received the given shipment.
TRACKING_NUMBER	Indicates a shipment's tracking number, as specified by the depot user.

Kits (Required) folder

This table describes the data elements included in the Kit (Required) folder.

Table 2-9 Data elements in the Kit folder

Data element	Description
KIT_TYPE	A kit's type, as specified by the study designer when they created the kit. The following values can be displayed: • Investigation Product • Device • Kit Type Titration For more information on these kit types, see the following topics: • Define the kits for investigational products • Define the kits for devices • Define how subjects titrate
DEVICE_TYPE	Indicates the type of device, as specified by the study designer when they created the device kit type. The following values can be displayed: • Activity Watch • Blood Pressure Monitor • Glucose Monitor • Weight Scale • ECG Reader • Spirometer • Mobile App • Smart Pill Bottle • Pulse Oximeter • Wearable Patch • Other
DEVICE_CONNECTION	Indicates the type of device connection, as specified by the study designer when they created the device kit type. The following values can be displayed: • No Connection • Device to Cloud • Cloud to Cloud For more information on what each connection consists of, see Define the kits for devices.
TRIAL_SUPPLY_TYPE	Indicates the supply type of the kit, as specified by the study designer. The following values can be displayed: • Blister Pack • Bottle • Device • Syringe • Topical Ointment • Vial • Inhaler • Infusion • Box • Other
MINIMUM_KITS_TO_SHIP	Indicates the minim number of kits to include in each shipment to meet packaging requirements, as specified by the study designer when they created the kit type.

Table 2-9 (Cont.) Data elements in the Kit folder

Data element	Description
UNITS_PER_KIT	Indicates the number of units in the kit, such as the number of pills in a bottle, as specified by the study designer. For more information on this value, see Define the kits for investigational products.
CRA_VERIFIED	Indicates whether a question, a form, or a visit has been verified by a Clinical Research Associate (CRA).
BALANCE_UNITS	Indicates the total units of a kit minus the missing and returned units.
KIT_STATUS	Indicates a kit's status in the study's inventory. For more information on what a kit's status may be, see What statuses can kits have?.
KIT_NUMBER	Indicates a kit's number, as assigned in the system.
DISPENSATION_DATE	Indicates a kit's dispensation date, as entered by a site user when they dispensed the kit to a subject.
DOSAGE	Indicates the dosage for the dispensed kit, when the kit contains calculated doses.
BAR_CODE	If included in a study, this indicates a kit's bar code as generated by the system.
DISPENSATION_CONFIRMED	Indicates whether a kit's dispensation was confirmed by a site user.
MEASUREMENT	Indicates the total numeric value for the product in a kit with calculated doses, as defined by a study designer.
FREQUENCY	Indicates the dosing frequency as defined by a study designer.
RETURNED_UNITS	Number of units 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.
CONSERVED	Indicates whether a kit was conserved by a site user.
QUANTITY	Indicates a kit's quantity, as specified by the study designer.
INSTANCE_NUMBER	Indicates the repeat instance number of the visit.
VERIFIED_BY	Indicates the user who verified data associated with a question, a form, or a visit.
VERIFIED_DATE	Indicates the date when a question, form, or visit was verified. Date is displayed in UTC.
CONFIRMED_BY	Indicates the email address of the user who confirmed the dispensation of a specified kit.
CONFIRMED_DATE	Indicates the date at which a specified kit's dispensation was confirmed.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-10 Datat elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.

Table 2-10 (Cont.) Datat elements in the audit folder

Data element	Description
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.

Reference folder

This table describes the data elements in the Reference folder.

Table 2-11 Data elements in the reference folder

Data element	Description
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
SUBJECT_WID	Indicates a subject's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.
COHORT_WID	Indicates a cohort's numeric identifier.
SHIPMENT_WID	A number that represents the unique identifier of a shipment.
VERIFIED_BY_WID	Indicates the numeric identifier of a user who verified data associated with a visit.
CONFIRMED_BY_WID	Indicates the numeric identifier of a user who confirmed the dispensation of a kit during a visit.
USER_WID	Indicates a user's numeric identifier.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.

Blinded Subject Event dataset

You can use the Blinded Subject Events dataset in Oracle Clinical One Analytics to analyze and visualize blinded data and audit history of events associated to each subject, including randomization and trials supply management (RTSM) related data.

Modes

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

What type of data can I include in a blinded custom report or visualization on subject events?

With this dataset, you can get custom data such as:

- All the week 3 visits for a site that have not been completed
- All skipped visits for a subject.
- All the subjects that have completed a screening visit in a country
- All events that occurred at a site during March
- All of the patients that have been randomized in a country in the last 2 weeks
- Are my events being completed within the event window?

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event (Required) folder
- Kit folder
- Audit folder
- Aggregation folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-12 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-13 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.

Table 2-13 (Cont.) Data elements in the site folder

Data element	Description
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.

Table 2-13 (Cont.) Data elements in the site folder

Data element	Description
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_TYPE	Indicates the type of organization.
EHR_ENABLED	Indicates if a site is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a site or if a site was disabled for EHR.

Country folder

This table describes the data elements included in the Country folder.

Table 2-14 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-15 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event (Required) folder

This table describes the data elements included in the event folder.

Table 2-16 Data elements in the event folder

Data element	Description
FREEZE	Indicates if a visit is frozen by a data manager or CRA.

Table 2-16 (Cont.) Data elements in the event folder

Data element	Description
VERIFIED	Indicates the visit's verification status. Data element can be populated with the following values: • VERIFIED: A question, form, or visit is verified. • UNVERIFIED: A question, form, or visit was once verified, then updated making it unverified. • VERIFY_REQUIRED: A question, form, or visit requires verification and is not yet verified. • NOT_APPLICABLE
SIGNED	Indicates if a valid casebook signature is applied to the event.
IS_REQUIRED	Indicates if the visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarily impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
EVENT_INSTANCE_NUM	Indicates the unscheduled visit instance number as designed by the study designer.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).

Table 2-16 (Cont.) Data elements in the event folder

Data element	Description
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
IS_MISSING_VISIT	• N (No) indicates that a standard visit has been started. • Y (Yes) indicates that a standard (expected) visit has not been started. Dynamic, branching, and unscheduled visits only appear when the visit has been started, and data entry has occurred.
IS_OVERDUE_VISIT	Indicates whether the current date has passed the projected visit date.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Kit folder

This table describes the data elements in the Kit folder.

Table 2-17 Data elements in the Kit folder

Data element	Description
RAND_NUMBER	Indicates the randomization number assigned to each randomized subject in a study. ***Note**: If the **Blind Randomization Number** option in your study's settings is set to **Yes**, data for this field displays as **Blinded**. For more information, see Specify study, enrollment, and visits settings.*
KIT_NUMBERS	Indicates a kit's number, as assigned in the system.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-18 Datat elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Aggregation folder

This table describes the data elements in the Aggregation folder.

Table 2-19 Data elements in the Aggregation folder

Data element	Description
FORM_TOTAL_COUNT	Count of all forms created as part of the study design.
FORM_COMPLETED_COUNT	Count of completed forms. Repeating instances are only counted once, meaning that repeating rows are not counted as an additional completed form.

Reference folder

Data element	Description
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
SUBJECT_EVENT_INST_WID	A number that represents the unique identifier of a subject event's instance.
SUBJECT_WID	Indicates a subject's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.

Data element	Description
SCHEDULED_FROM_EVENT_WID	A number that represents the unique identifier of the previously scheduled event.
USER_WID	Indicates a user's numeric identifier.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
COUNT	Represents the count of blinded events.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Dh Metrics dataset

You can use Dh Metrics dataset to ensure that you're looking at the latest version of your study's data in the Oracle Clinical One Analytics.

Modes

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

What type of data can I obtain from using the Dh Metrics dataset?

With this dataset, you can get custom data such as:

- The date and time of the latest study data refresh that occurred.
- Whether the system pulled all of the study data to the operational data store and through Oracle Clinical One Analytics.
- The exact date and time of when your study's inventory data was pulled from Clinical One and compare it to when that same inventory-related data was then refreshed into Oracle Clinical One Analytics.
- Overall, indicators to know if your data in Oracle Clinical One Analytics is currently consistent with what you have in Oracle Clinical One Platform.

There is no specific permission to access this dataset, but you must be assigned with the permission to view and work with at least one other dataset. For information about permissions required to access Oracle Clinical One Analytics and all datasets, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or not applicable.

- Study folder
- Metrics folder

Study folder

This table describes the data elements included in the Study folder.

Table 2-20 Data elements in the Study folder

Data element	Description
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_TITLE	A protocol's title as specified by the study manager.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_DESIGN_STATUS	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.

Metrics folder

This table describes the data elements included in the Metrics folder.

Table 2-21 Data elements in the Metrics folder

Data element	Description
C1_INVENTORIES_MAX_VER_START	Maximum version of the *inventories* table from the core Clinical One system.
C1_INVENTORIES_ROWCNT	Row counts of the *inventores* table from the core Clinical One system.
C1_STDY_VER_HIST_MAX_VER_START	Maximum version of the *study versions history* table from the core Clinical One system.
C1_STUDY_VERSIONS_HIST_ROWCNT	Row counts of the *study versions history* table from the core Clinical One system.
C1_SUB_FORMITEMS_MAX_VER_START	Maximum version of the *subject form items* table from the core Clinical One system.
C1_SUBJECT_FORMITEMS_ROWCNT	Row counts of the *subject form items* table from the core Clinical One system.
DATASOURCE_NUM_ID	This is an Oracle use-only column, used in the return of results to Oracle Clinical One Analytics. Avoid using this data element in your reports.
DH_INVENTORIES_MAX_VER_START	Maximum version of the *inventories* table from the data model in the Oracle Clinical One Analytics system.
DH_INVENTORIES_ROWCNT	Row counts of the *inventories* table from the data model in the Oracle Clinical One Analytics system.

Table 2-21 (Cont.) Data elements in the Metrics folder

Data element	Description
DH_STDY_VER_HIST_MAX_VER_START	Maximum version of the *study versions history* table from the data model in the Oracle Clinical One Analytics system.
DH_STUDY_VERSIONS_HIST_ROWCNT	Row counts of the *study versions history* table from the data model in the Oracle Clinical One Analytics system.
DH_SUB_FORMITEMS_MAX_VER_START	Maximum version of the *subject form items* table from the data model in the Oracle Clinical One Analytics system.
DH_SUBJECT_FORMITEMS_ROWCNT	Row counts of the *subject form items* table from the data model in the Oracle Clinical One Analytics system.
ETL_PROC_WID	This is an Oracle use-only column, used in the return of results to Oracle Clinical One Analytics. Avoid using this data element in your reports.
HEARTBEAT_CONSOLIDATION_TS	Last time that the identified study and mode sent data that was retrieved for Oracle Clinical One Analytics.
IS_DATA_CONSISTENT	**Yes/No** label for consistency check. Indicates whether the study's data is consistent by comparing row counts and maximum version history from core Oracle Clinical One Platform and the Oracle Clinical One Analytics data model.
LAST_ETL_RUN_TIMESTAMP	Last time that the instance of Oracle Clinical One Analytics was processed for Analytics. Data processing always occurs after data retrieval.
STUDY_ID	Indicates the ID of the study as in the system.

Kits and Randomization Design dataset

You can use the Kits and Randomization Design dataset to analyze and visualize data in Oracle Clinical One Analytics regarding the metadata of kit definition, dispensation schedule and randomization definition for the study.

Modes

This dataset displays kits and randomization design details of a study version available in any mode.

What type of data can I include in a custom report or visualization on Kits and Randomization design?

With this dataset you can:

- Identify the kits and randomization configurations
- Identify randomization and dispensation visits
- Identify dispensation schedules

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse description of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

Study folder

This table describes the data elements included in the Study folder

Table 2-22 Data elements in the Study folder

Data element	Description
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.
STUDY_DESIGN_STATUS	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
MODIFIED_BY	The user who last modify the study.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
VERSION_START	Indicates the date and time of when the data was changed.

Randomization folder

This table describes the data elements included in the Randomization folder.

Table 2-23 Data elements in the randomization folder

Data elements	Description
RANDOMIZATION_TITLE	Indicates the title of a randomization strategy, as specified by a study designer when they design the randomization in Study Design mode.
RANDOMIZATION_DESCRIPTION	Indicates the description a study designer provides in the Description field, on the Create Randomization dialog. Creating a randomization is done in Study Design mode.
RANDOMIZATION_TYPE	Indicates the type of randomization, as specified by a study designer when creating a randomization: • **Blinded**: if blinded users should never see any of the titles of the treatment arms used in the randomization design. • **Unblinded**: if blinded users should always see the titles of the treatment arms used in the randomization design.
COHORT_NAME	Indicates the type of cohort selected by a study designer when creating a randomization design: • **None**: this indicates that the study has no cohorts • **Adaptive**: this indicates that the study contains cohorts that allow site staff to open treatment arms in a gradual manner so that the study team can better measure safety and efficacy as the study progresses. • **Demography**: this indicates that the study contains population groups according to demographic criteria, such as age.
COHORTTYPE	Indicates the type of cohort selected by a study designer when creating a randomization design: • **None**: this indicates that the study has no cohorts • **Adaptive**: this indicates that the study contains cohorts that allow site staff to open treatment arms in a gradual manner so that the study team can better measure safety and efficacy as the study progresses. • **Demography**: this indicates that the study contains population groups according to demographic criteria, such as age.
RERANDOMIZATION	Indicates whether the study designer chose to use the current randomization design for a second or later randomization event in the study. Values can be **1** or **0**.
TREATMENT_ARM_TITLE	Indicates the title of the treatment arm from the protocol, as specified by the study designer when they created the treatment arm in Study Design mode. Displays the title for every treatment arm created in the study.
TREATMENT_ARM_DESCRIPTION	Indicates the additional details provided by a study designer in the Description field, when they created the treatment arm in Study Design mode.
TREATMENT_ARM_ID	Indicates the short name that helps a user identify a treatment arm, such as A or Active 1, as specified by the study designer when they created the treatment arm.
RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES	Indicates the option that a study designer chose (Yes or No) when configuring this setting. • **Yes**: Indicates that the study designer created the randomization to skip the randomization number for an out-of-stock kit and assign the randomization number for the next available kit. • **No**: Indicates that a study designer chose not to restrict the randomization to available kit types, determining a randomization failure to occur when there are no available kit types in the study for a site user to randomize a subject.

Table 2-23 (Cont.) Data elements in the randomization folder

Data elements	Description
ASSIGN_SKIPPED_RANDOMIZATION_NUMBERS	Indicates the option that a study designer chose (Yes or No) when configuring this setting. • **Yes**: indicates that, when a randomization number is skipped because its kit is not in stock, the skipped randomization number is assigned to a subject who enrolls after the out-of-stock kit is available again. • **No**: indicates that skipped randomization numbers are never assigned to subjects.
RANDOMIZATION_VERSION_START	Indicates the date and time of when the randomization data was entered.
RANDOMIZATION_VERSION_END	Indicates the date and time of when randomization data was changed, if the data is not current.

Event folder

This table describes the data elements included in the event folder.

Table 2-24 Data elements in the event folder

Data element	Description
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarily impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.

Table 2-24 (Cont.) Data elements in the event folder

Data element	Description
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_HOUR_SEQ_ORDER	The order in which subject visits occur, as configured in the study design.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Kit folder

This table describes the data elements included in the Kit folder.

Table 2-25 Data elements in the kit folder

Data element	Description
KIT_TYPE	A kit's type, as specified by the study designer when they created the kit. The following values can be displayed: • Investigation Product • Device • Kit Type Titration For more information on these kit types, see the following topics: • Define the kits for investigational products • Define the kits for devices • Define how subjects titrate

Table 2-25 (Cont.) Data elements in the kit folder

Data element	Description
DEVICE_TYPE	Indicates the type of device, as specified by the study designer when they created the device kit type. The following values can be displayed: • Activity Watch • Blood Pressure Monitor • Glucose Monitor • Weight Scale • ECG Reader • Spirometer • Mobile App • Smart Pill Bottle • Pulse Oximeter • Wearable Patch • Other
DEVICE_CONNECTION	Indicates the type of device connection, as specified by the study designer when they created the device kit type. The following values can be displayed: • No Connection • Device to Cloud • Cloud to Cloud For more information on what each connection consists of, see Define the kits for devices.
CALCULATING_DOSES	Indicates whether the study designer specified that the kit type should have calculations defined based on subjects' answers to one or more questions. The values following values can be displayed: 1 or 0.
DISTRIBUTION_SETTINGS	Indicates the type of distribution a kit has, as specified by the study designer. The following values can be displayed: • **Blinded**: if blinded users should never see the kit type description. • **Unblinded**: if blinded users should always see the kit type description. • **Unblinded Pharmacist**: if blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types.
KIT_TYPE_ID	Indicates the unique identifier for a kit type.
TYPE	Indicates the supply type of the kit, as specified by the study designer. The following values can be displayed: • Blister Pack • Bottle • Device • Syringe • Topical Ointment • Vial • Inhaler • Infusion • Box • Other
MINIMUM_KITS_TO_SHIP	Indicates the minim number of kits to include in each shipment to meet packaging requirements, as specified by the study designer when they created the kit type.

Table 2-25 (Cont.) Data elements in the kit folder

Data element	Description
UNITS_PER_KIT	Indicates the number of units in the kit, such as the number of pills in a bottle, as specified by the study designer. For more information on this value, see Define the kits for investigational products.
SINGLE_UNIT_DOSE_UNITS	Indicates how one unit in the kit is measured.
SINGLE_UNIT_DOSE_VALUE	Indicates how one unit in the kit is measured, specifically its specified value.
TITRATION	Indicates if a kit type is part of a kit type titration. Values can be 1 or 0.
KIT_VERSION_START	Indicates the date and time of when the kit data was entered.
KIT_VERSION_END	Indicates the date and time of when kit data was changed, if the data is not current.

Calculated dose folder

This table describes the data elements included in the Calculated dose folder.

> **Note:**
>
> For more information on each of these data elements, see Define kits with calculated doses.

Data element	Description
CALCULATED_DOSE_TITLE	Indicates the title of the kit type containing calculated doses, as specified by the study designer.
FORM_QUESTION_FOR_CALCULATED_DOSE	Indicates the question that is selected by the study designer to be used in calculating the appropriate dose.
VISIT_WHERE_FORM_IS_COLLECTED	Indicates the visit in which the question that is used to calculate the appropriate dose is asked, as specified by the study designer.
PRECISION_FOR_EACH_DOSE	Indicates the number of places after the decimal point that each dose should be calculated in, as specified by the study designer. For example, if the precision for each dose is 0.0001, this value displays the number 4.
ROUND_UP_FOR	Indicates how the rounding is performed to reach the dose precision, as specified by the study designer. This field displays a whole number indicating the minimal decimal value to round-up and reach dose precision. For example, if the precision for each dose is 0.0001 and the round up is 0.00006 (as entered in the Oracle Clinical One Platform): • For the dose precision, the number 4 is displayed (this value represents the number of places after the decimal point). • For the dose round up, the number 6 is displayed.
DOSING_FREQUENCY	Indicates how many doses the subject must consume, as specified by the study designer.

Data element	Description
USE_LEFTOVER_UNITS_IN_NEXT_DOSE	Indicates whether leftover units from a previous dose can be used in a next dose, during the study conduct period, as specified by the study designer.
KIT_MEASUREMENT	Indicates the total numeric value for the product in the kit, as specified by the study designer.
SUBJECT_MEASUREMENT	Indicates the value that, along with the answer for the subject and the value of a single unit, determines the dose, as specified by the study designer.

Reference folder

This table describes the data elements in the Reference folder.

Table 2-26 Data elements in the reference folder

Data element	Description
STUDY_WID	A number that represents the unique identifier of the study.
COHORT_WID	Indicates a cohort's numeric identifier.
KIT_WID	Indicates the numeric identifier of a kit.
MODIFIED_BY_WID	The unique numeric identifier of the user who modified the study.
ARM_WID	A number that represents the unique identifier of a treatment arm.
STUDYEVENT_WID	A number that represents the unique identifier of an event.
RAND_WID	Indicates the numeric identifier of the randomization design.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-27 Datat elements in the audit folder

Data element	Description
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Queries dataset

You can use the Queries dataset to analyze and visualize details and audit history of query data.

Modes

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

What type of data can I include in a custom report or visualization on queries?

With this dataset, you can:

- View all queries in a state of *Open* and *Answered* to find a quick resolution.
- Identify form questions and items with the most queries across your study.
- Identify all questions with queries raised against them.
- Visualize visit dates alongside with the queries raised against them.

> **Note:**
>
> Queries on visit dates are associated with the following metadata:
>
> – FORM_NAME = 'Visit Date'
> – FORM_REFNAME = 'Visit Date'
> – ITEM_NAME = 'Visit Date'
> – REFERENCE_CODE = 'Visit Date'
>
> Other columns not applicable to visit date queries are `null`.

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

> **Note:**
>
> This dataset supports data classifications security. All data that you have access to view in Oracle Clinical One Platform will be visible to you.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder

- Event folder
- Form folder
- Item folder
- Query (Required) folder
- Audit folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-28 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-29 Data elements in the Site folder

Data element	Description
PI_PREFIX	Indicates the principal investigator's prefix, as configured by a site manager
ADD_SUBJECTS	Indicates whether a site is restricted from adding subjects, as configured by a site manager

Table 2-29 (Cont.) Data elements in the Site folder

Data element	Description
SCREEN_SUBJECTS	Indicates whether a site is restricted from screening subjects, as configured by a site manager
RANDOMIZE_SUBJECTS	Indicates whether a site is restricted from randomizing subjects, as configured by a site manager
DISPENSE_TO_SUBJECTS	Indicates whether a site is restricted from dispensing kits to subjects, as configured by a site manager
DEA_NUMBER	Indicates the DEA Registration Number as defined by a site manager
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager
INITIAL_SUBJECTS_COUNT	Indicates the number of initial subjects at a site whose data must be verified by a CRA, as specified by a study manager
INITIAL_SUBJECTS_SDV_TYPE	Indicates the type of source data verification to be performed by a CRA for the data of initially enrolled subjects, as specified by a study manager
REMAINING_SUBJECTS_PERCENTAGE	Indicates the percentage of remaining subjects to be eligible for source data verification, as specified by a study manager
REMAINING_SUBJECTS_SDV_TYPE	Indicated the type of source data verification to be performed by a CRA for the data of the remaining subjects, as specified by a study manager
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code

Table 2-29 (Cont.) Data elements in the Site folder

Data element	Description
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
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site
SHIPPING_ADDRESS_2	The second line of a site's shipping address as entered by the site manager when they created or last modified the site
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site
SHIPPING_ZIP	Zip Postal Code associated with the shipping address
SHIPPING_PHONE	Phone number associated with the shipping address
SHIPPING_FAX	Fax number associated with the shipping address
SHIPPING_EMAIL	Email address associated with the shipping address
EHR_ENABLED	Indicates if a site is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a site or if a site was disabled for EHR.

Country folder

This table describes the data elements included in the Country folder.

Table 2-30 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-31 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event folder

This table describes the data elements included in the event folder.

Table 2-32 Data elements in the event folder

Data element	Description
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarily impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.

Table 2-32 (Cont.) Data elements in the event folder

Data element	Description
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Form folder

This table describes the data elements included in the Event folder.

Table 2-33 Data elements in the Form folder

Data element	Description
FORM_NAME	The name of the form, as specified by the study designer.
IS_ROLLOVER	Indicates whether the form contains a rollover type of question.
IS_REPEATING	Indicates if it is a repeating form.
FORM_STATUS	Can have one of the following values: • COMPLETED • COMPLETE_WITH_ERRORS • IN_PROGRESS • INCOMPLETE • INCOMPLETE_WITH_ERRORS • SCHEDULED • BLANK

Table 2-33 (Cont.) Data elements in the Form folder

Data element	Description
FORM_REFNAME	A form's reference name.
REPEAT_FORM_NUMBER	Refers to the form instance number of all applicable form types with repeating data: • **Two section forms:** indicates the form instance number. • **Lab forms:** defaulted to a value of 1. • **Repeating forms:** this value will be null.

Item folder

This table describes the data elements included in the Item folder.

> **Note:**
>
> There is a record for every change applied in Oracle Clinical One Platform. For each query, the query item displays the value at the time the query was raised. If a user updates the item and automatically closes the query or manually updates the query status, a new record is created and, for that record, the item displays its value at the time of the update.

Table 2-34 Data elements in the Item folder

Data element	Description
ITEM_NAME	Indicates the title of the question, as entered by a study designer.
VALIDATION_STATUS	Indicates if a form item passed validation. For example, if the question was entered correctly and a rule was not broken.
VALUE	The raw value of the form question value (can be an array in questions with decodes). For more details see Form item output mapping in data extracts.
MEASURE_UNIT	Indicates the measure of unit specified by a study designer for a Number type of question.
NORMALIZED_VALUE	Currently not populated.
VALIDATION_FAILURE	Reason for failure if validation status is failed or the rule validation failed.
NUM_VALUE	If the question type is a calculation, measurement, or number, this field is populated with that number.
FLOAT_VALUE	Item value without decimal places, if precision is provided in the study design.
UTC_DATETIME_VALUE	Indicates the date and time in UTC for a Date/Time type of question.
MONTH_VALUE	If the question type is Date/Time, this field is populated with the month value (1-12).
DAY_VALUE	If the question type is Date/Time, this field is populated with the day value (1-31).
YEAR_VALUE	If the question type is Date/Time, this field is populated with the year value (i.e. 2021).
HOUR_VALUE	If the question type is Date/Time, this field is populated with the hour value (0-23).

Table 2-34 (Cont.) Data elements in the Item folder

Data element	Description
MINUTE_VALUE	If the question type is Date/Time, this field is populated with the minute value (0-59).
SECOND_VALUE	If the question type is Date/Time, this field is populated with the second value (0-59).
ITEM_D	Decoded raw value, with additional considerations according to data type. If the question has a code value, it is populated in this field. For more details see Form item output mapping in data extracts.
ITEM_R	The raw value: alphanumeric value as entered in Oracle Clinical One Platform with no conversions. This includes data entry flags. For more details see Form item output mapping in data extracts.
ITEM_F	The formatted value: value as entered in Oracle Clinical One Platform converted to the question data type as per form design. For more details see Form item output mapping in data extracts.
ITEM_TYPE	The form item's question type.
QUESTION_TYPE	Indicates the type of question as defined by a study designer.
QUESTION_HINT	Indicates information that a study designer provided as a hint to help answer a question.
FORMITEM_IS_REQUIRED	Indicates if the question is required. Required questions must be answered in order to save the form that contains it.
READONLY	Indicates that the question is marked as read-only by a study designer.
SAS_VARIABLE	Indicates the SAS Variable of a form defined by a study designer.
SAS_LABEL	Indicates the SAS Label of a form defined by a study designer.
REFERENCE_CODE	Indicates a question's reference code.
HIDDEN	Indicates if a question is hidden, as marked by a study designer.
FREEZE	Indicates if a question is frozen by a data manager or CRA.
VERIFIED	Indicates the question's verification status. Data element can be populated with the following values: • VERIFIED: A question, form, or visit is verified. • UNVERIFIED: A question, form, or visit was once verified, then updated making it unverified. ***Note:*** VERIFY_REQUIRED *and* NOT_APPLICABLE *are not currently supported statuses in Oracle Clinical One Analytics.*
SIGNED	Indicates if a valid casebook signature is applied to the item.

Query (Required) folder

This table describes the data elements included in the Query (Required) folder.

Data element	Description
STATE	Indicates a query's status: • Opened • Answered • Closed • Candidate query
HAS_QUERY	Indicates if there is a query raised against a question, irrespective of the status.
ASSIGNED_ROLES	Indicates the roles that are assigned to receive a query.

Data element	Description
QUERYAGE	Indicates the number of days passed since a query was first opened.
QUERY_COMMENT	Indicates a comment associated with a query, as entered by the user who last modified the query.
IS_AUTO_QUERY	Indicates whether this is an automated query.
QUERY_TYPE	Indicates the query type.
PROPERTY_NAME	Name of the property to which the query is associated to. This only applies to queries on visit dates and the default is `visitStartDate`. ***Note**: For other queries, this value is `null`.*
PROPERTY_TYPE	Type of property to which the query is associated to. This only applies to queries on visit dates and the default is `visit`. ***Note**: For other queries, this value is `null`.*

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-35 Data elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.
EHR_IMPORTED	Indicates if a question was populated via an Electronic Health Record (EHR) data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.

Reference folder

This table describes data elements in the Reference folder.

Table 2-36 Data elements in the Reference folder

Data element	Description
QUERY_WID	A number that represents unique identifier of a query.
STATE_ID	Numeric value that represents a query state.
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
SUBJECT_WID	Indicates a subject's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.
EVENT_INSTANCE_NUM	Indicates the unscheduled visit instance number as designed by the study designer.
FORM_WID	A number that represents the unique identifier of a form.
REPEAT_SEQUENCE_NUMBER	Refers to the row instance number of all applicable form types with repeating data: • **Two section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** indicates the repeating form number.
ITEM_WID	A number that represents the unique identifier of an item.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
USER_WID	Indicates a user's numeric identifier.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
SUBJECT_EVENTINST_FORMITEM_WID	A number that represents the unique identifier of an item within a subject form associated with a specific visit instance.
SUBJECT_EVENT_INST_WID	A number that represents the unique identifier of a subject event's instance.
PARENT_WID	Currently not populated.
ROOT_WID	Currently not populated.
SCHEDULED_FROM_EVENT_WID	A number that represents the unique identifier of the previously scheduled event.
COUNT	Represents the count of queries.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Study Codelist dataset

You can use the Study Codelist dataset in Oracle Clinical One Analytics to analyze and visualize data regarding codelists at both study and global level, as well as current code configurations and changes made over time.

Modes

This dataset displays design details of a study version available in any mode.

Roles that can run the report

Any user that's assigned the *Run the Analytics Study Codelist Dataset* permission can generate this report.

Global level codelists data is only available to global users assigned with the *Code List Manager* or the *Oracle Admin* roles.

> **Note:**
>
> Datasets in Oracle Clinical One Analytics display the data that you are allowed to view or edit based on defined data classifications.

What type of data can I include in a custom report or visualization on study codelists?

The Study Codelist dataset can include detailed information about codes configured at study level. For instance, you can do the following:

- View all codelists available for your organization.
- View all available codelist items in multi-select questions, instead of just selected choices.
- Reference the study codelist dictionary when reviewing clinical data extracts.
- Review updates made to a codelist at the study level.
- Review updates made to code configuration at the global level.

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

Study folder

This table describes the data elements included in the Study folder

Table 2-37 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.
STUDY_DESIGN_STATUS	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.

Codelists folder

This table describes the data elements included in the Codelists folder.

Data element	Description
CODE	Custom defined identifier for a code in Oracle Clinical One Platform.
CODE_DESCRIPTION	The description of the code record.
CODE_GROUP_NAME	Name that identifies the code group.
CODE_LABEL	Full code name that gets displayed.
CODE_LEVEL	Describes whether the record is at a system or custom level codelist.
CODE_NAME	The name of the codelist.
CODE_VALUE	The code value.
COMMENTS	Comment for record change.
DH_CODELIST_LEVEL	Describes whether it is an item, study or tenant codelist.
LOCALE	Code locale. English, Chinese and Japanese languages are supported.
REASON	User provided reason for record change.
SEQUENCE	Corresponds to the order assigned to a code in a codelist. This determines the order in which the codes in a codelist get listed.
DISPLAY_CODE_NAME	Name that appears in a dropdown when a codelist is used.
TAG	User defined tag for the code.
CL_HIDDEN	Denotes if a code is hidden to end users.

Event folder

This table describes the data elements included in the event folder.

Table 2-38 Data elements in the event folder

Data element	Description
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_TYPE	Displays the type of event that primarly impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
VISIT_CREATION_ORDER	Numeric visit order that follows the visit schedule as it was created.
VISIT_HOUR_SEQ_ORDER	The order in which subject visits occur, as configured in the study design.
VISIT_IS_REQUIRED	Indicates if a visit is required.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).

Table 2-38 (Cont.) Data elements in the event folder

Data element	Description
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Form folder

This table describes the data elements included in the Form folder.

Table 2-39 Data elements in the Form folder

Data Element	Description
FORM_IS_REPEATING	Indicates whether the form is repeating.
FORM_IS_ROLLOVER	Indicates whether the form is rollover.
FORM_NAME	The name of the form, as specified by the study designer.
FORM_REFNAME	A form's reference name.
FORM_TYPE	Indicates the type of form: • One-section form • Two-section form • Lab form

Item folder

This table describes the data elements included in the Item folder.

Data Element	Description
GROUP_TYPE	Indicates if this is a group question.
HIDDEN	Indicates if a question is hidden, as marked by a study designer.
ITEM_GROUP	If this is a group question, indicates the group question title.
ITEM_GROUP_ID	If this is a group question, indicates the group question ID.
ITEM_NAME	Indicates the title of the question, as entered by a study designer.
MEASURE_UNIT	Indicates the measure of unit specified by a study designer for a Number type of question.
QUESTION_HINT	Indicates information that a study designer provided as a hint to help answer a question.
QUESTION_TYPE	Indicates the type of question as defined by a study designer.
READONLY	Indicates that the question is marked as read-only by a study designer.
REFERENCE_CODE	Indicates a question's reference code.
SAS_LABEL	Indicates the SAS Label of a form defined by a study designer.
SAS_VARIABLE	Indicates the SAS Variable of a form defined by a study designer.
FORMITEM_IS_REQUIRED	Indicates if the question is required. Required questions must be answered in order to save the form that contains it.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-40 Datat elements in the audit folder

Data element	Description
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
VERSION_START	Indicates the date and time of when the data was changed.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Reference folder

Data element	Description
CODE_GROUP_WID	A number that represents the unique identifier of a codelist group.
CODE_VALUE_WID	A number that represents the unique identifier of a code value.
CODE_WID	A number that represents the unique identifier of a code record.
EVENT_WID	A number that represents the unique identifier of an event.
FORM_WID	A number that represents the unique identifier of a form.
ITEM_WID	A number that represents the unique identifier of an item.
STUDY_WID	A number that represents the unique identifier of the study.
USER_WID	Indicates a user's numeric identifier.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.

This table describes the data elements included in the Reference folder.

Data Element	Description
CODE_GROUP_WID	A number that represents the unique identifier of a codelist group.
CODE_VALUE_WID	A number that represents the unique identifier of a code value.
CODE_WID	A number that represents the unique identifier of a code record.

Data Element	Description
EVENT_WID	A number that represents the unique identifier of an event.
FORM_WID	A number that represents the unique identifier of a form.
ITEM_WID	A number that represents the unique identifier of an item.
STUDY_WID	A number that represents the unique identifier of the study.
USER_WID	A number that represents the unique identifier of an user.
CURRENT_STUDY_ROLE_WID	A number that represents the unique identifier of the user study role who updated the record. If the user study role changes, this field will show the current study role of the given user.
DH_TIMESTAMP	A timestamp that idicates when the transaction's data became available in the dataset.

Study Design dataset

You can use the Study Design dataset data regarding the metadata of visits, forms and items included in study versions and applied across study versions and modes.

Modes

This dataset displays data collection design details of a study version available in any mode. However, this datset does not include study design details from any study version moved directly from draft mode to archived.

> **Note:**
>
> For a study version in draft mode to be available, you need to manually publish data by clicking *Send to Analytics* in the draft mode dropdown. This option is only available to the following template study roles:
>
> - Study Designer
> - View Study Design
> - Data Manager
> - User Administrator

What type of data can I include in a custom report or visualization on Data Collection design?

With this dataset you can:

- Create a report to analyze data collection design and schedule
- Identify visits schedule and forms design
- Identify differences between study versions and modes
- Verify changes made in a study version before moving it to production
- Create a time and events table

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse description of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

Study folder

This table describes the data elements included in the Study folder

Table 2-41 Data elements in the Study folder

Data element	Description
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.
STUDY_DESIGN_STATUS	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
MODIFIED_BY	The user who last modify the study.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
VERSION_START	Indicates the date and time of when the data was changed.
OCC_ENABLED	Indicates if a study is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a study or if a study was disabled for EHR.

Branch folder

This table describes the data elements included in the Branch folder

Data element	Description
BRANCH_TITLE	Indicates the branch title or name.
IS_CYCLE_BRANCH	States whether the branch is cycled.
CYCLE_COUNT	Specifies the number of cycles in case the branch is cycled.
ASSIGN_SUBJECTS_USING_TREATMENT_ARM	Indicates if subjects are assigned to the branch by Treatment arm.
ASSIGN_SUBJECTS_USING_FORM_QUESTION	Indicates if subjects get assigned to branch by a form question.
BRANCH_ARM	Specifies which treatment arm(s) correspond to the current branch, in case subjects are assigned to the branch by treatment arm.
BRANCH_FORM	Specifies which form contains the question used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_QUESTION	Specifies which question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_ANSWER	Specifies which exact answer to the selected question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_VISIT	Specifies the visit containing the selected form and question that is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.

Event folder

This table describes the data elements included in the event folder.

Table 2-42 Data elements in the event folder

Data element	Description
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.

Table 2-42 (Cont.) Data elements in the event folder

Data element	Description
EVENT_TYPE	Displays the type of event that primarly impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_HOUR_SEQ_ORDER	The order in which subject visits occur, as configured in the study design.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.
ALERT_OUTSIDE_VISIT_WINDOW	Indicates if there is any rule set to alert if visit date is out of window. Values can be: • Off • Warning • Query

Form folder

This table describes the data elements included in the Form folder.

Table 2-43 Data elements in Form folder

Data element	Description
FORM_NAME	The name of the form, as specified by the study designer.
FORM_TYPE	Indicates the type of form: • One-section form • Two-section form • Lab form
FORM_IS_ROLLOVER	Indicates whether the form is rollover.
FORM_IS_REPEATING	Indicates whether the form is repeating.
FORM_REFNAME	A form's reference name.
ALLOW_ADDITIONAL_ROWS	Indicates if this is a repeating form that allows additional rows.
SOURCE_DATAVIEW_NAME	If it is a copied form, indicates the original form it was copied from.
SOURCE_STUDY_NAME	If it is a copied form, indicates the name of the study it was copied from.
SOURCE_STUDY_VERSION	If it is a copied form, indicates the study version of the study it was copied from.
SOURCE_VERSION_START	If it is a copied form, indicates the date and time of when the copied data was entered.
RULE_COPY_STATUS	If it is a copied form, indicates the status of the source form rules copy.

Item folder

This table describes the data elements included in the Item folder.

Table 2-44 Data elements in Item folder

Data element	Description
ITEM_NAME	Indicates the title of the question, as entered by a study designer.
GROUP_TYPE	Indicates if this is a group question.
MEASURE_UNIT	Indicates the measure of unit specified by a study designer for a Number type of question.
QUESTION_HINT	Indicates information that a study designer provided as a hint to help answer a question.
QUESTION_TYPE	Indicates the type of question as defined by a study designer.
FORMITEM_IS_REQUIRED	Indicates if the question is required. Required questions must be answered in order to save the form that contains it.
READONLY	Indicates that the question is marked as read-only by a study designer.
SAS_VARIABLE	Indicates the SAS Variable of a form defined by a study designer.
SAS_LABEL	Indicates the SAS Label of a form defined by a study designer.
REFERENCE_CODE	Indicates a question's reference code.
ITEM_GROUP	If this is a group question, indicates the group question title.
HIDDEN	Indicates if a question is hidden, as marked by a study designer.

Table 2-44 (Cont.) Data elements in Item folder

Data element	Description
ITEM_VALUES	The raw value of the form question value (can be an array in questions with decodes). For more details see Form item output mapping in data extracts.
CODELIST_VALUES	Lists the codelist values added as answers to the current question.
VALIDATION_RULES	Specifies the question's validation rule if any. Validation rules types available depend on the type of question: • Text questions: – *Doesn't contain* • Date/Time and Date of birth questions: – *After* – *On or After* – *Before* – *On or Before* – *On* – *Not On* – *Not Between* – *Range* • Number and Age questions: – *Greater Than* – *Greater Than or Equal To* – *Less Than* – *Less Than or Equal To* – *Is* – *Not Equal To* – *Not Between* – *Range* • Drop-down and checkboxes questions – *Select at Least* – *Select at Most* – *Select Exactly* – *Answer Must Be* • Radio Buttons questions: – *Answer Must Be*
RULE_ERROR	Reason for failure if validation status is failed or the rule validation failed.
ACTION_RULES	Details the action rule of a question which can be of the types: • *Show Question* • *Show Form* • *Show Visit* • *Link & Show Form*
SDV	Specifies if the question has any SDV parameter and if it is of the type *SDV for All Subjects* or *Critical Variables (Targeted SDV)*.
CODE_QUESTION	If the question has a *Coding Question* property, lists the following information: • Dictionary • Coding Item Type • Tag for Central Coding
FORMAT	Specifies the answer format. For example an specific date format, or the number of decimals after the point.
EHR_MAPPING	Displays the OCC data dictionary mapping value for a question mapped for Electronic Health Record (EHR) data import.

Reference folder

This table describes the data elements in the Reference folder.

Data element	Description
SOURCE_DATAVIEW_WID	If it is a copied form, indicates the numeric identifier of the form it was copied from.
SOURCE_STUDY_WID	If it is a copied form, indicates the numeric identifier of the study it was copied from.
STUDY_WID	A number that represents the unique identifier of the study.
BRANCH_WID	Indicates the unique numeric identifier of the branch.
EVENT_WID	A number that represents the unique identifier of an event.
FORM_WID	A number that represents the unique identifier of a form.
ITEM_WID	A number that represents the unique identifier of an item.
MODIFIED_BY_WID	The unique numeric identifier of the user who modified the study.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Audit folder

This table describes the data elements included in the Audit folder.

Data Element	Description
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Subject dataset

You can use the Subject dataset to analyze and visualize subject level details and the audit history of a subject's data.

Modes

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

What type of data can I include in a custom report or visualization on subject data?

With this dataset, you can find information such as:

- The number of subjects that have been screened at a specific site
- All subjects over 60 that have been screened failed
- All the reasons why subjects have failed screening at a specific site
- The number of subjects that have been randomized in a selected country

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

Study folder

This table describes the data elements included in the Study folder

Table 2-45 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.
STUDY_SERIAL_NUMBER	*For internal use only.* Internal Clinical One study identifier.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-46 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.

Table 2-46 (Cont.) Data elements in the site folder

Data element	Description
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_SERIAL_NUMBER	The serial number of the site
FROM_SITE_NAME	If a subject is transferred, this field is populated with the site the subject was transferred from
SITE_TYPE	Indicates the type of organization.

Country folder

This table describes the data elements included in the Country folder.

Table 2-47 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject (Required) folder

This table describes data elements in the Subject (Required) folder.

Table 2-48 Data elements in the Subject folder

Data element	Description
OLD_SUBJECT_NUMBER	A subject's previously assigned number in the system for a transferred subject.
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.
DOB	Indicates the date of birth. Currently, this is a placeholder column that does not contain any data. This column is planned for a future release.
SCREENING_DATE	Date of the subject's initial screening visit.
STATE	A subject's state.
STATE_DATE	The date the subject entered a state.
SCREENING_FAILURE	Indicates whether a subject failed the screening.
ENROLLMENT_FAILURE	Indicates whether a subject could not be enrolled in the study. Currently, this is a placeholder column that does not contain any data. This column is planned for a future release.
ENROLLMENT_OVERRIDE	Indicates a subject's enrollment override. Currently, this is a placeholder column that does not contain any data. This column is planned for a future release.
INFORMED_CONSENT_DATE	The date on which the informed consent was signed by the subject. Currently, this is a placeholder column that does not contain any data. This column is planned for a future release.
GENDER	The selected gender a subject identifies as. Currently, this is a placeholder column that does not contain any data. This column is planned for a future release.
CODE_BREAK	Indicates whether a subject went through a Code Break event.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
EXTERNAL_SOURCE_STATUS_DATE	Indicates the date on which the subject status was updated by an external source.
EHR_LINK_STATUS	Displays Yes or No, indicating if a subject is currently linked for Electronic Health Record (EHR) data import.

Event folder

This table describes data elements in the Events folder.

Table 2-49 Data elements in the Event folder

Data element	Description
EVENT_TYPE	Displays the type of event that impacts a subject's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following subject events: • Code_Break • Complete • CompletionUpdate • Enrolled • New • Randomized • Screen_Fail_Update • Screen_Failed • Screened • SubjectNumberChanged • SubjectNumberReplaced • Transferred • Undo_Add_Subject • Undo_Complete • Undo_ScrFailed • Undo_Withdrawn • WithdrawalUpdate • Withdrawn

Audit folder

> **Note:**
>
> Consider the following notes for the REASON data element:
>
> - Only the reason specified for a subject's screen failure or withdrawal events is displayed. In Oracle Clinical One Platform, you are not required to specify a reason for the subject's study completion, therefore there is no reason to display for this event in the Subjects dataset.
> - While you can see the reason for change that is specified anytime an update occurs for a subject's screen failure, study completion, or withdrawal event, you cannot view any updates to the event's specific reason. For example, if a subject's **Reason for Screen Fail** is updated in Oracle Clinical One Platform, this update is not specified in this dataset.

This table describes the data elements included in the Audit folder.

Table 2-50 Datat elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.

Table 2-50 (Cont.) Datat elements in the audit folder

Data element	Description
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Aggregation

> **Note:**
>
> If a form contains a hidden and required question that wasn't answered, the form's status is considered **Incomplete** and is not counted in the **COMPLETED_FORMS** data element, despite its status being displayed as **Complete** in the Oracle Clinical One Platform.

This table describes data elements in the Aggregation folder.

Table 2-51 Data elements in the Aggregation folder

Data element	Description
COMPLETED_FORMS	Count of completed forms for a subject, irrespective of visit status and form status. Each instance of a repeating form is counted as one form.
COMPLETED_VISITS	Count of completed visits for a subject. When there are incomplete visits, the count is recalculated. This data element does not include unscheduled visits.
TOTAL_FORMS	The total number of forms across visits in the study version. • A repeating form instance is counted as one form. • Forms assigned to an unscheduled visit are not included in this count.
TOTAL_FORMS_COMPLETED_VISITS	The total number of completed forms associated with visits
TOTAL_VISITS	The total number of visits in a study version. This count does not include unscheduled visits.

Reference folder

This table describes data elements in the Reference folder.

Table 2-52 Data elements in the Reference folder

Data element	Description
USER_WID	Indicates a user's numeric identifier.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
FROM_SITE_WID	A number that represents a site's unique identifier from which a subject was transferred.
SUBJECT_WID	Indicates a subject's numeric identifier.
DESCRIPTION	This is a placeholder column that does not contain any data.
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
COUNT	Represents the count of subjects.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Subject Form Items dataset

You can use the Subject Form Items dataset in Oracle Clinical One Analytics to analyze and visualize item-level data and the audit history of data entered for a question in a form for individual subjects.

Modes

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

What type of data can I include in a custom report or visualization on questions?

With this dataset, you can get custom data such as:

- All the form questions and answers that have been completed for a specific subject.
- All the incomplete form items by visit for all active subjects. Or how many subjects have an incomplete form at a specific site for a particular visit.
- All subjects with a specified answer value.
- Show all missing forms and questions for a subject.
- How many form items that require verification are there pending to be verified for a subject, site or study.
- Calculate the completion percentage of SDV, either for the entire study, by subject or by site.
- Build a report to project how much data will be collected at a site over a period of time to schedule monitoring visits.

- Identify all questions with queries raised against them. Including visit dates.
  For this use case, consider that queries on visit dates are associated to the following metadata:
  - FORM_NAME = 'Visit Date'
  - FORM_REFNAME = 'Visit Date'
  - ITEM_NAME = 'Visit Date'
  - REFERENCE_CODE = 'Visit Date'

  Other columns not applicable to visit date queries are `null`.

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> - This dataset supports data classifications security. All data that you have access to view in Oracle Clinical One Platform, will be visible to you.
> - Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event folder
- Form folder
- Item (Required) folder
- Audit folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-53 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-54 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.

Table 2-54 (Cont.) Data elements in the site folder

Data element	Description
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.

Table 2-54 (Cont.) Data elements in the site folder

Data element	Description
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_TYPE	Indicates the type of organization.
EHR_ENABLED	Indicates if a site is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a site or if a site was disabled for EHR.

Country folder

This table describes the data elements included in the Country folder.

Table 2-55 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-56 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event folder

This table describes the data elements included in the event folder.

Table 2-57 Data elements in the event folder

Data element	Description
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
EVENT_INSTANCE_NUM	Indicates the unscheduled visit instance number as designed by the study designer.

Table 2-57 (Cont.) Data elements in the event folder

Data element	Description
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_TYPE	Displays the type of event that primarily impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_IS_REQUIRED	Indicates if a visit is required.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.

Table 2-57 (Cont.) Data elements in the event folder

Data element	Description
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Form folder

> **Note:**
>
> If a form contains a hidden and required question that wasn't answered, the status of the form is considered **Incomplete** and reflected in the **FORM_STATUS** data element, despite its status being displayed as **Complete** in the Oracle Clinical One Platform.

This table describes the data elements included in the Form folder.

Table 2-58 Data elements in Form folder

Data Element	Description
FORM_NAME	The name of the form, as specified by the study designer.
FORM_REFNAME	A form's reference name.
FORM_STATUS	Can have one of the following values: • COMPLETED • COMPLETE_WITH_ERRORS • IN_PROGRESS • INCOMPLETE • INCOMPLETE_WITH_ERRORS • SCHEDULED • BLANK
IS_REPEATING	Indicates if it is a repeating form.
IS_ROLLOVER	Indicates whether the form contains a rollover type of question.
REPEAT_SEQUENCE_NUMBER	Refers to the row instance number of all applicable form types with repeating data: • **Two section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** indicates the repeating form number.

Table 2-58 (Cont.) Data elements in Form folder

Data Element	Description
REPEAT_FORM_NUMBER	Refers to the form instance number of all applicable form types with repeating data: • **Two section forms:** indicates the form instance number. • **Lab forms:** defaulted to a value of 1. • **Repeating forms:** this value will be null.
INNER_REPEAT	Refers to the *Section Repeat* values of all applicable form types with repeating data: • **Two section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** this value will be null.
OUTER_REPEAT	Refers to the *Form Repeat* values of all applicable form types with repeating data: • **Two section forms:** unique identifier of the non-repeating section of the form, the form instance number. • **Lab forms:** defaulted to a value of 1. • **Repeating forms:** unique numeric identifier of the repeating form.

Item (Required) folder

This table describes the data elements included in the Item (Required) folder.

Table 2-59 Data elements in the Item folder

Data Element	Description
DAY_VALUE	If the question type is Date/Time, this field is populated with the day value (1-31).
FLOAT_VALUE	Item value without decimal places, if precision is provided in the study design.
FREEZE	Indicates if a question is frozen by a data manager or CRA.
HIDDEN	Indicates if a question is hidden, as marked by a study designer.
HOUR_VALUE	If the question type is Date/Time, this field is populated with the hour value (0-23).
IS_REQUIRED	Indicates if the question is required. Required questions must be answered in order to save the form that contains it.
ITEM_D	Decoded raw value, with additional considerations according to data type. If the question has a code value, it is populated in this field. For more details see Form item output mapping in data extracts.
ITEM_F	The formatted value: value as entered in Oracle Clinical One Platform converted to the question data type as per form design. For more details see Form item output mapping in data extracts.
ITEM_NAME	Indicates the title of the question, as entered by a study designer.
ITEM_R	The raw value: alphanumeric value as entered in Oracle Clinical One Platform with no conversions. This includes data entry flags. For more details see Form item output mapping in data extracts.
ITEM_TYPE	The form item's question type.

Table 2-59 (Cont.) Data elements in the Item folder

Data Element	Description
MEASURE_UNIT	Indicates the measure of unit specified by a study designer for a Number type of question.
MINUTE_VALUE	If the question type is Date/Time, this field is populated with the minute value (0-59).
MONTH_VALUE	If the question type is Date/Time, this field is populated with the month value (1-12).
NORMALIZED_VALUE	Currently not populated.
NUM_VALUE	If the question type is a calculation, measurement, or number, this field is populated with that number.
QUESTION_HINT	Indicates information that a study designer provided as a hint to help answer a question.
QUESTION_TYPE	Indicates the type of question as defined by a study designer.
READONLY	Indicates that the question is marked as read-only by a study designer.
REFERENCE_CODE	Indicates a question's reference code.
SAS_LABEL	Indicates the SAS Label of a form defined by a study designer.
SAS_VARIABLE	Indicates the SAS Variable of a form defined by a study designer.
SECOND_VALUE	If the question type is Date/Time, this field is populated with the second value (0-59).
SIGNED	Indicates if a valid casebook signature is applied to the item.
UTC_DATETIME_VALUE	Indicates the date and time in UTC for a Date/Time type of question.
VALIDATION_FAILURE	Reason for failure if validation status is failed or the rule validation failed.
VALIDATION_STATUS	Indicates if a form item passed validation. For example, if the question was entered correctly and a rule was not broken.
VALUE	The raw value of the form question value (can be an array in questions with decodes). For more details see Form item output mapping in data extracts.
VERIFIED	Indicates the question's verification status. Data element can be populated with the following values: • VERIFIED: A question, form, or visit is verified. • UNVERIFIED: A question, form, or visit was once verified, then updated making it unverified. ***Note:*** VERIFY_REQUIRED *and* NOT_APPLICABLE *are not currently supported statuses in Oracle Clinical One Analytics.*
YEAR_VALUE	If the question type is Date/Time, this field is populated with the year value (i.e. 2021).
LAB_ID	Indicates the associated lab ID, when the item is part of a lab form.
LAB_NAME	Indicates the associated lab name, when the item is part of a lab form.
HAS_QUERY	Indicates if there is a query raised against a question, irrespective of the status.

Table 2-59 (Cont.) Data elements in the Item folder

Data Element	Description
SDV_SELECTED_STATUS	Indicates if, after all applicable Source Data Verification (SDV) settings combined, the question requires verification or not for the subject. This is determined based on the study SDV settings, the SDV strategy assigned to the site, whether the subject is part of the pool of selected subjects for SDV, and SDV settings defined at the item level in form design. For more information, see Understand Source Data Verification. This data element is populated with four possible values: • OBLIGATORY: the question requires verification. This means that either the study has a 100% SDV configuration or it has a Targeted SDV configuration and the question is selected for SDV for that given subject. • OPTIONAL: the question may be verified but it is not required for that given subject. *This is only applicable for Targeted SDV studies that allow SDV overrides.* • OPTIONAL_CRITICAL: the question is set as a critical variable but the subject is not part of the SDV subject pool, hence the question may be verified but it is not required for that given subject. *This is only applicable for Targeted SDV studies that allow SDV overrides.* • IRRELEVANT: the question is not configured for SDV for this subject and it is not expected to be verified. This would be the case of: – Read-only questions. – Studies set up for no SDV. – Studies with Targeted SDV configuration that don't allow SDV overrides. – Screen failed subjects when excluded from SDV.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-60 Datat elements in the audit folder

Data element	Description
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.

Table 2-60 (Cont.) Datat elements in the audit folder

Data element	Description
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
VERSION_START	Indicates the date and time of when the data was changed.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.
EHR_IMPORTED	Indicates if a question was populated via an Electronic Health Record (EHR) data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.

Reference folder

This table describes the data elements included in the Reference folder.

Data Element	Description
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
EVENT_WID	A number that represents the unique identifier of an event.
FORM_WID	A number that represents the unique identifier of a form.
ITEM_WID	A number that represents the unique identifier of an item.
PARENT_WID	Currently not populated.
ROOT_WID	Currently not populated.
SCHEDULED_FROM_EVENT_WID	A number that represents the unique identifier of the previously scheduled event.
SITE_WID	A number that represents the unique identifier of a site.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
STUDY_WID	A number that represents the unique identifier of the study.
SUBJECT_EVENT_INST_WID	A number that represents the unique identifier of a subject event's instance.
SUBJECT_EVENTINST_FORM_WID	A number that represents the unique identifier of a subject form associated with a specific visit instance.
SUBJECT_EVENTINST_FORMITEM_WID	A number that represents the unique identifier of an item within a subject form associated with a specific visit instance.
SUBJECT_WID	Indicates a subject's numeric identifier.
USER_WID	Indicates a user's numeric identifier.
COUNT	Represents the count of items.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Subject Forms dataset

You can use the Subject Forms dataset in Oracle Clinical One Analytics to analyze and visualize data and autdit history of forms associated to individual subjects.

Modes

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

What type of data can I include in a custom report or visualization on subject forms?

With this dataset you can get valuable information, such as:

- How many incomplete forms are there for a specific site, visit, and subject
- What forms are available for source data verification (SDV) at a particular site (CRA)
- When you should schedule a site visit based on the amount of completed forms there are at a site (CRA)
- The percentage of forms with a status of Incomplete, Completed, Frozen, Source Data Verification Complete, Signed by country, site, subject, and visit

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse descriptions of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event folder
- Form (Required) folder
- Form Association folder
- Audit folder
- Aggregation folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-61 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-62 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.

Table 2-62 (Cont.) Data elements in the site folder

Data element	Description
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.

Table 2-62 (Cont.) Data elements in the site folder

Data element	Description
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_TYPE	Indicates the type of organization.
EHR_ENABLED	Indicates if a site is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a site or if a site was disabled for EHR.

Country folder

This table describes the data elements included in the Country folder.

Table 2-63 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-64 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event folder

This table describes the data elements included in the event folder.

Table 2-65 Data elements in the event folder

Data element	Description
EVENT_TITLE	The event's title, defined by the user when an event is created.

Table 2-65 (Cont.) Data elements in the event folder

Data element	Description
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarly impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.

Table 2-65 (Cont.) Data elements in the event folder

Data element	Description
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
EVENT_INSTANCE_NUM	Indicates the unscheduled visit instance number as designed by the study designer.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Form (Required) folder

> **Note:**
>
> If a form contains a hidden and required question that wasn't answered, the status of the form is considered **Incomplete** and reflected in the **FORM_STATUS** data element, despite its status being displayed as **Complete** in the Oracle Clinical One Platform.

This table describes the data elements included in the Form (Required) folder.

Table 2-66 Data elements in the Form folder

Data Element	Description
FREEZE	Indicates if a form is frozen by a data manager or CRA.
VERIFIED	Indicates the form's verification status. Data element can be populated with the following values: • VERIFIED: A question, form, or visit is verified. • UNVERIFIED: A question, form, or visit was once verified, then updated making it unverified. ***Note:** VERIFY_REQUIRED and NOT_APPLICABLE are not currently supported statuses in Oracle Clinical One Analytics.*
SIGNED	Indicates if a valid casebook signature is applied to the form.
FORM_NAME	The name of the form, as specified by the study designer.
FORM_REFNAME	A form's reference name.

Table 2-66 (Cont.) Data elements in the Form folder

Data Element	Description
REPEAT_SEQUENCE_NUMBER	Refers to the row instance number of all applicable form types with repeating data: • **Two section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** indicates the repeating form number.
FORM_STATUS	Can have one of the following values: • COMPLETED • COMPLETE_WITH_ERRORS • IN_PROGRESS • INCOMPLETE • INCOMPLETE_WITH_ERRORS • SCHEDULED • BLANK
IS_REPEATING	Indicates if it is a repeating form.
IS_ROLLOVER	Indicates whether the form contains a rollover type of question.
REPEAT_FORM_NUMBER	Refers to the form instance number of all applicable form types with repeating data: • **Two section forms:** indicates the form instance number. • **Lab forms:** defaulted to a value of 1. • **Repeating forms:** this value will be null.
INNER_REPEAT	Refers to the *Section Repeat* values of all applicable form types with repeating data: • **Two section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** this value will be null.
OUTER_REPEAT	Refers to the *Form Repeat* values of all applicable form types with repeating data: • **Two section forms:** unique identifier of the non-repeating section of the form, the form instance number. • **Lab forms:** defaulted to a value of 1. • **Repeating forms:** unique numeric identifier of the repeating form.
IS_MISSING_FORM	• N (No) indicates that a form has been started. • Y (Yes) indicates that a form has not been started or all questions on that form were cleared/deleted. Dynamic and unscheduled forms only appear when the form has been started, and data entry has occurred.

Form Association folder

This table describes the data elements included in the Form Association folder.

Data element	Description
ASSOCIATED_EVENT_INSTANCE_NUM	The unique identifier for an associated event. ***Note**: If the visit is not UnScheduleAbleVisit, this field will not be populated with any value*.
ASSOCIATED_EVENT_NAME	The name of the associated event.
ASSOCIATED_FORM_NAME	The name of the associated form.
ASSOCIATED_FORM_REFNAME	Indicates the reference code of the associated form.
ASSOCIATED_FORM_TYPE	Indicates the form type of the associated form.
ASSOCIATED_REPEAT_SEQUENCE_NUM	When association is with a repeating form, indicates the associated sequence number.
ASSOCIATED_STUDY_VERSION	Indicates the study version of the associated form.
ASSOCIATED_REPEAT_FORM_NUM	When association is with a repeating form, indicates the associated repeating form number.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-67 Data elements in the audit folder

Data element	Description
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
VERSION_START	Indicates the date and time of when the data was changed.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Aggregation folder

This table describes the data elements included in the Aggregation folder.

Table 2-68 Data elements in the Aggregation folder

Data Element	Description
TOTAL_ITEMS	Number of total questions in a form
ENTERED_ITEMS	Number of questions answered in a form

Reference folder

This table describes the data elements included in the Reference folder.

Data Element	Description
SCHEDULED_FROM_EVENT_WID	A number that represents the unique identifier of the previously scheduled event.
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
SUBJECT_WID	Indicates a subject's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.
SUBJECT_EVENTINST_FORM_WID	A number that represents the unique identifier of a subject form associated with a specific visit instance.
FORM_WID	A number that represents the unique identifier of a form.
USER_WID	Indicates a user's numeric identifier.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
SUBJECT_EVENT_INST_WID	A number that represents the unique identifier of a subject event's instance.
COUNT	Represents the count of forms.
ASSOCIATED_EVENT_WID	A number that represents the unique identifier of the event to which the form is assigned when a form association is present.
ASSOCIATED_FORM_WID	A number that represents the unique identifier of the associated form, if present.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Unblinded Kits dataset

You can use the Unblinded Kits dataset to analyze and visualize data and the audit history of specific kits in the study, from management and dispensation. This dataset includes information that could potentially unblind a user.

In Oracle Clinical One Platform you can define kits to be **Blinded**, **Unblinded** (open label) or **Unblinded Pharmacist** for distribution. This dataset includes data about all blinded, unblinded and unblinded pharmacist kits, including details that may compromise the integrity of the study blind, such as treatment arm information. To work with blinded data see Blinded Kits dataset.

Modes

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

What type of data can I include in an unblinded custom report or visualization?

With this dataset, you can get custom data such as:

- Kit inventory status at all sites in a study.

> **Note:**
>
> Non-serialized kits are managed in bulk and only display the current status for a count of kits grouped in a lot. To track each kit individually, you need to use serialized kits.

- What kit numbers are included in a shipment and the shipment status.
- Randomization and treatment arm details for all subjects in a study.
- Manufacturing and blinded lots status data.
- Kit dispensation data.

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

Browse description of data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event folder
- Randomization folder
- Lot folder
- Shipment folder
- Kits (Required) folder
- Calculated dose folder
- Audit folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-69 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-70 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.

Table 2-70 (Cont.) Data elements in the site folder

Data element	Description
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.

Table 2-70 (Cont.) Data elements in the site folder

Data element	Description
SITE_TYPE	Indicates the type of organization.

Country folder

This table describes the data elements included in the Country folder.

Table 2-71 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-72 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.

Event folder

This table describes the data elements included in the event folder.

Table 2-73 Data elements in the event folder

Data element	Description
VISIT_IS_REQUIRED	Indicates if a visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.

Table 2-73 (Cont.) Data elements in the event folder

Data element	Description
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarily impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_TITLE	The event's title, defined by the user when an event is created.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Randomization folder

This table describes the data elements included in the Randomization folder.

Table 2-74 Data elements in the randomization folder

Data elements	Description
RANDOMIZATION_TITLE	Indicates the title of a randomization strategy, as specified by a study designer when they design the randomization in Study Design mode.
RANDOMIZATION_DESCRIPTION	Indicates the description a study designer provides in the Description field, on the Create Randomization dialog. Creating a randomization is done in Study Design mode.
RANDOMIZATION_TYPE	Indicates the type of randomization, as specified by a study designer when creating a randomization: • **Blinded**: if blinded users should never see any of the titles of the treatment arms used in the randomization design. • **Unblinded**: if blinded users should always see the titles of the treatment arms used in the randomization design.
COHORT_NAME	Indicates the type of cohort selected by a study designer when creating a randomization design: • **None**: this indicates that the study has no cohorts • **Adaptive**: this indicates that the study contains cohorts that allow site staff to open treatment arms in a gradual manner so that the study team can better measure safety and efficacy as the study progresses. • **Demography**: this indicates that the study contains population groups according to demographic criteria, such as age.
RERANDOMIZATION	Indicates whether the study designer chose to use the current randomization design for a second or later randomization event in the study. Values can be **1** or **0**.
TREATMENT_ARM_TITLE	Indicates the title of the treatment arm from the protocol, as specified by the study designer when they created the treatment arm in Study Design mode. Displays the title for every treatment arm created in the study.
TREATMENT_ARM_DESCRIPTION	Indicates the additional details provided by a study designer in the Description field, when they created the treatment arm in Study Design mode.
TREATMENT_ARM_ID	Indicates the short name that helps a user identify a treatment arm, such as A or Active 1, as specified by the study designer when they created the treatment arm.
RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES	Indicates the option that a study designer chose (Yes or No) when configuring this setting. • **Yes**: Indicates that the study designer created the randomization to skip the randomization number for an out-of-stock kit and assign the randomization number for the next available kit. • **No**: Indicates that a study designer chose not to restrict the randomization to available kit types, determining a randomization failure to occur when there are no available kit types in the study for a site user to randomize a subject.

Table 2-74 (Cont.) Data elements in the randomization folder

Data elements	Description
ASSIGN_SKIPPED_RANDOMIZATION_NUMBERS	Indicates the option that a study designer chose (Yes or No) when configuring this setting. • **Yes**: indicates that, when a randomization number is skipped because its kit is not in stock, the skipped randomization number is assigned to a subject who enrolls after the out-of-stock kit is available again. • **No**: indicates that skipped randomization numbers are never assigned to subjects.
RAND_NUMBER	Indicates the randomization number assigned to each randomized subject in a study. ***Note**: If the **Blind Randomization Number** option in your study's settings is set to **Yes**, data for this field displays as **Blinded**. For more information, see Specify study, enrollment, and visits settings.*
RND_STATUS	Indicates whether a subject has been randomized or not in a study. • If randomized, a subject's status must be updated to **Active**. • If a subject is not randomized, their status can be: – **New**: If they're newly enrolled in the study at the time that you are creating a report using this data element. – **Screened**: If they're screened in the study at the time that you are creating a report using this data element. – **Enrolled**: If they're enrolled in the study at the time that you are creating a report using this data element, but they have been screened in a different system outside of Oracle Clinical One Platform.
RANDOMIZATION_DATE	Indicates the date on which a subject has been randomized in the study.

Lot folder

This table describes the data elements included in the Lot folder.

Table 2-75 Data elements in the lot folder

Data element	Description
MANFACTURING_LOT_TITLE	Indicates the unique name of a manufacturing lot title, as specified by a clinical supply manager when they created the manufacturing lot.
BLINDED_LOT_TITLE	Indicates the unique name of a blinded lot, as specified by a clinical supply manager when they created the blinded lot.
BLINDED_LOT_DO_NOT_COUNT_DAYS	Indicates the number of days before the expiration date when the kit is no longer counted in a site's inventory, as specified by the clinical supply manager when they created the blinded lot.
BLINDED_LOT_DO_NOT_SHIP_DAYS	Indicates the number of days before the expiration date when a kit can no longer be shipped from a depot to a site, as specified by the clinical supply manager when they created the blinded lot.
BLINDED_LOT_EXPIRATION_DATE	Indicates the expiration date for the entire blinded lot, as specified by the clinical supply manager when they created the blinded lot.

Table 2-75 (Cont.) Data elements in the lot folder

Data element	Description
BLINDED_LOT_SHORT_NAME	Indicates an alternative blinded lot label, as specified by the clinical supply manager when they created the blinded lot. A blinded lot short name can be used when multiple depots use the same lot and have different naming conventions. One depot can use the title of a blinded lot, whereas another depot can use the short name.
MANFACTURING_LOT_SHORT_NAME	Indicates an alternative manufacturing lot label, as specified by the clinical supply manager when they created the manufacturing lot. A manufacturing lot short name can be used when your organization's labeling conventions differ from the lot name supplied by the depot.
MANFACTURING_LOT_DO_NOT_COUNT_DAYS	Indicates the number of days before the expiration date when the kit is no longer counted in a site's inventory, as specified by the clinical supply manager when they created the blinded lot.
MANFACTURING_LOT_DO_NOT_SHIP_DAYS	Indicates the number of days before the expiration date when a kit can no longer be shipped from a depot to a site, as specified by the clinical supply manager when they created the manufacturing lot.
MANFACTURING_LOT_EXPIRATION_DATE	Indicates the expiration date for the kits in the manufacturing lot, as specified by the clinical supply manager when they created the manufacturing lot.

Shipment folder

This table describes the data elements included in the Shipment folder.

Table 2-76 Data elements in the shipment folder

Data elements	Description
SHIPMENT_NAME	Indicates a shipment's full name.
SHIPMENT_STATUS	Indicates the status of a shipment, as updated by the system or by a user in the study: • Pending • In Transit • Received • Cancelled • Lost • Confirmed • Invalid • Pending Destruction • Received for Destruction • Destroyed
SHIPMENT_CREATED_DATE	Indicates the date a shipment was created, whether it is a: • **Manual shipment**: this is a shipment that is created by either a depot or sponsor user. The date during which the shipment was created in displayed in Coordinated Universal Time (UTC). • **Automatic shipment**: this is a shipment that is automatically created and sent based on the study's resupply strategy (as designed by the clinical supply manager) or based on a study's integration with a clinical depot facility (as designed by your Oracle point of contact). The date during which the shipment was created in displayed in Coordinated Universal Time (UTC).

Table 2-76 (Cont.) Data elements in the shipment folder

Data elements	Description
SHIPMENT_DATE	Indicates a shipment's ship date, either automatically specified by an integration with the clinical depot facility or manually specified by someone from either the sponsor or depot.
TRACKING_NUMBER	Indicates a shipment's tracking number, as specified by the depot user.

Kits (Required) folder

This table describes the data elements included in the Kit (Required) folder.

Table 2-77 Data elements in the Kit folder

Data element	Description
KIT_TYPE	A kit's type, as specified by the study designer when they created the kit. The following values can be displayed: • Investigation Product • Device • Kit Type Titration For more information on these kit types, see the following topics: • Define the kits for investigational products • Define the kits for devices • Define how subjects titrate
DEVICE_TYPE	Indicates the type of device, as specified by the study designer when they created the device kit type. The following values can be displayed: • Activity Watch • Blood Pressure Monitor • Glucose Monitor • Weight Scale • ECG Reader • Spirometer • Mobile App • Smart Pill Bottle • Pulse Oximeter • Wearable Patch • Other
DEVICE_CONNECTION	Indicates the type of device connection, as specified by the study designer when they created the device kit type. The following values can be displayed: • No Connection • Device to Cloud • Cloud to Cloud For more information on what each connection consists of, see Define the kits for devices.
CALCULATING_DOSES	Indicates whether the study designer specified that the kit type should have calculations defined based on subjects' answers to one or more questions. The values following values can be displayed: 1 or 0.

Table 2-77 (Cont.) Data elements in the Kit folder

Data element	Description
DISTRIBUTION_SETTINGS	Indicates the type of distribution a kit has, as specified by the study designer. The following values can be displayed: • **Blinded**: if blinded users should never see the kit type description. • **Unblinded**: if blinded users should always see the kit type description. • **Unblinded Pharmacist**: if blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types.
KIT_TYPE_ID	Indicates the unique identifier for a kit type.
MINIMUM_KITS_TO_SHIP	Indicates the minim number of kits to include in each shipment to meet packaging requirements, as specified by the study designer when they created the kit type.
UNITS_PER_KIT	Indicates the number of units in the kit, such as the number of pills in a bottle, as specified by the study designer. For more information on this value, see Define the kits for investigational products.
SINGLE_UNIT_DOSE_UNITS	Indicates how one unit in the kit is measured.
BALANCE_UNITS	Indicates the total units of a kit minus the missing and returned units.
TITRATION	Indicates if a kit type is part of a kit type titration. Values can be 1 or 0.
KIT_NUMBER	Indicates a kit's number, as assigned in the system.
KIT_DESCRIPTION	Indicates a kit's description, as specified by the study designer when they created the kit type.
DISPENSATION_DATE	Indicates a kit's dispensation date, as entered by a site user when they dispensed the kit to a subject.
DOSAGE	Indicates the dosage for the dispensed kit, when the kit contains calculated doses.
BAR_CODE	If included in a study, this indicates a kit's bar code as generated by the system.
DISPENSATION_CONFIRMED	Indicates whether a kit's dispensation was confirmed by a site user.
MEASUREMENT	Indicates the total numeric value for the product in a kit with calculated doses, as defined by a study designer.
FREQUENCY	Indicates the dosing frequency as defined by a study designer.
RETURNED_UNITS	Number of units 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.
CONSERVED	Indicates whether a kit was conserved by a site user.
QUANTITY	Indicates a kit's quantity, as specified by the study designer.
INSTANCE_NUMBER	Indicates the repeat instance number of the visit.

Table 2-77 (Cont.) Data elements in the Kit folder

Data element	Description
TRIAL_SUPPLY_TYPE	Indicates the supply type of the kit, as specified by the study designer. The following values can be displayed: • Blister Pack • Bottle • Device • Syringe • Topical Ointment • Vial • Inhaler • Infusion • Box • Other
SINGLE_UNIT_DOSE_VALUE	Indicates how one unit in the kit is measured, specifically its specified value.
CRA_VERIFIED	Indicates whether a question, a form, or a visit has been verified by a Clinical Research Associate (CRA).
KIT_STATUS	Indicates a kit's status in the study's inventory. For more information on what a kit's status may be, see What statuses can kits have?.
VERIFIED_BY	Indicates the user who verified data associated with a question, a form, or a visit.
VERIFIED_DATE	Indicates the date when a question, form, or visit was verified. Date is displayed in UTC.
CONFIRMED_BY	Indicates the email address of the user who confirmed the dispensation of a specified kit.
CONFIRMED_DATE	Indicates the date at which a specified kit's dispensation was confirmed.
SEQUENCE_NUMBER	Indicates a kit's sequence number, as specified by a clinical supply manager when setting up whether kits should be dispensed by sequence.
BLOCK_NUMBER	Indicates the block number of randomization assigned to a site, country or region, for fixed randomization designs.
ITEM_NUMBER	Numeric value used as a reference element for batch processing. ***Note**: This field is part of the SAP system and populated via integration. This field does not display in Oracle Clinical One Platform*.
MATERIAL_ID	Alphanumeric identifier of the material of a given kit, used as a reference element for batch processing. ***Note**: This field is part of the SAP system and populated via integration. This field does not display in Oracle Clinical One Platform.*

Calculated dose folder

This table describes the data elements included in the Calculated dose folder.

> **Note:**
>
> For more information on each of these data elements, see Define kits with calculated doses.

Data element	Description
CALCULATED_DOSE_TITLE	Indicates the title of the kit type containing calculated doses, as specified by the study designer.
FORM_QUESTION_FOR_CALCULATED_DOSE	Indicates the question that is selected by the study designer to be used in calculating the appropriate dose.
VISIT_WHERE_FORM_IS_COLLECTED	Indicates the visit in which the question that is used to calculate the appropriate dose is asked, as specified by the study designer.
DOSE_FREQUENCY	Indicates how many doses the subject must consume, as specified by the study designer.
KIT_MEASUREMENT	Indicates the total numeric value for the product in the kit, as specified by the study designer.
SUBJECT_MEASUREMENT	Indicates the value that, along with the answer for the subject and the value of a single unit, determines the dose, as specified by the study designer.
DOSE_PRECISION	Indicates the number of places after the decimal point that each dose should be calculated in, as specified by the study designer. For example, if the precision for each dose is 0.0001, this value displays the number 4.
DOSE_ROUND_UP	Indicates how the rounding is performed to reach the dose precision, as specified by the study designer. This field displays a whole number indicating the minimal decimal value to round-up and reach dose precision. For example, if the precision for each dose is 0.0001 and the round up is 0.00006 (as entered in the Oracle Clinical One Platform): • For the dose precision, the number 4 is displayed (this value represents the number of places after the decimal point). • For the dose round up, the number 6 is displayed.
DOSE_LEFT_OVER_UNITS	Indicates whether leftover units from a previous dose can be used in a next dose, during the study conduct period, as specified by the study designer.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-78 Datat elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.

Table 2-78 (Cont.) Datat elements in the audit folder

Data element	Description
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Reference folder

Data element	Description
SITE_WID	A number that represents the unique identifier of a site.
STUDY_WID	A number that represents the unique identifier of the study.
SUBJECT_WID	Indicates a subject's numeric identifier.
COUNT	Represents the count of kits.
COHORT_WID	Indicates a cohort's numeric identifier.
INVENTORY_WID	Indicates the numeric identifier of the study's inventory.
KIT_DESIGN_WID	Indicates the numeric identifier of a kit's design.
SHIPMENT_WID	A number that represents the unique identifier of a shipment.
TREATMENT_WID	A number that represents the unique identifier of a treatment arm.
USER_WID	Indicates a user's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.
CALCULATED_DOSE_WID	Indicates the numeric identifier of a kit containing calculated doses.
VERIFIED_BY_WID	Indicates the numeric identifier of a user who verified data associated with a visit.
CONFIRMED_BY_WID	Indicates the numeric identifier of a user who confirmed the dispensation of a kit during a visit.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

Unblinded Subject Event dataset

You can use the Unblinded Subject Events dataset in Oracle Clinical One Analytics to analyze and visualize data and audit history of events associated to individual subjects, including randomization and trials supply management (RTSM) related data.. This dataset includes information that could potentially unblind a user.

Modes

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

What type of data can I include in an unblinded custom report or visualization?

With this dataset, you can get custom data such as:

- All the week 3 visits for a site that have not been completed
- All the subjects that have completed a screening visit in a country
- All skipped visits for a subject.
- All events that occurred at a site during March
- All of the patients that have been randomized in a country in the last 2 weeks
- Are my events being completed within the event window?

For information about permissions required to access this dataset, see About your access to Oracle Clinical One Analytics.

The unblinded subject event dataset consists of numerous elements that differ from the blinded subject event dataset. Browse the descriptions of the data elements exclusive to the Unblinded Subject Event dataset:

Data element	Description
KIT_TYPE_SRC_ID	A kit type's ID as entered by a study designer when the kit was created
INVENTORY_STATUS_ID	Number value that maps to the INVENTORY_STATUS column
INVENTORY_STATUS	The status of the kit
DISPENSATION_DATE	Date of the kit dispensation
MHEALTH_DEVICE_ID	The ID of an IoT-enabled device managed with Oracle Health Sciences mHealth Connector Cloud Services
DOSAGE	Dosage for the kit dispensed
BAR_CODE	If included in a study, this indicated a kit's barcode as generated by the system
DISPENSATION_CONFIRMED	Indicates whether a kit's dispensation was confirmed by a site user or not
MEASUREMENT	Indicates the total numeric value for the product in a kit with calculated doses, as defined by a study designer
FREQUENCY	Indicates the dosing frequency as defined by a study designer
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
CONSERVED	Indicates whether a kit was conserved by a site user or not
KIT_DESCRIPTION	Indicates a kit's description, as defined by a study designer, the amount of dispensed kits,
QUANTITY	Kit quantity is defined in study design

Data element	Description
TREATMENT_NAME	Indicates the treatment arm title as entered by a study designer
RANDOMIZATION_DATE	Indicates the date and time of when a subject is randomized
RND_STATUS	Randomization status of the subject
COHORT_NAME	Name of the cohort part of the randomization design
INSTANCE_NUMBER	The repeat instance number of the visit

Browse the descriptions of other data elements included in this dataset:

> **Note:**
>
> Blank columns in Oracle Clinical One Analytics indicate `null` or *not applicable*.

> **Tip:**
>
> In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from the Required folder to your workbook. For more information, see Create and edit a data visualization.

- Study folder
- Site folder
- Country folder
- Subject folder
- Event (Required) folder
- Kit folder
- Audit folder
- Aggregation folder
- Reference folder

Study folder

This table describes the data elements included in the Study folder

Table 2-79 Data elements in the Study folder

Data element	Description
STUDY_MODE	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
STUDY_ID_NAME	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	A protocol's title as specified by the study manager.

Table 2-79 (Cont.) Data elements in the Study folder

Data element	Description
STUDY_REFNAME	Indicates the study's reference name used by the system. This value is composed by the STUDY_ID_NAME converted to uppercase with blank spaces removed. Once created, this value never changes, even if STUDY_ID_NAME is changed.
STUDY_PHASE	A study's phase as indicated by the study manager when they created the study.
THERAPEUTIC_AREA	Indicates the therapeutic area as specified by the study manager when they created the study.
BLINDING_TYPE	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	Indicates the study version number of the referencing data in a custom report.

Site folder

This table describes the data elements included in the Site folder.

> **Note:**
>
> Only a site's primary address is transmitted to Oracle Clinical One Analytics.

Table 2-80 Data elements in the site folder

Data element	Description
ADD_SUBJECTS	Flag that enables or prevents site users from adding subjects at one or multiple sites.
ADDRESS_CITY	A site's city as entered by the site manager when they created or last modified the site.
ADDRESS_COUNTRY	A site's country as entered by the site manager when they created or last modified the site. The field display the country ISO code.
ADDRESS_POSTALCODE	The Zip Postal Code associated with a site's address.
ADDRESS_STATE_OR_PROV_OR_CNTY	A site's state, province, or county as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_1	A site's first address as entered by the site manager when they created or last modified the site.
ADDRESS_STREET_2	A site's second address as entered by the site manager when they created or last modified the site.
DEA_NUMBER	The DEA registration number.
DISPENSE_TO_SUBJECTS	Flag that enables or prevents site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites.
DRUG_DESTRUCTION_CAPABLE	Flag that defines if the kit type is destructible at the site.
EMAIL	Email address of the site as entered by the site administrator when they created or last modified the site.
EXPIRATION	Indicates the expiration date of the DEA Registration Number as defined by a site manager.

Table 2-80 (Cont.) Data elements in the site folder

Data element	Description
FAX	The contact fax number as entered by the site administrator when they created or last modified the site.
INITIAL_SUBJECTS_COUNT	Number of initial subjects included in the SDV strategy.
INITIAL_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
PHONE	The contact phone number as entered by the site manager when they created or last modified the site.
PI_PREFIX	The principal investigator's prefix at the site.
RANDOMIZE_SUBJECTS	Flag that enables or prevents site users from randomizing subjects at one or multiple sites.
REMAINING_SUBJECTS_PERCENTAGE	Number of remaining subjects included in the SDV strategy.
REMAINING_SUBJECTS_SDV_TYPE	Type of Source Data Verification: All Questions or Critical Questions.
SCREEN_SUBJECTS	Flag that enables or prevents site users from screening subjects at one or multiple sites.
SDV_GROUP_NAME	Name of the SDV Strategy, as entered by the study manager.
SHIPPING_ADDRESS_1	The first line of a site's shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ADDRESS_2	The second line of a site's second shipping address as entered by the site manager when they created or last modified the site.
SHIPPING_ATTENTION	Indicates the name of the person who will receive shipments at the site, as specified by a site manager.
SHIPPING_CITY	City associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_COUNTRY	Country associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_EMAIL	Email address associated with the shipping address.
SHIPPING_FAX	Fax number associated with the shipping address.
SHIPPING_PHONE	Phone number associated with the shipping address.
SHIPPING_STATE_OR_PROV_OR_CNTY	State, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.
SHIPPING_ZIP	Zip Postal Code associated with the shipping address.
SITE_ID_NAME	Indicates the site ID as entered by a site manager when they created or last modified a site.
SITE_STATUS	Indicates the status of a site whether it is New, Active, or Retired.
SITE_STUDY_VERSION	The study version assigned to the site, as configured by a site manager.
TIMEZONE	Indicates the time zone the site is currently placed on as specified by a site manager.
INVESTIGATOR	A Principal Investigator's Full Name as listed when the site manager created the site.
SITE_NAME	Indicates the site's name as entered by a site manager when they created or last modified a site.
SITE_TYPE	Indicates the type of organization.

Table 2-80 (Cont.) Data elements in the site folder

Data element	Description
EHR_ENABLED	Indicates if a site is currently enabled for Electronic Health Record (EHR) data import. No is displayed if EHR has never been enabled for a site or if a site was disabled for EHR.

Country folder

This table describes the data elements included in the Country folder.

Table 2-81 Data elements in the Country folder

Data element	Description
COUNTRY_NAME	Indicates a country's two-digit ISO code.

Subject folder

This table describes the data elements included in the Subject folder.

Table 2-82 Data elements in the Subject folder

Data element	Description
SUBJECT_NUMBER	The number currently assigned to the subject in the system as identifier.
SCREENING_NUMBER	Always displays the original screening number, assigned to the subject at screening.
SUBJECT_STATE	A subject's state.
PREVIOUS_SUBJECT_NUMBER	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
UNBLIND_COMMENT	Comment provided by the user when the first code break was performed and the subject's treatment arm was unblinded. ***Note**: Even if subject undergoes multiple code breaks, this filed displays only the first code break comment*.
UNBLIND_DATE	Indicates the date and time when the first code break was performed and the subject's treatment arm was unblinded. This value is a timestamp. ***Note**: Even if subject undergoes multiple code breaks, this filed displays only the first code break date*.
UNBLIND_REASON	Reason provided by the user when the first code break was performed and the subject's treatment arm was unblinded. ***Note**: Even if subject undergoes multiple code breaks, this filed displays only the first code break reason*.

Event (Required) folder

This table describes the data elements included in the event folder.

Table 2-83 Data elements in the event folder

Data element	Description
EVENT_TITLE	The event's title, defined by the user when an event is created.
EVENT_REFNAME	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. ***Note**: This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version*.
EVENT_ID_NAME	The event's id as in Oracle Clinical One Platform.
FREEZE	Indicates if a visit is frozen by a data manager or CRA.
VERIFIED	Indicates the visit's verification status. Data element can be populated with the following values: • VERIFIED: A question, form, or visit is verified. • UNVERIFIED: A question, form, or visit was once verified, then updated making it unverified. • VERIFY_REQUIRED: A question, form, or visit requires verification and is not yet verified. • NOT_APPLICABLE
SIGNED	Indicates if a valid casebook signature is applied to the event.
VISIT_STATUS	Indicates a visit's status in the system. Future visits are included with the status of 'SCHEDULED'. Dynamic and cycle visits will not be included until an event happens that causes their creation on the subject's schedule.
VISIT_START_DATE	Date stamp of a visit's start date.
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	Displays the type of event that primarly impacts a visit's status. Upon selecting this data element, only events that occurred in your study are displayed. For example, you may see some of the following events: • Visit_Complete • Visit_Date_Changed • VisitDateCleared • VisitDateEntered • Visit_Not_Started • Visit_Skip_Undone • Visit_Skipped • Visit_Started • Visit_Inserted: this option refers to new visits inserted into the study's schedule as an Advanced Study Versioning change.
EVENT_INSTANCE_NUM	Indicates the unscheduled visit instance number as designed by the study designer.
PROJECTED_VISIT_START_DATE	Date when the next scheduled visit should start in the study, based on the configured visit schedule.
PROJECTED_VISIT_END_DATE	Date when the next scheduled visit should end in the study, based on the configured visit schedule.
PROJECTED_VISIT_DATE	Date when the next scheduled visit should take place in the study, based on the configured visit schedule.
IS_REQUIRED	Indicates if the visit is required.
IS_SCHEDULED_VISIT	Indicates if the visit is scheduled.

Table 2-83 (Cont.) Data elements in the event folder

Data element	Description
SCHEDULED_FROM_EVENT_NAME	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule*.
DELAY_DAYS	The number of days between the prior scheduled visit.
DELAY_HOURS	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_ORDER	The order in which subject visits occur, as configured in the study design.
IS_MISSING_VISIT	• N (No) indicates that a standard visit has been started. • Y (Yes) indicates that a standard (expected) visit has not been started. Dynamic, branching, and unscheduled visits only appear when the visit has been started, and data entry has occurred.
IS_OVERDUE_VISIT	Indicates whether the current date has passed the projected visit date.
SCHEDULED_FROM_EVENT_REFNAME	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule. ***Note**: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENINGVISIT is displayed for the Screening Visit, as it is the first visit in the schedule*.

Kit folder

This table describes the data elements in the Kit folder.

Table 2-84 Data elements in the kit folder

Data element	Description
KIT_NUMBER	Indicates a kit's number, as assigned in the system.
INVENTORY_STATUS	Indicates a kit's status in the study's inventory. For more information on what a kit's status may be, see What statuses can kits have?.
DISPENSATION_DATE	Indicates a kit's dispensation date, as entered by a site user when they dispensed the kit to a subject.
DOSAGE	Indicates the dosage for the dispensed kit, when the kit contains calculated doses.

Table 2-84 (Cont.) Data elements in the kit folder

Data element	Description
BAR_CODE	If included in a study, this indicates a kit's bar code as generated by the system.
DISPENSATION_CONFIRMED	Indicates whether a kit's dispensation was confirmed by a site user.
MEASUREMENT	Indicates the total numeric value for the product in a kit with calculated doses, as defined by a study designer.
FREQUENCY	Indicates the dosing frequency as defined by a study designer.
RETURNED_UNITS	Number of units 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.
CONSERVED	Indicates whether a kit was conserved by a site user.
KIT_DESCRIPTION	Indicates a kit's description, as specified by the study designer when they created the kit type.
QUANTITY	Indicates a kit's quantity, as specified by the study designer.
TREATMENT_NAME	Indicates the title of the treatment arm from the protocol, as specified by the study designer when they created the treatment arm in Study Design mode. Displays the title for every treatment arm created in the study.
RAND_NUMBER	Indicates the randomization number assigned to each randomized subject in a study. ***Note**: If the **Blind Randomization Number** option in your study's settings is set to **Yes**, data for this field displays as **Blinded**. For more information, see Specify study, enrollment, and visits settings.*
RANDOMIZATION_DATE	Indicates the date on which a subject has been randomized in the study.
RND_STATUS	Indicates whether a subject has been randomized or not in a study. • If randomized, a subject's status must be updated to **Active**. • If a subject is not randomized, their status can be: – **New**: If they're newly enrolled in the study at the time that you are creating a report using this data element. – **Screened**: If they're screened in the study at the time that you are creating a report using this data element. – **Enrolled**: If they're enrolled in the study at the time that you are creating a report using this data element, but they have been screened in a different system outside of Oracle Clinical One Platform.
COHORT_NAME	Indicates the type of cohort selected by a study designer when creating a randomization design: • **None**: this indicates that the study has no cohorts • **Adaptive**: this indicates that the study contains cohorts that allow site staff to open treatment arms in a gradual manner so that the study team can better measure safety and efficacy as the study progresses. • **Demography**: this indicates that the study contains population groups according to demographic criteria, such as age.
INSTANCE_NUMBER	Indicates the repeat instance number of the visit.
TITRATION	Indicates if a kit type is part of a kit type titration. Values can be 1 or 0.

Table 2-84 (Cont.) Data elements in the kit folder

Data element	Description
TREATMENT_ARM_DESCRIPTION	Indicates the additional details provided by a study designer in the Description field, when they created the treatment arm in Study Design mode.
TREATMENT_ARM_TITLE	Indicates the title of the treatment arm from the protocol, as specified by the study designer when they created the treatment arm in Study Design mode. Displays the title for every treatment arm created in the study.

Audit folder

This table describes the data elements included in the Audit folder.

Table 2-85 Datat elements in the audit folder

Data element	Description
VERSION_START	Indicates the date and time of when the data was changed.
VERSION_END	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	Audit trail field that represents the type of operation performed (i.e. create, modify).
USER_NAME	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
OBJECT_VERSION_NUMBER	Audit trail field that represents the version number of the data.
REASON	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENTS	Required comment in a reason for change if 'Other' is selected. Populated as Rule Execution for calculated values.
IS_CURRENT	Audit trail field to display either current status or full audit trail of the data.
CURRENT_STUDY_ROLE_NAME	Specifies of the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.

Aggregation folder

This table describes the data elements in the Aggregation folder.

Table 2-86 Data elements in the Aggregation folder

Data element	Description
FORM_TOTAL_COUNT	Count of all forms created as part of the study design.
FORM_COMPLETED_COUNT	Count of completed forms. Repeating instances are only counted once, meaning that repeating rows are not counted as an additional completed form.

Reference folder

Data element	Description
INVENTORY_STATUS_ID	A number that represents the unique identifier of the inventory status.
SUBJECT_EVENT_INST_WID	A number that represents the unique identifier of a subject event's instance.
STUDY_WID	A number that represents the unique identifier of the study.
SITE_WID	A number that represents the unique identifier of a site.
SUBJECT_WID	Indicates a subject's numeric identifier.
EVENT_WID	A number that represents the unique identifier of an event.
SCHEDULED_FROM_EVENT_WID	A number that represents the unique identifier of the previously scheduled event.
USER_WID	Indicates a user's numeric identifier.
SOFTWARE_VERSION_NUMBER	A number that represents an incremental increase every time a data point is modified.
DH_TIMESTAMP	A timestamp that indicates when the data became available in the dataset.
TREATMENT_WID	A number that represents the unique identifier of a treatment arm.
RND_STATUS_ID	Indicates the numeric identifier of the randomization status.
COHORT_WID	Indicates a cohort's numeric identifier.
COUNT	Represents the count of events.
CURRENT_STUDY_ROLE_WID	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.

3

Visualize data

Visualize the most relevant clinical data in your study in different ways. Choose the one that works best for you to analyze that data so it provides you with answers to business-related and clinical questions.

- About visualizations and dashboards
  Visualizations allow you to display data in graphical format for analysis, so it provides you with answers related to business-related and clinical questions.
- Create and edit a data visualization
  In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add your visualizations into a workbook that can be shared with analysts and statisticians on your study team.
- Add multiple visualizations in a canvas
  In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add multiple visualizations into a workbook that can be shared with analysts and statisticians on your study team.
- Organize visualizations in dashboards
  You can create dashboards to provide personalized views of your study data by purpose. A dashboard consists of one or more pages that display related reports and visualizations with interactive filters.
- Create a story
  A workbook can have one story that includes one or more pages, each page containing a canvas. Use stories to capture and share relevant information.
- Export data analyses
  Once you have created visualizations in workbooks, dashboards or stories, you can export your analyses in different formats to share your insights with your study team.
- Create a pixel-perfect report using BI Publisher
  A pixel-perfect report is a highly formatted report that can be sent and scheduled using Oracle BI Publisher. You can access Oracle Business Intelligence (BI) Publisher directly from your Oracle Clinical One Analytics portal.

About visualizations and dashboards

Visualizations allow you to display data in graphical format for analysis, so it provides you with answers related to business-related and clinical questions.

Visualizations enable you to dynamically explore multiple datasets, already organized by purpose of analysis, in a graphical way. You can combine multiple datasets to visualize data from your studies in Oracle Clinical One Platform and share your insights with analysts and statisticians on your study team for best data-driven decisions.

Workbooks and canvases enable you to organize and share your visualizations. As you create a workbook, you have canvases available in your Visualize pane to add visualizations that provide answers to your questions in a graphical format. Learn more about the different types of visualizations available in about visualization types.

You can the add additional canvases as pages to organize your customized views of study data into dashboards. Dashboards provide you with personalized views of information in the form of one or more pages, with each page identified with a tab at the bottom. Each of these pages enable you to explore and interact with information visually in tables, graphs, pivot tables, and other data views, as well as with dynamic filters. Cointaining related visualizations grouped together by pourpose of analysis, all of them related to a main topic, dashboards can then give you a complete and consistent view of your study's information.

Use the Narrate pane to include canvases and add notes of your insights to create stories. Export your analyses in a variety of formats, such as CSV, PPT, PDF, and PNG, so you can share results with your study team to improve your decision-making and data management processes.

Besides the main actions that you can perform in Oracle Clinical One Analytics, there are numerous tips and tricks that you can use to better organize the data that you work with.

To read detailed instructions on the tasks available for you to perform in Oracle Clinical One Analytics, see the curated list of links in the **Related Topics** section below.

Related Topics

- Edit a visualization and add data using Grammar Panel
- Sort data in visualizations
- Adjust visualization properties
- Change visualization types
- Apply color to visualizations
- Create and apply filters
- Enhance Data in Visualizations with Advanced Analytics Functions
- Drill in results

Create and edit a data visualization

In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add your visualizations into a workbook that can be shared with analysts and statisticians on your study team.

Now that you have prepared your data, it is time you build a visualization.

To perform this task you need authoring access, which is controlled by global roles and permissions assigned in Oracle Clinical One Platform. These permissions provide you the access you need and allow you to use specific datasets when building visualizations using the Data Visualizer interface in Oracle Clinical One Analytics. For more information about permissions and datasets, see About your access to Oracle Clinical One Analytics.

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

Video

This procedure takes you through the high-level steps for performing this task in Oracle Clinical One Analytics. Many of the steps required for this task depend on a multitude of things, including the purpose of your visualization. For more information, see Build a visualization.

> **Tip:**
>
> At any moment, you can undo and redo last edits as you work. Use the Undo () and Redo () buttons repectively. You can use these options only if you haven't saved the workbook since making the changes.

1. Open a workbook:
   - Open an existing workbook as described in Access workbooks in your catalog.
   - Create a workbook and add a dataset to work with
2. If required, Create calculated data elements to use as values and measure data.
3. From the Data Panel, expand folders within the loaded datasets to see available data elements, and select one or more data elements to include in your visualization.

   For multiselction, press the Ctrl key as you select data elements.
4. Add data elements into your canvas to create a visualization:

   > **Note:**
   >
   > In order for Oracle Clinical One Analytics to perform optimally, begin by adding data elements from a dataset's Required folder.

Option	Description
Drag/Drop	You can drag and drop data elements into your Visualize canvas, one by one or using multiselction. This will generate a Table type visualization by default, which you may change later if required.
Create Best Visualization	You can right-click on your data elements selection and click **Create Best Visualization**. This will add the best visualization type defined by the system based on the set of data elements selected.
Pick Visualization...	You can right-click on your data elements selection and click **Pick Visualization...**, then select a visualization type. This will add a visualization of the selected type for your data.

5. Drag and drop data elements and calculations into the Grammar Panel to configure your visualization.

   The Grammar Panel contains sections that you can customize by associating with various data elements.

> **Note:**
>
> The sections available in the Grammar Panel for customization depend on the visualization type.

- Change the visualization type by selecting it from the dropdown in the top section of the Grammar panel. Learn more about visualization types.
- Add, delete, replace and rearrange rows and columns.
- Assign data to the X and Y-axis.
- Add color or shape indicators according to specific data elements.
- Add details to the tool tip.
- Add filters to your data specific to that visualization

For more information, check out the Related Topics section.

6. To save your work, click **Save** or **Save As** from the save drop-down () in the top menu bar.
   - If you select **Save** your work is saved in the current location with current name and description.
   - If you select **Save As**, in the Save Workbook dialog, enter a name and a description for your workbook and select a folder to save your work.

> **Note:**
>
> You can either save it for personal use in **My Folders** or share it in **Shared Folders**.

You can open a saved workbook and make edits at any time. Once you have created a visualization you can:

- Add multiple visualizations in a canvas.
- Create and apply filters.
- Organize visualizations in dashboards.
- Create stories.
- Export and share your work.

Related Topics

- Edit a visualization and add data using Grammar Panel
- Sort data in visualizations
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters
- Enhance Data in Visualizations with Advanced Analytics Functions

Add multiple visualizations in a canvas

In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add multiple visualizations into a workbook that can be shared with analysts and statisticians on your study team.

To perform this task you need authoring access, which is controlled by global roles and permissions assigned in Oracle Clinical One Platform. These permissions provide you the access you need and allow you to use specific datasets when building visualizations using the Data Visualizer interface in Oracle Clinical One Analytics. For more information about permissions and datasets, see About your access to Oracle Clinical One Analytics.

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

Video

> **Tip:**
>
> At any moment, you can undo and redo last edits as you work. Use the Undo ( ) and Redo ( ) buttons repectively. You can use these options only if you haven't saved the workbook since making the changes.

1. Open a workbook:
   - Open an existing workbook as described inAccess workbooks in your catalog.
   - Create a workbook and add a dataset to work with
2. If required, Create calculated data elements to use as values and measure data.
3. From the Data Panel, expand folders within the loaded datasets to see available data elements, and select one or more data elements to include in your visualization.

   For multiselction, press the Ctrl key as you select data elements.
4. Add data elements into a new or existing visualization:

Option	Description
Drag/Drop	**Existing visualization:** You can drag and drop data elements into an existing visualization, one by one or using multiselction. This will add the data elements to the current visualization without changing the actual format. **New visualization:**You can drag and drop data elements into a new space in your Visualize canvas to create a new visualization. When you drag the elements to any of the borders of an existing visualization, the border line gets bold indicating the position for the new visualization. For example, if you drop elements at the right border line position, a new visulization gets added to the right of the existing visualization. This will generate a Table type visualization by default, which you may change later if required.

Option	Description
Add to Selected Visualization	(Available only if a visualization is already created and selected) You can right-click on your data elements selection and click **Add to Selected Visualization**. This will add the selected data elements to the exisiting visualization currently selected.
Create Best Visualization	You can right-click on your data elements selection and click **Create Best Visualization**. This will add a new visualization defined as the best visualization type by the system, based on the set of data elements selected.
Pick Visualization...	You can right-click on your data elements selection and click **Pick Visualization...**, then select a visualization type. This will add a new visualization of the selected type for your data.

5. Drag and drop data elements and calculations into the Grammar Panel to configure your visualization.

   The Grammar Panel contains sections that you can customize by associating with various data elements.

   > **Note:**
   >
   > The sections available in the Grammar Panel for customization depend on the visualization type.

   - Change the visualization type by selecting it from the dropdown in the top section of the Grammar panel. Learn more about visualization types.
   - Add, delete, replace and rearrange rows and columns.
   - Assign data to the X and Y-axis.
   - Add color or shape indicators according to specific data elements.
   - Add details to the tool tip.
   - Add filters to your data specific to that visualization

   For more information, check out the Related Topics section.

6. Add as many visulaizations as required and organize them as desired.
   a. Select a visualization, the border lines turn blue.
   b. Drag it and drop it to the new position.

      When you drag the visualization to any of the borders of another visualization, that border line gets bold in blue indicating the new position. For example, if you drop the visualization *A* at the right border line position af another visualization *B*, the selected visualization *A* gets moved to the right of visualization *B*.

7. To save your work, click **Save** or **Save As** from the save drop-down () in the top menu bar.

- If you select **Save** your work is saved in the current location with current name and description.
- If you select **Save As**, in the Save Workbook dialog, enter a name and a description for your workbook and select a folder to save your work.

> **Note:**
>
> You can either save it for personal use in **My Folders** or share it in **Shared Folders**.

You can open a saved workbook and make edits at any time. Once you have added visualizations to your workbook you can:

- Create and apply filters.
- Organize visualizations in dashboards.
- Create stories.
- Export and share your work.

Related Topics

- Edit visualizations and add data using Grammar Panel
- Sort data in visualizations
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters
- Enhance Data in Visualizations with Advanced Analytics Functions

Organize visualizations in dashboards

You can create dashboards to provide personalized views of your study data by purpose. A dashboard consists of one or more pages that display related reports and visualizations with interactive filters.

To perform this task you need authoring access, which is controlled by global roles and permissions assigned in Oracle Clinical One Platform. These permissions provide you the access you need and allow you to use specific datasets when building visualizations using the Data Visualizer interface in Oracle Clinical One Analytics. For more information about permissions and datasets, see About your access to Oracle Clinical One Analytics.

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

Video

> **Tip:**
>
> At any moment, you can undo and redo last edits as you work. Use the Undo ( ) and Redo ( ) buttons repectively. You can use these options only if you haven't saved the workbook since making the changes.

For more information see Build Dashboards.

1. Open a workbook:
   - Open an existing workbook as described inAccess workbooks in your catalog.
   - Create a workbook and add a dataset to work with
2. Give a name to your first page:
   a. At the bottom of the Visualize Pane locate the page tab, named as **Canvas 1** by default.
   b. Click the arrow to expand the dropdown and select **Rename**.
   c. Enter a new name and click the accept button ( ).
3. Click the plus icon ( ) to add pages as needed.
4. Right-clik on each page tab, or use the dropdown, to see options and manage pages:
   - **Rename** lets you add a new name for your page.
   - **Canvas Properties** lets you update advanced properties.
   - **Duplicate Canvas** creates an identical page.
   - **Clear Canvas** clears all content from the current page.
   - **Delete Canvas** deletes the current page.

   > **Tip:**
   >
   > Drag and drop the page title tab to a new position to rearrange pages.

5. Add content to your pages.

   See Add multiple visualizations in a canvas.
6. Create and apply filters:
   - Add filters to the page or canvas
   - Create filters on a visualization
   - Use visualizations as a filter
7. To save your work, click **Save** or **Save As** from the save drop-down ( ) in the top menu bar.
   - If you select **Save** your work is saved in the current location with current name and description.
   - If you select **Save As**, in the Save Workbook dialog, enter a name and a description for your workbook and select a folder to save your work.

   > **Note:**
   >
   > You can either save it for personal use in **My Folders** or share it in **Shared Folders**.

You can open a saved workbook and make edits at any time. You can:

- Update visualizations.
- Change visualizations types.
- Rearrange visualizations.
- Apply additional filters.
- Add or remove visualizations or pages.
- Manage pages.
- Create stories.
- Export and share your work.

Related Topics

- Add multiple visualizations in a canvas
  In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add multiple visualizations into a workbook that can be shared with analysts and statisticians on your study team.
- Edit a visualization and add data using Grammar Panel
- Sort data in visualizations
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters
- Enhance Data in Visualizations with Advanced Analytics Functions

Create a story

A workbook can have one story that includes one or more pages, each page containing a canvas. Use stories to capture and share relevant information.

1. In Oracle Clinical One Analytics, in an open workbook, navigate to the **Narrate** pane from the top bar.
2. Select a Canvs from the Canvases Panel at the left of the screen. Right-click and select **Add To Story**.

   > **Tip:**
   >
   > You can also drag and drop a canvas to the main workspace. If page is blank, canvas will be added to existing page, otherwise a new page will be created.

3. Build your story with the following functions:
   - Add one or more canvases to the story.
   - Add notes clicking the Add Note button ( ). Enter text, select format, and move to the desired position.
   - For each page, go to the page settings below the Canvases Panel and configure it:
     – Use the **General** tab to hide or show page, page title and page description.

> **Tip:**
>
> Use titles and descriptions to introduce visualizations.

  - Use the **Adjustments** tab to set layout and to hide or show visuals from canvas in current page.
  - Use **Filters** tab to include or exclude existing canvas filters.
  - Use **Notes** tab to hide or show notes.
- To rearrange pages, drag and drop them in the pages area at the bottom of the Narrate page.
- To delete, hide, duplicate or rename page, right-click the page in the pages area for options.

> **Tip:**
>
> You can rearrange or delete visualization in a page without affecting the base canvas.

4. To display the story click the Present icon ( ) on the top menu bar. Click the 'X' icon to exit presentation mode.
5. Save the story as part of your workbook. Click **Save** or **Save As** from the save drop-down ( ) in the top menu bar.
   - If you select **Save** your work is saved in the current location with current name and description.
   - If you select **Save As**, in the Save Workbook dialog, enter a name and a description for your workbook and select a folder to save your work.

> **Note:**
>
> You can either save it for personal use in **My Folders** or share it in **Shared Folders**.

You can print or export stories in different formats to share your insights, see Export data analyses.

Export data analyses

Once you have created visualizations in workbooks, dashboards or stories, you can export your analyses in different formats to share your insights with your study team.

1. In Oracle Clinical One Analytics, in an open workbook, click the export icon ( ) located in the top menu bar.
   - You can export Canvases (or visuals in a Canvas) from the **Visualize** pane.
   - You can export story Pages (or visuals in a Page) from the **Narrate** pane.
2. Select an option:

- **File**
- **Print**

3. In the File or Print dialog respectively, fill in the fields with the availabe options as required:
   - Name *(enter a name)*
   - Format:

     > **Note:**
     >
     > Promted only when you export as a file.

     - Powerpoint (pptx)
     - Acrobat (pdf)
     - Image (png)
     - Data (csv)
     - Package (dva)

       > **Note:**
       >
       > *dva* files are specific to Oracle Analytics and exports the whole workbook. If you choose this format you are promted with different export settings, relevant to this format only:
       >
       > * Include Data
       > * Include Connection Credentials
       > * Include Permissions
       > * Protect Password

   - Include:
     - Active Canvas/ Active Page
     - Active Visual
     - All Canvas/ All Story Pages
   - Size:
     - Standard Ratio (4:3)
     - Widescreen Ratio (16:9)
     - US Letter (8.5" x 11")
     - A3 (297mm x 420mm)
     - A4 (210mm x 297mm)
     - A5 (148mm x 210mm)
     - Folio (8.5" x 13")
     - Legal (8.5" x 14")
     - Custom

> **Note:**
>
> If you choose custom size, enter measure and units for promted Width and Height fields.

- Orientation:
  - Portrait
  - Landscape

4. Click **Save** or **Print** to continue.

> **Tip:**
>
> To go back, click **Cancel**.

Create a pixel-perfect report using BI Publisher

A pixel-perfect report is a highly formatted report that can be sent and scheduled using Oracle BI Publisher. You can access Oracle Business Intelligence (BI) Publisher directly from your Oracle Clinical One Analytics portal.

To use Oracle BI Publisher functionality you need specific authoring access to Oracle BI Publisher, which is controlled by global roles and permissions assigned in Oracle Clinical One Platform. These permissions provide you the authoring access you need and allow you to use specific datasets when creating pixel-perfect reports using Oracle BI Publisher. For more information about permissions and datasets, see About your access to Oracle Clinical One Analytics.

> **Note:**
>
> The intention of this topic is to guide you through the steps to access Oracle BI Publisher from the Oracle Clinical One Analytics portal and a very high level guidance on report creation. For more information refer to Oracle Business Intelligence Publisher documentation:
>
> - Report Designer's Guide for Oracle Business Intelligence Publisher
> - User's Guide for Oracle Business Intelligence Publisher

1. Open Oracle Clinical One Analytics.
2. Click the page menu button () from the top menu bar and select **Open Classic Home**.

   Oracle Clinical One Analytics opens on a new tab.
3. In Oracle Clinical One Analytics (the new tab) locate the **Create...** panel to the left.
4. Click **Report** below the Published Reporting section.

   The Create Report wizard appears and guides you through the creation process.
5. Fill in the fields in the Select Data screen.
   a. Click **Use Subject Area**.

> **Note:**
>
> Oracle Clinical One Analytics datasets are loaded as Subject Areas.

b. From the **Subject Area** drop-down select the desired dataset to work with.

c. Click **Next**.

6. In the Select Layout screen, select among the available page and layout options and choose whether to include a page header and footer or not. Then click **Next**.

   According to the selected layout the Create Report wizard will take you through one or more of the following screens:

   - **Create Chart**
   - **Create 2nd Chart**
   - **Create Table**

7. Use the data elements on the left to build the given report element by drag and drop, the same way you do it to create a data visualization. Then click **Next**.

   The data elements display following a folder hierarchy. Expand each folder to see its contained data elements.

8. In the Save Report screen, select one of the following options, then click **Finish**.

   - Select **View Report** to run and view the report.
   - **Customize Report Layout** to use the layout editor to customize the report

9. In the Save As dialog, select a location to save your report, then enter a name and an optional description. Then click **Ok**.

Your report will open either in view mode or in the layout editor, according to your last selection. From any of those screens you can further manage your report with the following options:

- Specify parameters
- Edit layout
- Select output type
- Export
- Share via link
- Send via email
- Schedule a job to run and distribute the report
- Manage report jobs

4

Work with templates

Oracle Clinical One Analytics provides you with interactive templates containing dashboards, reports and visualizations that leverage the existing functionality of datasets. Because they are templates, you can customize them to meet your needs. All you have to do is simply tweak the data in each template and adjust their filters to make sure you are viewing data relevant to your work.

- Access templates
  As an Oracle Clinical One Analytics user, you have access to standard reports and dashboards templates available in the shared folders in your catalog.
- Create a modifiable copy of a template
  Templates available in the *Clinical One Report Templates* are read-only. To customize a template you must first export it as a *.dva* file and import it in another location to create a modifiable copy and work from there.
- Customize templates
  Templates included in Oracle Clinical One Analytics contain dashboards, reports and visualizations that leverage the existing functionality of datasets. Because they are templates, you can customize them to meet your needs.
- Standard report templates descriptions
  Oracle Clinical One Analytics provides you with report templates to use. These templates are available through the *Clinical One Report Templates* shared folder.
- Dashboard templates descriptions
  Oracle Clinical One Analytics provides you with dashboard templates to use. These templates are available through the *Clinical One Report Templates* shared folder.

Access templates

As an Oracle Clinical One Analytics user, you have access to standard reports and dashboards templates available in the shared folders in your catalog.

Before you can access a template, you must have access to the respective dataset used so you can properly view data. Access to a dataset is given based on a permission that you must be assigned in Oracle Clinical One Platform. For more information on these permissions, see About your access to Oracle Clinical One Analytics.

1. In Oracle Clinical One Analytics, navigate to your catalog as described in Access workbooks in your catalog.
2. Along the top of the page, click **Shared Folders**.
3. Locate the *Clinical One Report Templates* folder and click to open.
4. Browse the available reports and dashboards and open one to view.

> **Note:**
>
> Content in *Clinical One Report Templates* folder is read-only.

Create a modifiable copy of a template and customize templates to analyze aspects relevant to your work.

Create a modifiable copy of a template

Templates available in the *Clinical One Report Templates* are read-only. To customize a template you must first export it as a *.dva* file and import it in another location to create a modifiable copy and work from there.

To create and to modify a copy of a template you must have authoring access in the Data Visualizer interface. Also, before you can access a template, you must have access to the respective dataset used so you can properly view data. Both types of access are given based on roles and permissions that you must be assigned in Oracle Clinical One Platform. For more information see About your access to Oracle Clinical One Analytics.

Export the template as *.dva* file:

1. Go to the *Clinical One Report Templates* folder as described in Access templates.
2. Locate the template you want to work with and expand the options menu. To do this you can:
   - Right-click on the template.
   - Click the actions menu icon ( ) next to the template title.

   > **Note:**
   >
   > You must export the file from the folder view. If you try to export from the open template the *.dva* file option is not availabe.

3. Select **Export**.
4. In the Export dialog, make sure the **Include Permissions** option is deactivated and customize name and password settings as needed.
5. Click **Save**.

Import the file in a new location:

6. Go to the desired location as described in Access workbooks in your catalog.
7. From the Page Menu ( ), in the top menu bar, select **Import Workbook/Flow**.
8. In the Import Workbook/Flow dialog, add the exported *.dva* file:
   - Drag and drop the file into the file area.
   - Use **Select file** to locate it from the File Explorer.

   > **WARNING:**
   >
   > Make sure the **Import Permissions (if applicable)** checkbox is not selected.

9. Click **Import** and when you get the completion message click **Ok**.

If you work from your modifiable copy, you are able to update and save any changes made. See Customize templates for additional details on how you can update a template to meet your needs.

Customize templates

Templates included in Oracle Clinical One Analytics contain dashboards, reports and visualizations that leverage the existing functionality of datasets. Because they are templates, you can customize them to meet your needs.

To modify a copy of a template you must have authoring access in the Data Visualizer interface. Also, before you can access a template, you must have access to the respective dataset used so you can properly view data. Both types of access are given based on roles and permissions that you must be assigned in Oracle Clinical One Platform. For more information see About your access to Oracle Clinical One Analytics.

To customize a template, all you have to do is simply tweak the data in each template and adjust their filters to make sure you are viewing data relevant to your work. Additionally, you can add and rearrange visualizations or pages in a dashboard if needed, or you can create stories to export and share your work.

1. In Oracle Clinical One Analytics, create a modifiable copy of a template and open it.

   > **Note:**
   >
   > Content in *Clinical One Report Templates* folder is read-only and cannot be customized and saved.

   Each template displays only data from the sites and studies you are assigned to.

2. Adjust filters.

   For more information, see Create and Apply Filters.

3. If required, you can add, remove or update existing content:
   - Update visualizations.
   - Change visualization types.
   - Rearrange visualizations.
   - Apply additional filters.
   - Add or remove visualizations or pages.
   - Manage pages in a dashboard.

4. Save your work and access your customized template at any time. Click **Save** or **Save As** from the save drop-down () in the top menu bar.

   > **Note:**
   >
   > Save icon is not available in read-only files.

   - If you select **Save** your work is saved in the current location with current name and description.

- If you select **Save As**, in the Save Workbook dialog, enter a name and a description for your workbook and select a folder to save your work.

You can create stories and either print or export your work in different formats to share your insights, see Export data analyses.

Related Topics

- Create and edit a data visualization
  In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add your visualizations into a workbook that can be shared with analysts and statisticians on your study team.
- Add multiple visualizations in a canvas
  In Oracle Clinical One Analytics, you can visualize clinical data from a study in Oracle Clinical One Platform and add multiple visualizations into a workbook that can be shared with analysts and statisticians on your study team.
- Edit a visualization and add data using Grammar Panel
- Sort data in visualizations
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters
- Enhance Data in Visualizations with Advanced Analytics Functions
- Organize visualizations in dashboards
  You can create dashboards to provide personalized views of your study data by purpose. A dashboard consists of one or more pages that display related reports and visualizations with interactive filters.

Standard report templates descriptions

Oracle Clinical One Analytics provides you with report templates to use. These templates are available through the *Clinical One Report Templates* shared folder.

For more information about how to access the shared folders, see Access templates.

- Study Design Delta report
  This report assists study designers in identifying study design configuration differences and verify changes between study versions across modes before moving to Production.

Study Design Delta report

This report assists study designers in identifying study design configuration differences and verify changes between study versions across modes before moving to Production.

Modes

Available for data in any mode.

Users that can run the report

Any user assigned the *Run the Data Collection Design Dataset* permission can generate this report. To save a copy in a different location, and to modify it you must have authoring access. See About your access to Oracle Clinical One Analytics.

You can create a story and either print or export your work in different formats to share your insights, see Export data analyses.

> **Note:**
>
> If you export Branch, Event, Form or Item details report as *.csv* file, *Row Color* and *Rank* columns are added at the end. These columns contain irrelevant information about how data is displayed and ordered in the UI, so they can be ignored for data analysis purposes.

Browse descriptions of data elements included in this report:

- Study design differences
- Branch Details
- Event Details
- Form Details
- Item details

Study design differences

This table describes the data elements included in the Study Design Differences section.

Data element	Description
Comparing Versions	Color legend listing the study versions being compared. Includes the following data of each version: **STUDY_ID_NAME** A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number **STUDY_DESIGN_STATUS** Indicates the study mode used in the referencing data in a custom report, such as *Testing*, *Approved*, or *Archived*. **Note:** Study versions can also have a *Hisory* status. A study design reaches this status when the study version is moved from Testing to Apporved. So, for example, if **v1.0.0.24** is moved from Testing to Approved container, then it will become **v1.1.0.24** and so it will get displayed in UI, having an *Approved* status. Study design **v1.0.0.24** will still exist in the system with *History* status and it will be the same study design as **v1.1.0.24** (*Approved*) but will not be seen in the Approved container in the UI. **STUDY_VERSION** Indicates the study version number of the referencing data in a custom report
Total Branch Differences	Indicates the total number of differences for branches between study versions.
Total Event Differences	Indicates the total number of differences for events between study versions.
Total Form Differences	Indicates the total number of differences for forms between study versions.

Data element	Description
Total Item Differences	Indicates the total number of differences for items between study verisons.

Branch Details

This table describes the data elements included in the Branch Details.

Data element	Description
Delta Exists	**Y** indicates a difference between versions and the row color represents in which version the branch exists. **N** indicates no difference between versions exists.
BRANCH_TITLE	Indicates the branch title or name.
BRANCH_ID	A branch's ID as specified by a study designer.
IS_CYCLE_BRANCH	States whether the branch is cycled or not.
CYCLE_COUNT	Specifies the number of cycles in case the branch is cycled.
ASSIGN_SUBJECTS_USING_TREATMENT_ARM	Indicates if subjects are assigned to the branch by Treatment arm.
ASSIGN_SUBJECTS_USING_FORM_QUESTION	Indicates if subjects get assigned to branch by a form question.
BRANCH_ARM	Specifies which treatment arm(s) correspond to the current branch, in case subjects are assigned to the branch by treatment arm.
BRANCH_FORM	Specifies which form contains the question used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_QUESTION	Specifies which question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_ANSWER	Specifies which exact answer to the selected question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_VISIT	Specifies the visit containing the selected form and question that is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.

Event Details

This table describes the data elements included in the Event Details.

Data element	Description
Delta Exists	**Y** indicates a difference between versions and the row color represents in which version the event exists. **N** indicates no difference between versions exists.
VISIT_IS_REQUIRED	Indicates whether or not a visit is required

Data element	Description
IS_SCHEDULED_VISIT	Indicates whether the visit is scheduled or not
SCHEDULED_FROM_EVENT_NAME	The previous visit to this visit, as defined in the study design
VISIT_TYPE	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion
EVENT_TYPE	Displays the type of event (visit started, visit completed)
DELAY_DAYS	The number of days between the prior scheduled visit
DELAY_HOURS	This column is reserved for future use
VISIT_WINDOW_BEFORE_DAYS	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer
VISIT_WINDOW_BEFORE_HOURS	This column is reserved for future use
VISIT_WINDOW_AFTER_DAYS	Indicates how many days after the scheduled date and time the visit can occur, as entered by a study designer
VISIT_WINDOW_AFTER_HOURS	This column is reserved for future use
EVENT_TITLE	A visit or event's title as specified by a study designer
EVENT_REFNAME	A visit or even's reference code as specified by a study designer
EVENT_ID_NAME	A visit or event's ID as specified by a study designer
VISIT_HOUR_SEQ_ORDER	The order in which subject visits occur, as configured in the study design

Form Details

This table describes the data elements included in the Form Details.

Data element	Description
Delta Exists	**Y** indicates a difference between versions and the row color represents in which version the form exists. **N** indicates no difference between versions exists.
FORM_NAME	The name of the form, as specified by the study designer.
FORM_TYPE	Indicates the form type.
FORM_IS_ROLLOVER	Indicates whether or not it is a rollover form.
FORM_IS_REPEATING	Indicates whether or not it is a repeating form.
FORM_REFNAME	A form's reference name.
ALLOW_ADDITIONAL_ROWS	Indicates if this is a repeating form that allows additional rows.
SOURCE_DATAVIEW_NAME	If it is a copied form, indicates the original form it was copied from.
SOURCE_STUDY_NAME	If it is a copied form, indicates the name of the study it was copied from.

Data element	Description
SOURCE_STUDY_VERSION	If it is a copied form, indicates the study version of the study it was copied from.
SOURCE_VERSION_START	If it is a copied form, indicates the date and time of when the copied data was entered.
RULE_COPY_STATUS	If it is a copied form, indicates the status of the source form rules copy.

Item details

This table describes the data elements included in the Item Details.

Data element	Description
Delta Exists	**Y** indicates a difference between versions and the row color represents in which version the item exists. **N** indicates no difference between versions exists.
ITEM_NAME	Indicates the title of the question, as entered by a study designer
GROUP_TYPE	Indicates if this is a group question.
MEASURE_UNIT	Indicates the measure of unit specified by a study designer for a Number type of question
ITEM_TYPE	Indicates the item type.
QUESTION_TYPE	The form item's question type
QUESTION_HINT	Indicates information that can be provided as a hint to help answer a question.
FORMITEM_IS_REQUIRED	Indicates whether or not the question requires an answer
READONLY	Indicates that the question is in Read Only form
SAS_VARIABLE	Indicates the SAS Variable of a question defined by a study designer
SAS_LABEL	Indicates the SAS Label of a question defined by a study designer
REFERENCE_CODE	An item's reference code
ITEM_GROUP	If this is a group question, indicates the group question title.
HIDDEN	Indicates whether or not is hidden
ITEM_VALUES	The raw value of the form question value (can be an array in questions with decodes)
CODELIST_VALUES	Lists the codelist values added as answers to the current question.

Data element	Description
VALIDATION_RULE	Specifies the question's validation rule if any. Validation rules types available depend on the type of question: • Text questions: – *Doesn't contain* • Date/Time and Date of birth questions: – *After* – *On or After* – *Before* – *On or Before* – *On* – *Not On* – *Not Between* – *Range* • Number and Age questions: – *Greater Than* – *Greater Than or Equal To* – *Less Than* – *Less Than or Equal To* – *Is* – *Not Equal To* – *Not Between* – *Range* • Drop-down and checkboxes questions – *Select at Least* – *Select at Most* – *Select Exactly* – *Answer Must Be* • Radio Buttons questions: – *Answer Must Be*
RULE_ERROR	Reason for failure if validation status is failed or the rule validation failed
ACTION_RULES	Details the action rule of a question which can be of the types: • *Show Question* • *Show Form* • *Show Visit* • *Link & Show Form*
SDV	Specifies if the question has any SDV parameter and if it is of the type *SDV for All Subjects* or *Critical Variables (Targeted SDV)*.
CODE_QUESTION	If the question has a *Coding Question* property, lists the following information: • Dictionary • Coding Item Type • Tag for Central Coding
FORMAT	Specifies the answer format. For example an specific date format, or the number of decimals after the point

Dashboard templates descriptions

Oracle Clinical One Analytics provides you with dashboard templates to use. These templates are available through the *Clinical One Report Templates* shared folder.

For more information about how to access the shared folders, see Access templates.

- Audit trail dashboard
  Use the Audit Trail Dashboard to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.
- Clinical Research Associate dashboard
  The Clinical Research Associate Dashboard can highlight which monitoring reports require completion or approval, as well as display key data points related to a site's health.
- Data Manager dashboard
  The Data Manager Dashboard includes sets of actionable visualizations and detailed listings of queries, subjects states, and general subject data that is relevant to any clinical data manager.
- Diversity & Inclusion dashboard
  The Diversity & Inclusion dashboard includes sets of actionable visualizations and reports about the subjects in a study. The data in this dashboard can provide an insight of the study's objectivity to test the safety and efficacy of the drug's formulation.
- RTSM dashboard
  The Randomization and Trial Supply Management (RTSM) dashboard includes a set of interactive reports and visualizations that provide key information related to randomization and supply management.
- Subject Data Analysis dashboard
  The Subject Data Analysis dashboard offers you insights on a subject's journey through the different stages of a study by showcasing data related to demographics, events, adverse events, concomitant medications, as well as lab, and vitals data.

Audit trail dashboard

Use the Audit Trail Dashboard to easily visualize and gain an in-depth understanding of the creation, changes, and integrity of study data.

About access and filters

To properly view data in the Audit Trail Dashboard, you must have access to the Subject Form Items dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

Because a dashboard is interactive, it displays any study data you already have access to in a study. You can determine what information to display using the following filters:

- STUDY_MODE (default to *active*)
- STUDY_TITLE
- SITE_NAME
- COUNTRY_NAME
- SUBJECT_NUMBER
- OPERATION_TYPE

- Date range

> **Tip:**
>
> Analyze data from your studies one by one. If multiple studies or sites are used in a dashboard filter, there is a possibility that data does not appear in this dashboard's visualizations due to their default sizes.

Additionally, some charts can be used as filters. Look for the filter icon ( ) to the left of the visualization chart. Click on any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse selection on the chart, click on any white space within it or use the undo button ( ) in the upper right corner of the screen.

> **Note:**
>
> If the selected filters point to data not present on another chart, *No Data Found* will be displayed.

Reports

The Audit Trail Dashboard includes the following reports:

- Data Operations Summary
- Data Operations Evolution
- Data Operations Analysis
- Data Modifications Analysis
- Form Data Modifications Analysis
- Subject Audit Trail Data

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation: upper case, with words separated by underscores. On the other hand, custom calculations are listed using title case. These notations match what you see in the dashboard template.

Data Operations Summary
Use case: to review the volume of data across studies, sites, subjects, visits, forms, and Oracle Clinical One Platform objects, as well as the distribution of data operations.
Insights:

- Overall key performance indicator for data volume.
- Identify high volume data operations across studies and sites.
- Data operations breakdown across studies and sites, based on operation type.

Visualizations:

Title	Description	Interactivity
Study Count	Represents the total count of studies. • **Type**: Tile chart. • **Count**: Studies with distinct `STUDY_WID`.	Filtered data.
Site Count	Represents the total count of sites. • **Type**: Tile chart. • **Count**: Sites with distinct `SITE_WID`.	Filtered data.
Subject Count	Represents the total count of subjects. • **Type**: Tile chart. • **Count**: Subjects with distinct `SUBJECT_WID`.	Filtered data.
Visit Count	Represents the total count of visits. • **Type**: Tile chart. • **Count**: Visits with distinct `EVENT_WID`.	Filtered data.
Form Count	Represents the total count of forms. • **Type**: Tile chart. • **Count**: Forms with distinct `FORM_WID`.	Filtered data.
Item Count	Represents the total count of items. • **Type**: Tile chart. • **Count**: Items with distinct `ITEM_WID`.	Filtered data.
Created Actions	Represents the total count of created items. • **Type**: Tile chart. • **Count**: Actions with an `OPERATION_TYPE` of **'CREATED'**.	Filtered data.
Modified Actions	Represents the total count of modified items. • **Type**: Tile chart. • **Count**: Actions with an `OPERATION_TYPE` of **'MODIFIED'**.	Filtered data.
Removed Actions	Represents the total count of removed items. • **Type**: Tile chart. • **Count**: Actions with an `OPERATION_TYPE` of **'REMOVED'**.	Filtered data.

Title	Description	Interactivity
Cleared Actions	Represents the total count of cleared items. • **Type**: Tile chart. • **Count**: Actions with an `OPERATION_TYPE` of **'CLEARED'**.	Filtered data.
Data operations metrics	Represents the count of subjects, visits, forms, items, created items, modified items, removed items as well as cleared items, all against their respective studies, sites, and countries. • **Type:** Pivot chart. • **Columns:** – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – Subject Count – Visit Count – Form Count – Item Count – Created Count – Modified Actions – Removed Actions – Cleared Actions	Filtered data.
Data operations by site and study	Represents operation counts for different sites in a study. • **Type**: Combo chart • **X-Axis**: Item counts. Different colors represent a different item operation count: – Created Item Count – Modified Item Count – Removed Item Count – Cleared Item Count • **Y-Axis**: SITE_NAME.	Filtered data.

Data Operations Evolution
Use case: to review the volume of data modifications by country, site, subject, user, visit, form, and items.
Insights:

- Large volumes of data modifications may indicate the necessity for an investigation into data integrity.
- Overview of user performance by country, site, subject, user, visit, form, or items.

Visualizations:

Title	Description	Interactivity
Data Operations Evolution	Represents the totality of data operations from the inception of the study. • **Type**: Combo chart. • **X-Axis**: Operation Month. • **Y-Axis**: – Total Created Item Count – Total Modified Item Count – Total Removed Item Count – Total Cleared Item Count The chart represents Total Created Item Count with a line, and Total Modified, Removed, and Cleared Item Counts with separate bars of different colors.	Filtered data.
Data Operations Created vs Verified	Represents a comparison between the volumes of created and verified data, over a set interval. • **Type**: Combo chart. • **X-Axis**: Operation Month. • **Y-Axis**: Total Created Item Count and Total Verified Item Count, each displayed as lines of different colors.	Filtered data.

Title	Description	Interactivity
Data Operations Updated vs Unverified	Represents a comparison between the total volumes of updated and of unverified data operations from the inception of the study. • **Type**: Combo chart. • **X-Axis**: Operation Month • **Y-Axis**: Total Item Updates Count (Modified + Cleared + Removed) and Total Unverified Count, each displayed as lines of different colors.	Filtered data.
Data Operations Evolution Details	Represents the total count of created, modified, removed, and cleared items against study, country, and site. • **Type**: Pivot chart • **Columns**: – STUDY_TITLE – COUNTRY_NAME – SITE_NAME – A monthly breakdown of each of the following metrics: * Total Created Count * Total Modified Count * Total Removed Count * Total Cleared Count	Filtered data.

Data Operations Analysis
Use cases: to review the volume of data and data operations by country, site, user, visit, and form.
Insights:

- Large volumes of data operations may indicate the necessity for oversight of changes to critical data.
- Can help proactively bring process improvements based on trends.

Visualizations:

Title	Description	Interactivity
Data volume by country	Represents the total volume of data operations on a country by country basis. • **Type**: Heat map.	This chart operates as a filter for all other charts on the page.
Operations by site	Represents the total number of operations across each site. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Represents the item count by site for different operations with different colors: – Create – Modify – Remove – Clear • **Y-Axis**: SITE_NAME.	Filtered data.
Operations by user	Represents the total number of operations each user has performed. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Represents with different colors the item count by user for different operations: – Create – Modify – Remove – Clear • **Y-Axis**: USER_NAME	This chart can be used as a filter for other charts on the dashboard.

Title	Description	Interactivity
Operations by study role	Represents the total number of operations all users of a particular study role have performed. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Represents with different colors the item count by study role for different operations: – Create – Modify – Remove – Clear • **Y-Axis**: CURRENT_STUDY_ROLE	This chart can be used as a filter for other charts on the dashboard.
Operations by visit	Represents the total number of operations performed for each of a study's visits. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Represents with different colors the item count by visit for different operations: – Create – Modify – Remove – Clear • **Y-Axis**: EVENT_NAME.	This chart can be used as a filter for other charts on the dashboard.
Operations by form	Represents the total number of operations performed for each of a study's forms. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Represents with different colors the Item count by form for different operations: – Create – Modify – Remove – Clear • **Y-Axis**: FORM_NAME.	This chart can be used as a filter for other charts on the dashboard.

Title	Description	Interactivity
Data updates where item has query	Represents the totality of operations for which a query has been raised. • **Type**: Vertical stacked bar chart. • **X-Axis**: OPERATION_TYPE • **Y-Axis**: Total items and items with queries counts represented as bars of different colors: – Total Item Count – Has Query Count	This chart can be used as a filter for other charts on the dashboard.
Data changes by reason	Represents reasons for data changes in accordance with how commonly they have been used. • **Type**: Tab cloud chart. • The chart represents REASON items as individual elements, the colors of which change in accordance with their associated OPERATION_TYPE.	This chart can be used as a filter for other charts on the dashboard.

Data Modifications Analysis
Use cases: to review the volume of data modifications by country, site, subject, user, visit, form, and items.
Insights:

- Large volumes of data modifications may indicate the necessity for an investigation into data integrity.
- Can help with improving the performance of users.

Visualizations:

Title	Description	Interactivity
Data modifications by top 5 countries	Represents the five most active countries when it comes to the volume of data modifications. • **Type**: Stacked bar chart. • **X-Axis**: COUNTRY_NAME. • **Y-Axis**: Modified actions count. Different colors represent item count for different modification operations.	This chart can be used as a filter for other charts on the dashboard.
Data modifications by top 5 sites	Represents the five most active sites when it comes to the volume of data modifications. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Modified actions count. Different colors represent item count for different modification operations. • **Y-Axis**: SITE_NAME.	This chart can be used as a filter for other charts on the dashboard.
Data modifications by top 5 users	Represents the five most active users when it comes to the volume of data modifications. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Modified Actions count. Different colors represent item count for different modification operations. • **Y-Axis**: USER_NAME.	This chart can be used as a filter for other charts on the dashboard.

Title	Description	Interactivity
Data modifications by top 5 subjects	Represents five subjects the data of which has been most modified. • **Type**: Stacked bar chart. • **X-Axis**: SUBJECT_NUMBER. • **Y-Axis**: Modified actions count. Different colors represent item count for different modification operations.	This chart can be used as a filter for other charts on the dashboard.
Data modifications by top 5 forms	Represents five forms for which the most data modification operations have been recorded. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Modified actions count. Different colors represent item count for different modification operations. • **Y-Axis**: FORM_NAME.	This chart can be used as a filter for other charts on the dashboard.
Data modifications by top 5 items	Represents five items for which the most data modification operations have been recorded. • **Type**: Horizontal stacked bar chart. • **X-Axis**: Modified actions count. Different colors represent item count for different modification operations. • **Y-Axis**: ITEM_NAME	This chart can be used as a filter for other charts on the dashboard.

Title	Description	Interactivity
Subject Audit Trail Data	Lists all of the creation, modification, and removal operations performed as part of a study. • **Type**: Table chart. • **Columns**: – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – FORM_NAME – Form Sequence – Value – VERSION_START – OPERATION_TYPE – USER_NAME – REASON – COMMENTS – IS_CURRENT • The chart represents the nature of the operation using different colors.	Filtered data.

Form Data Modifications Analysis
Use cases: to review the volume of data modifications by country, site, subject, user, visit, form, and items.
Insights:

- Large volumes of data modifications may indicate the necessity for an investigation into data integrity.
- Can help with improving the performance of users.

Visualizations:

Title	Description	Interactivity
Form Modification Volume	Represents the total volume of modification, removal, and clearance actions performed for a study's forms. • **Type**: Pivot chart. • **Columns**: – FORM_NAME – Modified Actions – Cleared Actions – Removed Actions • This chart represents the volume of operations using color-coded cells, with the forms with the most performed actions appearing at the top. Color shades are also used to represent the volumes of data operations.	This chart can be used as a filter for the Modifications by Visit, Form & Item chart from this dashboard.
Modification by Visit, Form & Item	Represents a study's forms and the actions of modification performed on their associated data, as well as their volume. • **Type**: Tree Map chart • Represents FORM_NAME, EVENT_TITLE, and ITEM_NAME as categories, as well as the count of Modified Actions. The volume of each operation is also represented using color shades.	Filtered data.

Subject Audit Trail Data
Use cases: to review the volume of data modifications by country, site, subject, user, visit, form, and items.
Insights:

- Large volumes of data modifications may indicate the necessity for an investigation into data integrity.
- Can help with improving the performance of users.

Visualizations:

Title	Description	Interactivity
Subject Audit Trail Data	Lists all of the creation, modification, and removal operations performed as part of a study. • **Type**: Table chart. • **Columns**: – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – FORM_NAME – Form Sequence – Value – VERSION_START – OPERATION_TYPE – USER_NAME – REASON – COMMENTS – IS_CURRENT • The chart represents the nature of the operation using different colors.	Filtered data.

Clinical Research Associate dashboard

The Clinical Research Associate Dashboard can highlight which monitoring reports require completion or approval, as well as display key data points related to a site's health.

About access and filters

To properly view corresponding data in the Clinical Research Associate (CRA) Dashboard, you must have access to the Subject dataset, Queries dataset, Subject Forms dataset, and Blinded Subject Events dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

> **Note:**
>
> You must have access to both datasets to view all information. If you only have access to one of the required datasets, you can still view the dashboard, but data in the reports related to the datasets you don't have access to displays as not available.

Because a dashboard is interactive, it displays any study data you already have access to. You can select what information to display using the following filters:

- IS_CURRENT
- STUDY_MODE

- STUDY_TITLE
- COUNTRY_NAME
- SITE_NAME
- Date Range
- Subject State
- Query State (Default to *Answered*, *Candidate* and *Opened*)

> **Tip:**
>
> Select data to analyze from a study one by one. If multiple studies or sites are used in a dashboard's filters, there is a possibility that data doesn't appear in the different visualizations due to their default sizes.

Additionally, some charts can be used as filters. Look for the filter icon ( ) to the left of the visualization title. Click any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse selection on the chart, click the white space within it or use the undo button ( ) at the upper right corner of the screen.

> **Note:**
>
> If the selected filters point to data that isn't present on another chart, it displays a *No Data Found* message.

Reports

The Clinical Research Associate (CRA) Dashboard includes the following reports:

- Study Overview
- Screening Overview
- Enrollment Report
- Subject Dropout Count by Reason
- Outstanding Queries by Site and Visit
- Query Aging by Site
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Volume by Form
- Subject Counts with Outstanding Queries
- Missing Forms Report
- Missing Visits Report

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation, upper cases with words separated by underscores. In contrast, custom calculation elements are listed using title case. These notations match with what you see in the dashboard template.

Study Overview
Use case: review overall enrollment performance to assess sites in relation to study performance.
Insights:

- Overall enrollment key performance indicators.

Visualizations:

Title	Description	Interactivity
Study Overview	Represents subject counts by study and by subject status. • **Type:** Horizontal stacked bar chart. • **X-axis:** Subject counts. Colored stacks represent counts by subject status. • **Y-axis:** Study titles.	This chart can be used as a filter.
KPI: *Total Screened*	Key Performance Indicator of total screened subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screening_Initiated – Active – Complete – Withdrawn – Enrolled – Screen_Failed	Filtered data.
KPI: *Current Screen Count*	Key Performance Indicator of current screened subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screening_Initiated	Filtered data.

Title	Description	Interactivity
KPI: *Screen Failed Count*	Key Performance Indicator of subjects with screen failure. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screen_Failed	Filtered data.
KPI: *Enrolled*	Key Performance Indicator of enrolled subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Enrolled	Filtered data.
KPI: *Current Active*	Key Performance Indicator of current active subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Active	Filtered data.
KPI: *Randomized Count*	Key Performance Indicator of randomized subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Randomized	Filtered data.
KPI: *Completed Study*	Key Performance Indicator of complete subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Complete	Filtered data.
KPI: *Early Terminations*	Key Performance Indicator of withdrawn subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Withdrawn	Filtered data.

Title	Description	Interactivity
Study Details	Lists subject counts by status for every study, study version, phase and therapeutic area. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – STUDY_VERSION – STUDY_PHASE – THERAPEUTIC_AREA – Current Active – Completed Study – Early Terminations	Filtered data.

Screening Overview
Use case: review screen failure volume and identify possible reasons, by study, country and site.
Insights:

- High screen failure may indicate a site is screening the wrong patient population, or existing issues with the inclusion/ exclusion criteria. In this case, contact site to review protocol and screening population.
- Review screen failure reasons to identify issues with protocol, raise with your study manager.
- In case of rapid screening and enrollment of subjects, schedule monitoring visits.

Visualizations:

Title	Description	Interactivity
KPI: *Total Screened*	Key Performance Indicator of total screened subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screening_Initiated – Active – Complete – Withdrawn – Enrolled – Screen_Failed	Filtered data.
KPI: *Current Screen Count*	Key Performance Indicator of current screened subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screening_Initiated	Filtered data.

Title	Description	Interactivity
KPI: *Screened Failed Count*	Key Performance Indicator of subjects with screen failure. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screen_Failed	Filtered data.
KPI: *Enrollment Count*	Key Performance Indicator of enrolled subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Active – Complete – Withdrawn – Enrolled	Filtered data.
Screening vs. Enrollment by Country	Represents subject counts by subject status. • **Type:** Bar chart. • **X-axis:** Country name. • **Y-axis:** Subject counts. Different colored bars represent counts by subject status: – Total Screened – Screen Failed Count – Enrollment Count – Current Screen Count	This chart can be used as a filter.
Screen Failure Reason by Site	Represents counts of subject with screen failure by reason. • **Type:** Horizontal stacked bar chart. • **X-axis:** Count of subjects with screen failure. Colored stacks represent different screen failure reasons. • **Y-axis:** Reasons of screen failure.	Filtered data.

Title	Description	Interactivity
Screening Overview	Lists subject details by country and site, including reason of screen failure when applicable. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SITE_ID_NAME – SIBJUECT_NUMBER – STATE – Screen Failure Reason	Filtered data.

Enrollment Report
Use case: review and analyze the enrollment volume for different sites and countries.
Insights:

- Contact the site for the reason of low enrollment to provide guidance on protocol training, patient population, prompts to enter data, etc.

Visualizations:

Title	Description	Interactivity
Subjects' enrollment Counts by Site/Country	Represents the enrollment count and respective percent by site for all countries. • **Type:** Donut chart. **Note:** There is a different donut chart for each country. • **Data:** Subject enrollment count by site. Total count is displayed at the center of the Donut.	This chart can be used as a filter.

Title	Description	Interactivity
Month-wise Enrollment Trend	Represents total screened subjects count vs. enrollment count by month. • **Type:** Bar chart with reference line. • **X-axis:** Enrollment month. • **Y-axis:** Total screened and enrolled subjects count. Different colored bars represent screening and enrollment respectively. • **Reference line:** Average total screened subject count.	Filtered data.
Subject Enrollment Details	Lists screening and enrollment counts by site, study and country. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – STUDY_TITLE – SITE_NAME – SITE_ID_NAME – Total Screened – Current Screen Count – Enrollment Count – Current Active – Completed Study – Dropout Count	Filtered data.

Subject Dropout Count by Reason
Use case: review subject dropout trend volume and reasons, for the overall study and by site and country.
Insights:

- High dropout volume may indicate a site is screening the wrong patient population. In this case contact site to review protocol and screening population.
- High dropout volume may indicate existing issues with the inclusion/ exclusion criteria, the drug itself, adverse events, protocol design or site conduct of the protocol. In this case, contact site to review protocol.
- Review dropout reasons to identify issues with protocol, raise with your study manager.
- In case of rapid screening and enrollment of subjects, schedule monitoring visits.

Visualizations:

Title	Description	Interactivity
Total Dropout Counts by Reason	Represents subject dropout counts by reason. • **Type:** Horizontal bar chart. • **X-axis:** Dropout count. • **Y-axis:** Dropout reason.	This chart can be used as a filter.
Total Dropouts by Site/ Country	Represents subject dropout counts by country and by site. • **Type:** Horizontal stacked chart. • **X-axis:** Dropout counts. • **Y-axis:** Country name. Colored stacks represent counts by site.	This chart can be used as a filter.
Total Dropouts by Study	Represents total subject dropout counts by study. • **Type:** Donut chart. • **Data:** Total dropout counts by study. Total count is displayed at the center of the Donut.	This chart can be used as a filter.
Subject Dropout Count by Reason Details	Lists subject dropout count by reason for every site in all countries. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – STATE – REASON – Dropout count	Filtered data.

Outstanding Queries by Site and Visit
Use case: to review high volume of queries by status at a site and to compare with other sites.
Insights:

- Plan workload distribution and additional resources implementation to handle high volume of queries.
- Work along with Clinical team and schedule monitoring visits to pro-actively provide training for site users to conduct a particular visit.

Visualizations:

Title	Description	Interactivity
Outstanding queries by Site	Represents the total count of queries as well as the count of queries grouped by state for each site. • **Type:** Vertical stacked bar chart. • **X-axis:** Site name. • **Y-axis:** Queries count. Colored stacks represent counts by query status.	This chart can be used as a filter.
Count and duration of Open Queries by Site	Represents open queries count by age range for every site. • **Type:** Vertical stacked bar chart. • **X-axis:** Site name. • **Y-axis:** Open queries count. Colored stacks represent age ranges: – 6 to 10 days – 11 to 30 days – 31 to 60 days – greater than 60 days	This chart can be used as a filter.
Count and duration of Open Queries by Visit	Short description • **Type:** Bar chart. • **X-axis:** Visit. • **Y-axis:** Open queries count. Different colored bars represent age ranges: – 6 to 10 days – 11 to 30 days – 31 to 60 days – greater than 60 days	This chart can be used as a filter.

Title	Description	Interactivity
Outstanding Queries by Site and Visit Details	Lists the total count of queries as well as the count of queries grouped by state in every visit for every subject in all sites. • **Type:** Listing table • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – Visit – Open Queries Count – Answered Queries Count – Candidate Queries Count – Total queries count – 0-5 Days Opened – 6-10 Days Opened – 11-30 Days Opened – 31-60 Days Opened – >60 Days Opened	Filtered data.

Query Aging by Site
Use case: review high volume of open queries and query age at a site as compared to other sites.
Insights:

- Plan workload distribution and additional resources implementation to handle high volume of queries.
- Work along with Clinical team and schedule monitoring visits to pro-actively provide training for site users to conduct a particular visit.

Visualizations:

Title	Description	Interactivity
Count and Duration of Open Queries by Site	Represents open queries count by age ranges for every site. • **Type:** Vertical bar chart. • **X-axis:** Site name. • **Y-axis:** Open queries count. Different colored bars represent age ranges: – 0 to 5 days – 6 to 10 days – 11 to 30 days – 31 to 60 days – greater than 60 days	This chart can be used as a filter.
Outstanding Queries by Site and Visit Details	Lists queries counts by query state, by age range for open queries and by visit, for every subject in all sites. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – Visit – Open Queries Count – Answered Queries Count – Candidate Queries Count – 0-5 Days Opened – 6-10 Days Opened – 11-30 Days Opened – 31-60 Days Opened – >60 Days Opened	Filtered data.

Query Status by Site and Subject
Use case: review specific query volume by Subject, Country and Site
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Count by Country	Heat map of queries counts by country. • **Type:** Map chart. Countries appear in heat map colors. **Tip:** Hover on a country to view country name and total queries count.	This chart can be used as a filter
Query Count by Country and state	Lists countries upon selection along with queries count, in total and by query state. • **Type:** Pivot table. • **Columns:** – COUNTRY_NAME – COUNT **Note:** One COUNT column for each query state. – Grand Total	Filtered data.
Query Count by Study and Site	Represents total queries count vs. open queries count by site. Study name details appear on hover. • **Type:** Horizontal bar chart. • **X-axis:** Queries count. Different colored bars represent total queries count and open queries count respectively. • **Y-axis:** Site name.	This chart can be used as a filter.

Title	Description	Interactivity
Query Status by Site and Subject Details	Lists counts of queries by state for every subject in all sites. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – SUBJECT_STATE – Open Query Count – Answered Query Count – Candidate Query Count – Closed Query Count – Deleted Query Count – Started Visits Count – % of Queries within Country	Filtered data.

Query Volume by Month
Use case: review specific query volume by month, for every site and country and by Subject.
Insights:

- Identify which Sites have more or less queries in particular month or visit.
- In case of high query volume,contact site for workload prioritization based on queries.
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Count by Status	Represents the evolution of query volume by month. • **Type:** Line chart. • **X-axis:** Year-month to evaluate for active queries. • **Y-axis:** Total queries count. Different colored lines represent different query states.	This chart can be used as a filter.

Title	Description	Interactivity
Query Volume by Month by Site	Lists queries count by state by month for each site. • **Type:** Pivot table. • **Columns:** – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Month – COUNT **Note:** One COUNT column for each query state. Subtotal counts per site appear in red.	Filtered data.
Query Count by Subject by Month	Lists queries count and state by month for every subject in all sites. • **Type:** Listing table. • **Columns:** – SITE_NAME – SUBJECT_NUMBER – Total Queries Count – Month – Query State	Filtered data.

Query Management Detail Report
Use case: review query details for total query volume or by query state, for all subjects or by site. Use this information to indicate a problem with certain visit or the data collection forms.
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Unresolved Queries by Site	Represents the total count of queries as well as the count of queries grouped by state for each site. • **Type:** Vertical stacked chart. • **X-axis:** SITE_ID_NAME. • **Y-axis:** Total queries count. Colored stacks represent counts by query status.	This chart can be used as a filter
Query Management Detail Report	Lists query details for every subject in every site. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – STUDY_TITLE – SITE_ID – SITE_NAME – SUBJECT_NUMBER – Visit – FORM_NAME – ITEM_NAME – QUERY_COMMENT – STATE – QUERY_AGE – VERSION_START – USER_NAME	Filtered data.

Query Volume by Form
Use case: identify issues on specific forms causing high query volume. Use this information to indicate a problem with certain visit or the data collection forms.
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Volume by Form	Represents total queries count, as well as queries count by status, by form. • **Type:** Horizontal stacked bar chart. • **X-axis:** Queries count. Colored stacks represent counts by query status. • **Y-axis:** Form name.	This chart can be used as a filter.
Query Volume by Form	Lists queries count, total and by status, by form, grouped by visit and by site. • **Type:** Pivot table. • **Columns:** – SITE_NAME – Visit – FORM_NAME – Open Query Count – Answered Query Count – Candidate Query Count – Grand Total	Filtered data.

Subject Counts with Outstanding Queries
Use case: review specific query volume by subject, country and site.
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Subject Count with Query Status by Site	Represents the subject count with opened, answered and candidate queries, as well as the total, by site. • **Type:** Vertical stacked bar chart. • **X-axis:** SITE_ID_NAME. • **Y-axis:** Subject count. Colored stacks represent subject counts with specific query status.	This chart can be used as a filter.

Title	Description	Interactivity
Avg. Age of Queries Open by Site/Study	Represents the average age of open queries by site. • **Type:** Vertical stacked bar chart with reference line. • **X-Axis:** SITE_ID_NAME. • **Y-Axis:** Average age of open queries for each site. • **Reference line:** Average age of queries across all sites.	This chart can be used as a filter.
Subject Counts with Outstanding Queries	Lists queries count by state for every subject by site and country. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SITE_ID_NAME – SUBJECT_NUMBER – STATE – COUNT	Filtered data.

Missing Forms Report
Use case: Measure study performance by analyzing the forms that have not yet been entered.

> **Note:**
>
> Forms form Cycle Visits and Branch Visits are not included.

Insights:

- Identify key performance indicators related to missing forms.

Visualizations:

Title	Description	Interactivity
KPI: *Forms Completed Count*	Key Performance Indicator of completed forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Completed	Filtered data.

Title	Description	Interactivity
KPI: *Forms Partially Completed Count*	Key Performance Indicator of partially completed forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Incomplete – In_progress	Filtered data.
KPI: *Forms Missing Count*	Key Performance Indicator of missing forms. • **Type:** Tile chart. • **Count:** Forms with IS_MISSING_FORM= – Yes	Filtered data.
KPI: *Forms Overdue Count*	Key Performance Indicator of overdue forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Incomplete – Invalid – In_progress – Scheduled – Valid and VISIT_STATUS= – In progress – Incomplete	Filtered data.
Missing Forms by Site	Represents missing and completed forms count by site and study. • **Type:** Horizontal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms count. • **Y-Axis:** Study titles and Sites.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Forms by Subject	Represents missing and completed forms for each subject by study. • **Type:** Horizontal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms count. • **Y-Axis:** Study titles and Subjects.	This chart can be used as a filter.
Missing Forms by Visit	Represents missing and completed forms for each visit by study. • **Type:** Horizontal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms counts. • **Y-Axis:** Study titles and Visits.	This chart can be used as a filter.
Missing Forms Timeline	Represents missing and completed forms for each subject by study. • **Type:** Line chart with two lines. • **X-Axis:** Visit date or projected visit date for the completed or missing forms respectively. • **Y-Axis:** Form counts. Different colored lines represent the completed and the missing forms counts.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Forms Details	Lists forms count by status (completed, partially completed, missing or overdue) for every subject by site and country. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – VISIT_START_DATE – FORM_NAME – Completed Forms Count – Forms Partially Completed Count – Forms Missing Count – Forms Overdue Count	Filtered data.

Missing Visits Report
Use case: Measure study performance by analyzing the visits that have not yet been started.

> **Note:**
>
> Cycle Visits and Branch Visits are not included.

Insights:

- Identify key performance indicators related to missing visits.

Visualizations:

Title	Description	Interactivity
KPI: *Visits Completed Count*	Key Performance Indicator of completed visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Completed	Filtered data.

Title	Description	Interactivity
KPI: *Visits Partially Completed Count*	Key Performance Indicator of partially completed visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Incomplete – Incomplete_Err – Inprogress – Complete_Err	Filtered data.
KPI: *Visits Skipped Count*	Key Performance Indicator of skipped visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Skipped	Filtered data.
KPI: *Visits Missed Count*	Key Performance Indicator of missing visits. • **Type:** Tile chart. • **Count:** Visits with IS_MISSING_VISIT= – Yes	Filtered data.
KPI: *Visits Overdue Count*	Key Performance Indicator of overdue visits. • **Type:** Tile chart. • **Count:** Visits with IS_OVERDUE_VISIT= – Yes	Filtered data.
Missing Visits by Site	Represents missing and completed visits count by site and study. • **Type:** Horizontal bar chart. • **X-Axis:** Visit counts. Different colored bars represent the completed and the missing visits counts. • **Y-Axis:** Study titles and Sites.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Visits by Subject	Represents missing and completed visits for each subject by study. • **Type:** Horizontal bar chart. • **X-Axis:** Visit counts. Different colored bars represent the completed and the missing visits counts. • **Y-Axis:** Study titles and Subjects.	This chart can be used as a filter.
Missing Visits Timeline	Represents missing and completed forms for each subject by study. • **Type:** Line chart with two lines. • **X-Axis:** Visit date or projected visit date for the completed or missing visits respectively. • **Y-Axis:** Visit counts. Different colored lines represent the completed and the missing visits counts.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Visits Details	Lists visits count by status (completed, partially completed, skipped, missing or overdue) for every subject by site and country. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – VISIT_START_DATE – Visits Completed Count – Visits Partially Completed Count – Visits Skipped Count – Visits Missing Count – Visits Overdue Count	Filtered data.

Data Manager dashboard

The Data Manager Dashboard includes sets of actionable visualizations and detailed listings of queries, subjects states, and general subject data that is relevant to any clinical data manager.

About access and filters

To properly view corresponding data in the Data Manager Dashboard, you must have access to the Queries dataset, Subject Forms dataset, and Blinded Subject Event dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

Because a dashboard is interactive, it displays any study data you already have access to. You can select what information to display using the following filters:

- IS_CURRENT
- STUDY_MODE
- STUDY_TITLE
- COUNTRY_NAME
- SITE_NAME
- Date Range
- Query State (Default to *Answered*, *Candidate* and *Opened*)

> **Tip:**
>
> Analyze data from your studies one by one. If multiple studies or sites are used in a dashboard filter there is a possibility that data doesn't appear in the different visualizations due to their default sizes.

Additionally, some charts can be used as filters. Look for the filter icon ( ) to the left of the visualization title. Click on any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse selection on the chart, click on any white space within it or use the undo button ( ) at the upper right corner of the screen.

> **Note:**
>
> If the selected filters point to data not present on another chart, it displays *No Data Found* Message.

Reports

The Data Manager Dashborad includes the following reports:

- Outstanding Queries by Site and Visit
- Query Status by Site and Subject
- Query Volume by Month
- Query Management Detail Report
- Query Ageing by Site
- Query Volume by Form
- Missing Forms Report
- Missing Visits Report

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation, upper cases with words separated by underscores. In contrast, custom calculation elements are listed using title case. These notations match with what you see in the dashboard template.

Outstanding Queries by Site and Visit
Use case: to review high volume of queries by status at a site and to compare with other sites.
Insights:

- Plan workload distribution and additional resources implementation to handle high volume of queries.
- Work along with Clinical team and schedule monitoring visits to pro-actively provide training for site users to conduct a particular visit.

Visualizations:

Title	Description	Interactivity
Outstanding queries by Site	Represents the total count of queries as well as the count of queries grouped by state for each site. • **Type:**Vertical stacked bar chart. • **X-axis:** Site name. • **Y-axis:** Queries count. Colored stacks represent counts by query status.	This chart can be used as a filter.
Outstanding Queries by Site and Visit Details	Lists the total count of queries as well as the count of queries grouped by state in every visit for every subject in all sites. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – Visit – Open Query Count – Answered Query Count – Candidate Query Count – Total Outstanding Queries	Filtered data.

Query Status by Site and Subject
Use case: review specific query volume by Subject, Country and Site
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Count by Country	Heat map of queries counts by country. • **Type:** Map chart. Countries appear in heat map colors. **Tip:** Hover on a country to view country name and total queries count.	This chart can be used as a filter
Query Count by Country and state	Lists countries upon selection along with queries count, in total and by query state. • **Type:** Pivot table. • **Columns:** – COUNTRY_NAME – COUNT **Note:** One COUNT column for each query state. – Grand Total	Filtered data.
Query Count by Study and Site	Represents total queries count vs. open queries count by site. Study name details appear on hover. • **Type:** Horizontal bar chart. • **X-axis:** Queries count. Different colored bars represent total queries count and open queries count respectively. • **Y-axis:** Site name.	This chart can be used as a filter.

Title	Description	Interactivity
Query Status by Site and Subject Details	Lists counts of queries by state for every subject in all sites. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – SUBJECT_STATE – Open Query Count – Answered Query Count – Candidate Query Count – Closed Query Count – Deleted Query Count – Started Visits Count – % of Queries within Country	Filtered data.

Query Volume by Month
Use case: review specific query volume by month, for every site and country and by Subject.
Insights:

- Identify which Sites have more or less queries in particular month or visit.
- In case of high query volume, contact site for workload prioritization based on queries.
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Count by Status	Represents the evolution of query volume by month. • **Type:** Line chart. • **X-axis:** Year-month to evaluate for active queries. • **Y-axis:** Total queries count. Different colored lines represent different query states.	This chart can be used as a filter.

Title	Description	Interactivity
Query Volume by Month by Site	Lists queries count by state by month for each site. • **Type:** Pivot table. • **Columns:** – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Month – COUNT **Note:** One COUNT column for each query state. Subtotal counts per site appear in red.	Filtered data.
Query Count by Subject by Month	Lists queries count and state by month for every subject in all sites. • **Type:** Listing table. • **Columns:** – SITE_NAME – SUBJECT_NUMBER – Total Queries Count – Month – Query State	Filtered data.

Query Management Detail Report
Use this report to review query details for total query volume or by query state, for all subjects or by site. Use this information to indicate a problem with certain visit or the data collection forms.
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries
- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Unresolved Queries by Site	Represents the total count of queries as well as the count of queries grouped by state for each site. • **Type:** Vertical stacked chart. • **X-axis:** Site name. • **Y-axis:** Total queries count. Colored stacks represent counts by query status.	This chart can be used as a filter
Query Management Detail Report	Lists query details for every subject in every site. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – STUDY_TITLE – SITE_ID – SITE_NAME – SUBJECT_NUMBER – Visit – FORM_NAME – ITEM_NAME – QUERY_COMMENT – STATE – QUERY_AGE – VERSION_START – USER_NAME	Filtered data.

Query Ageing by Site
Use case: review high volume of open queries and query age at a site as compared to other sites.
Insights:

- Plan workload distribution and additional resources implementation to handle high volume of queries.
- Work along with Clinical team and schedule monitoring visits to pro-actively provide training for site users to conduct a particular visit.

Visualizations:

Title	Description	Interactivity
Count and Duration of Open Queries by Site	Represents open queries count by age ranges for every site. • **Type:** Vertical bar chart. • **X-axis:** Site name. • **Y-axis:** Open queries count. Different colored bars represent age ranges for the queries count: – 6 to 10 days – 11 to 30 days – 31 to 60 days – greater than 60 days	This chart can be used as a filter.
Outstanding Queries by Site and Visit Details	Lists queries counts by query state, by age range for open queries and by visit, for every subject in all sites. • **Type:** Listing table. • **Columns:** – COUNTRY_NAME – SITE_NAME – SUBJECT_NUMBER – Visit – Open Query Count – Answered Query Count – Candidate Query Count – Total queries count – 6-10 Days Opened – 11-30 Days Opened – 31-60 Days Opened – >60 Days Opened	Filtered data.

Query Volume by Form
Use case: identify issues on specific forms causing high query volume. Use this information to indicate a problem with certain visit or the data collection forms.
Insights:

- In case of high query volume, contact site for workload prioritization based on open queries

- Identify the need of additional training for a site.

Visualizations:

Title	Description	Interactivity
Query Volume by Form	Represents total queries count, as well as queries count by status, by form. • **Type:** Horizontal stacked bar chart. • **X-axis:** Queries count. Colored stacks represent counts by query status. • **Y-axis:** Form name.	This chart can be used as a filter.
Query Volume by Form	Lists queries count, total and by status, by form, grouped by visit and by site. • **Type:** Pivot table. • **Columns:** – SITE_NAME – Visit – FORM_NAME – Open Query Count – Answered Query Count – Candidate Query Count – Grand Total	Filtered data.

Missing Forms Report
Use case: Measure study performance by analyzing the forms that have not yet been entered.

> **Note:**
>
> Forms form Cycle Visits and Branch Visits are not included.

Insights:

- Identify key performance indicators related to missing forms.

Visualizations:

Title	Description	Interactivity
KPI: *Forms Completed Count*	Key Performance Indicator of completed forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Completed	Filtered data.

Title	Description	Interactivity
KPI: *Forms Partially Completed Count*	Key Performance Indicator of partially completed forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Incomplete – In_progress	Filtered data.
KPI: *Forms Missing Count*	Key Performance Indicator of missing forms. • **Type:** Tile chart. • **Count:** Forms with IS_MISSING_FORM= – Yes	Filtered data.
KPI: *Forms Overdue Count*	Key Performance Indicator of overdue forms. • **Type:** Tile chart. • **Count:** Forms with FORM_STATUS= – Incomplete – Invalid – In_progress – Scheduled – Valid and VISIT_STATUS= – In progress – Incomplete	Filtered data.
Missing Forms by Site	Represents missing and completed forms count by site and study. • **Type:** Horizontal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms counts. • **Y-Axis:** Study titles and Sites.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Forms by Subject	Represents missing and completed forms for each subject by study. • **Type:** Horizintal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms counts. • **Y-Axis:** Study titles and Subjects.	This chart can be used as a filter.
Missing Forms by Visit	Represents missing and completed forms for each visit by study. • **Type:** Horizintal bar chart. • **X-Axis:** Form counts. Different colored bars represent the completed and the missing forms counts. • **Y-Axis:** Study titles and Visits.	This chart can be used as a filter.
Missing Forms Timeline	Represents missing and completed forms for each subject by study. • **Type:** Line chart with two lines. • **X-Axis:** visit date or projected visit date for the completed or missing forms respectively. • **Y-Axis:** Form counts. Different colored lines represent the completed and the missing forms counts.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Forms Details	Lists forms count by status (completed, partially completed, missing or overdue) for every subject by site and country. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – VISIT_START_DATE – FORM_NAME – Completed Forms Count – Forms Partially Completed Count – Forms Missing Count – Forms Overdue Count	Filtered data.

Missing Visits Report
Use case: Measure study performance by analyzing the visits that have not yet been started.

> **Note:**
>
> Forms form Cycle Visits and Branch Visits are not included.

Insights:

- Identify key performance indicators related to missing visits.

Visualizations:

Title	Description	Interactivity
KPI: *Visits Completed Count*	Key Performance Indicator of completed visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Completed	Filtered data.

Title	Description	Interactivity
KPI: *Visits Partially Completed Count*	Key Performance Indicator of partially completed visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Incomplete – Incomplete_Err – Inprogress – Complete_Err	Filtered data.
KPI: *Visits Skipped Count*	Key Performance Indicator of skipped visits. • **Type:** Tile chart. • **Count:** Visits with VISIT_STATUS= – Skipped	Filtered data.
KPI: *Visits Missed Count*	Key Performance Indicator of missing visits. • **Type:** Tile chart. • **Count:** Visits with IS_MISSING_VISIT= – Yes	Filtered data.
KPI: *Visits Overdue Count*	Key Performance Indicator of overdue visits. • **Type:** Tile chart. • **Count:** Visits with IS_OVERDUE_VISIT= – Yes	Filtered data.
Missing Visits by Site	Represents missing and completed visits count by site and study. • **Type:** Horizontal bar chart. • **X-Axis:** Visit counts. Different colored bars represent the completed and the missing visits counts. • **Y-Axis:** Study titles and Sites.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Visits by Subject	Represents missing and completed visits for each subject by study. • **Type:** Horizontal bar chart. • **X-Axis:** Visit counts. Different colored bars represent the completed and the missing visits counts. • **Y-Axis:** Study titles and Subjects.	This chart can be used as a filter.
Missing Visits Timeline	Represents missing and completed forms for each subject by study. • **Type:** Line chart with two lines. • **X-Axis:** visit date or projected visit date for the completed or missing visits respectively. • **Y-Axis:** Visit counts. Different colored lines represent the completed and the missing visits counts.	This chart can be used as a filter.

Title	Description	Interactivity
Missing Visits Details	Lists visits count by status (completed, partially completed, skipped, missing or overdue) for every subject by site and country. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – SITE_NAME – COUNTRY_NAME – SUBJECT_NUMBER – EVENT_TITLE – VISIT_START_DATE – Visits Completed Count – Visits Partially Completed Count – Visits Skipped Count – Visits Missing Count – Visits Overdue Count	Filtered data.

Diversity & Inclusion dashboard

The Diversity & Inclusion dashboard includes sets of actionable visualizations and reports about the subjects in a study. The data in this dashboard can provide an insight of the study's objectivity to test the safety and efficacy of the drug's formulation.

> **Note:**
>
> This is a dashboard specific to study design, meaning special configurations are needed on form design for some visualizations to work properly. These configurations include specific form names (`FORM_NAME`), question names (`ITEM_NAME`) and code list configurations (`ITEM_F`,`ITEM_D`). For more details see Required configuration for the Diversity & Inclusion dashboard.

About access and filters

To properly view corresponding data in the Diversity & Inclusion dashboard, you must have access to the Subject Form Items dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

Because a dashboard is interactive, it displays any study data you already have access to. You can select what information to display using the following filters:

- IS_CURRENT

- STUDY_MODE
- STUDY_TITLE
- COUNTRY_NAME
- SITE_NAME

> **Tip:**
>
> Analyze data from your studies one by one. If multiple studies or sites are used in a dashboard filter there is a possibility that data doesn't appear in the different visualizations due to their default sizes.

Additionally, some charts can be used as filters. Look for the filter icon ( ) to the left of the visualization title. Click on any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse selection on the chart, click on any white space within it or use the undo button ( ) at the upper right corner of the screen.

> **Note:**
>
> If the selected filters point to data not present on another chart, it displays *No Data Found* Message.

Reports

The Diversity & Inclusion dashboard includes the following reports:

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

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation, upper cases with words separated by underscores. In contrast, custom calculation elements are listed using title case. These notations match with what you see in the dashboard template.

Diversity & Inclusion Overview
Use case: review volume of patients across countries and sites, as well as distribution by gender and race.
Insights:

- Visualize an overall key performance indicator of diversity and inclusion.
- Identify high-performance studies and sites.
- Analyze a participant breakdown across a study based on gender and race.

Visualizations:

Title	Description	Interactivity
KPI: *Study Count*	Key Performance Indicator of total studies. • **Type:** Tile chart. • **Count:** Total studies.	Filtered data.
KPI: *Country Count*	Key Performance Indicator of total countries. • **Type:** Tile chart. • **Count:** Total Countries.	Filtered data.
KPI: *Site Count*	Key Performance Indicator of total sites. • **Type:** Tile chart. • **Count:** Total sites.	Filtered data.
KPI: *Subject Count*	Key Performance Indicator of total subjects. • **Type:** Tile chart. • **Count:** Total subjects.	Filtered data.
KPI: *Male Count*	Key Performance Indicator of total male subjects. • **Type:** Tile chart. • **Count:** Total male subjects.	Filtered data.
KPI: *Female Count*	Key Performance Indicator of total female subjects. • **Type:** Tile chart. • **Count:** Total female subjects.	Filtered data.
KPI: *Other Sex Count*	Key Performance Indicator of total subjects with gender other than male or female. • **Type:** Tile chart. • **Count:** Total subjects with gender other than make or female.	Filtered data.
KPI: *Sex not Specified*	Key Performance Indicator of total subjects with gender not specified. • **Type:** Tile chart. • **Count:** Total subjects with gender not specified.	Filtered data.

Title	Description	Interactivity
Top 5 Countries by Patient Volume	Represents the total count of subjects for the top 5 countries with higher subject volume. • **Type:**Vertical bar chart. • **X-axis:** Country name. • **Y-axis:** Subject count.	This chart can be used as a filter.
Top 10 sites by patient volume	Represents the total count of subjects for the top 10 sites with higher subject volume. • **Type:**Vertical bar chart. • **X-axis:** Site name. • **Y-axis:** Subject count.	This chart can be used as a filter.
Overall Patient Breakdown by Sex	Represents the total count of subjects and percentages by gender. • **Type:** Donut chart. • **Count:** Total subjects by gender. Different colors represent the subject gender.	Filtered data.
Overall Patient Breakdown by Race	Represents the total count of subjects and percentages by race. • **Type:** Donut chart. • **Count:** Total subjects by race. Different colors represent the subject races.	Filtered data.

Diverity by Sites
Use case: Identify sites with greatest access to patients of a given race, ethnicity or gender.
Insights:

- Analyze the diversity ratio and participant distribution across sites.
- Identify distribution of population, as well as race, ethnicity and gender density at each site, particularly for Hispanic and Asian populations.

Visualizations:

Title	Description	Interactivity	Required configuration
Diversity ratio by Sites	Represents the subject ratio for male and female subjects at each site. • **Type:**Scatter chart. • **X-axis:** Male subjects count. • **Y-axis:** Female subjects count. • Different colors represent different sites within a study.	This chart can be used as a filter.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'gender'** or **'sex'** • `ITEM_F` = **'Male'**, **'Female'**
Overall Patient Distribution by Sex across Sites	Represents the general patient distribution by gender for all sites. • **Type:** Horizontal stacked bar chart. • **X-axis:** Subjects count. Different colored stacks represent subject count for different genders. • **Y-axis:** Site name.	Filtered data.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'gender'** or **'sex'**

Title	Description	Interactivity	Required configuration
Top Sites by Asian & Hispanic Patient Density	Represents the sites with higher patient density for different ethnic groups, specifically for Asian and Hispanic. • **Type:** Grid heat map chart. • **X-axis:** Ethnicity. • **Y-axis:** Site name. • Different colors represent density of subject count for the given ethnic group.	Filtered data.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'ethnicity'**
Ratio of Ethnicity populations at each site	Represents the percentages of the subject count for different ethnic groups at each site. • **Type:** Horizontal 100% stacked bar chart. • **X-axis:** Subjects count. Different colors represent the percentage of the subject count for different ethnic groups. • **Y-axis:** Site name.	Filtered data	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'ethnicity'**

Diversity by Age Group
Use case: Analyze the diversity and inclusion data by age.
Insights:

- Analyze the population distribution by age at a study and site.
- Visualize the randomized participants breakdown by different age groups.

Visualizations:

Title	Description	Interactivity	Required configuration
Population Composition by Age at Sites	Represents the total subject count for each age group and in total for every site. • **Type:**Horizontal stacked bar chart. • **X-axis:** Age group of subjects. • **Y-axis:** Site name. Different color shades stacks represent the subject count for different age groups.	This chart can be used as a filter.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'date of birth'**
Population composition by Age per Year	Represents the total subject counts by age group for each year of the study. • **Type:** Vertical bar chart. • **X-axis:** Year. • **Y-axis:** Subject count. Different color shades represent different age groups.	This chart can be used as a filter.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'date of birth'**
Population composition by Age at Study	Represents the total count of subjects and the percentages of the subject count for different age groups in the study. • **Type:** Donut chart. • **Count:** Total subject counts. Different color shades represent the count of subjects for different age groups.	This chart can be used as a filter.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'date of birth'**

Patient Demographics
Use case: Analyze patient demographics for diversity and inclusion.
Insights:

- Visualize metrics for participants classified by race and ethnicity.
- Visualize different age group distribution for every study and site.

Visualizations:

Title	Description	Interactivity	Required configuration
Ethnicity and Race for Participants	Lists the count of subjects of a given ethnicity and race combination for each site a long with the grand total of subjects per site. • **Type:** Pivot table. • **Columns:** Site name. • **Rows:** Ethnicity and race combinations. • Grand total per site.	Filtered data.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'race'** • `REFERENCE_CODE` = **'ETHNICITY'**
Patient Composition by Age Group	Lists the count of subjects for different age groups for every site in every study. • **Type:** Pivot table. • **Columns:** Age groups: – < 15 – 14-64 – >=15 • **Rows:** Site name by study.	Filtered data.	• `FORM_NAME` like **'demography'** • `ITEM_NAME` like **'date of birth'**

- Required configuration for the Diversity & Inclusion dashboard
  The Diversity & Inclusion dashboard is specific to study design. This means that special configurations are needed on form design for some visualizations to work properly. These configurations include specific form names (`FORM_NAME`), question names (`ITEM_NAME`), and code lists configuration(`ITEM_F`, `ITEM_D`).

Required configuration for the Diversity & Inclusion dashboard

The Diversity & Inclusion dashboard is specific to study design. This means that special configurations are needed on form design for some visualizations to work properly. These

configurations include specific form names (`FORM_NAME`), question names (`ITEM_NAME`), and code lists configuration(`ITEM_F`, `ITEM_D`).

Most of the visualizations in the Diversity & Inclusion dashboard use custom calculations to specify which form and question is used to get data to display. For this reason, your form names, questions and even code list values must match with the specified values in the dashboard template's custom calculations.

Review the list of requirements and make sure your study design complies with all of them. In case your study design doesn't meet a requirement, you can either update your study design to match the given configuration or modify the custom calculations used in the dashboard to match your study design. If you choose to modify the dashboard's custom calculations, keep in mind that all impacted custom calculations must be updated, and updates can only be made on a modifiable copy of the Diversity & Inclusion dashboard template. For more details, see Create a modifiable copy of a template.

Note:

Updating the custom calculations requires a basic understanding of programming. Reach out to your study manager for further assistance.

Tip:

If your study doesn't use a question listed in this table, there is no need for you to modify anything. The impacted visualizations will still be part of the dashboard and show a *No Data Found* message, which you can simple ignore. If you prefer, you can also delete the given visualization from your copy to get rid of the empty spaces.

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must contain the string `'Demog'`.	The form used in your study to collect demographic data must contain the string **`'Demog'`** as part of its name. For example, *Demography*, *Demographics*, *Demographic information*, etc.	• Male Count • Female Count • Other Gender Count • Gender • Race • Ethnicity • Age < 15 • Age 15-64 • Age >= 65	*Update to match with your current form name when it doesn't contain the 'demog' string as part of it.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `lower(FORM_NAME) like '%demog%'` 3. Replace `'%demog%'` with your current form name. • Keep the single quotes.

Note: This form must contain all of the request

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		ionslistedinthistable.	
ITEM_NAME must contain the word 'gender' or 'sex'.	The form question used to collect data related to gender must have the word **'gender'** or **'sex'** on its name.	• Male Count • Female Count • Other Gender Count • Gender	*Update to match with your current question related to gender, when it doesn't contain either the "gender" or "sex" keywords.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `lower(ITEM_NAME) like '%gender%' or lower(ITEM_NAME) like '%sex%'` 3. Replace either `'%gender%'` or `'%sex%'` with any keyword from your current question. • Keep the single quotes and perecentage signs (%).

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation

`ITEM_F` must be `'Male'` for male subjects and `'Female'` for female subjects.	The code list associated to the gender question must contain the values **`'Male'`** and **`'Female'`** for male and female subjects respectively.	• Male Count
		• Female Count
		• Other Gender Count
		• Gender
			Update to match with your current answer options when they don't use "Male" and "Female" for male and female subjects respectively (for example, if you use "Man" and "Woman").
			1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**.
			2. In the Edit Calculation dialog, locate the line referring to `ITEM_F`:
			`ITEM_F = 'Male'`
			`ITEM_F = 'Female'`
			`ITEM_F not in ('Male','Female')`
			3. Replace the words `'Male'` and `'Female'` with the words in your study used for male and female subjects respectively.
			• Keep the single quotes and make sure they are capitalized exactly as in your study design.

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the phrase `'date of birth'`.	The form question used to collect age related data must be an Age type question collecting the date of birth of the subject and have the phrase **`'date of birth'`** on its name.	• Age < 15 • Age 15-64 • Age >= 65	*Update to match with your current question related to age, when it is collected as the date of birth but it doesn't contain the prhase "date of birth" as part of the question.* **Note:** These calculations expect you to collect age data as the date of birth, rather than the age value, as when you use an age-type question. 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME` (All instances): `ITEM_NAME like '%date of birth%'` 3. Replace `'%date of birth%'` with any keyword from your current question. • Keep the single quotes and perecentage signs (%).

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'race'`.	The form question used to collect race related data must have the word **`'race'`** on its name.	• Race	*Update to match with your current question related to race, when it doesn't contain the "race" keyword.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `lower(ITEM_NAME) like '%race%'` 3. Replace `'%race%'` with any keyword from your current question. • Keep the single quotes and perecentage signs (%).
`ITEM_NAME` must contain the word `'ethnicity'`.	The form question used to collect ethnicity related data must have the word **`'ethnicity'`** on its name.	• Ethnicity	*Update to match with your current question related to ethnicity, when it doesn't contain the "ethnicity" keyword.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `lower(ITEM_NAME) like '%ethnicity%'` 3. Replace `'%ethnicity%'` with any keyword from your current question. • Keep the single quotes and perecentage signs (%).

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`REFERENCE_CODE` must start with the string `'ETHNIC'`.	The form question used to collect ethnicity related data must have the string `'ETHNIC'` on its Reference Code.	• Hispanic/Non Hispanic	*Update to match with the reference code of your current question related to ethnicity, when it doesn't start with the 'ETHNIC' string.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `REFERENCE_CODE` (All instances): `REFERENCE_CODE LIKE 'ETHNIC%'` 3. Replace `'ETHNIC%'` with the current reference code of your ethnicity question. • Keep the single quotes.

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation

`ITEM_D` must be `'1'` for Hispanic ethnicity and `'0'` for non-Hispanic ethnicity.	The code list associated to the ethnicity question must have the code list code `'1'` for *Hispanic* and the codelist code `'0'` for *Non Hispanic*.	• Hispanic/Non Hispanic	*Update to match with the answer options for your current question related to ethnicity, when they don't have code list code '0' for* Non Hispanic*, and code list code '1' for* Hispanic.
			1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**.
			2. In the Edit Calculation dialog, locate the line referring to `ITEM_D` (All instances):
			`WHEN (REFERENCE_CODE LIKE 'ETHNIC%' AND ITEM_D='1') THEN 'Hispanic'`
			`WHEN (REFERENCE_CODE LIKE 'ETHNIC%' AND ITEM_D='0')THEN 'Non Hispanic'`
			3. Replace `ITEM_D` values `'1'` and `'0'` with the current code list codes used for *Hispanic* and *Non Hispanic* repectively.
			Tip:
			If any of these ethnicity classifications corresponds to multiple codelist values (for example different ethnicity options that are non Hispanic instead of just one listed as "Non Hispanic"), use the following format:
			`ITEM_D in ('x','y','z')`
			with *'x','y','z'* being all given codelists codes.
			• Keep the single quotes.

RTSM dashboard

The Randomization and Trial Supply Management (RTSM) dashboard includes a set of interactive reports and visualizations that provide key information related to randomization and supply management.

About access and filters

To properly view corresponding data in the RTSM Dashboard, you must have access to the Unblinded Kits dataset and Subject dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

> **Note:**
>
> You must have access to both datasets to view all information. If you only have access to one of the required datasets, you can still view the dashboard, but data in the reports related to the datasets you don't have access to displays as not available.

Because a dashboard is interactive, it displays any study data you already have access to in a study. You can select what information to display using the following filters:

- IS_CURRENT
- STUDY_MODE
- STUDY_TITLE
- COUNTRY_NAME
- SITE_NAME
- Date Range

> **Tip:**
>
> Analyze data from your studies one by one. If multiple studies or sites are used in a dashboard filter there is a possibility that data doesn't appear in the different visualizations due to their default sizes.

Additionally, some charts can be used as filters. Look for the filter icon ( ) to the left of the visualization title. Click on any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse selection on the chart, click on any white space within it or use the undo button ( ) at the upper right corner of the screen.

> **Note:**
>
> If the selected filters point to data not present on another chart, it displays a *No Data Found* message.

Reports

The RTSM Dashboard includes the following interactive reports:

- Overall Summaries
- Subject Details
- Subjects Enrolment Summary
- Site Status
- Unblinded Randomization
- Site Overall and Monthly
- Site Overall - Shipments
- Unblinded Shipment
- Site Inventory
- Unblinded Visit Summary
- Unblinded Clinical Supplies Return
- Unblinded Site and Depot Kit Status
- Unblinded Depot Inentory

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation, upper cases with words separated by underscores. In contrast, custom calculation elements are listed using title case. These notations match with what you see in the dashboard template.

Overall Summaries
Use case: analyze key performance indicators accorss studies.
Insights:

- Clinical Supply Managers (CSMs) can identify required action to be taken on particular sites.

Visualizations:

Title	Description	Interactivity
KPI: *Total Studies Count*	Key Performance Indicator of total studies. • **Type:** Tile chart. • **Count:** Total studies.	Filtered data.
KPI: *Total Countries Count*	Key Performance Indicator of total countries at which selected studies are present. • **Type:** Tile chart. • **Count:** Total countries.	Filtered data.
KPI: *Total Sites Count*	Key Performance Indicator of total sites at which selected studies are present. • **Type:** Tile chart. • **Count:** Total sites.	Filtered data.

Title	Description	Interactivity
KPI: *Total Subjects Count*	Key Performance Indicator of total subjects. • **Type:** Tile chart. • **Count:** Total subjects.	Filtered data.
KPI: *Screen Failed Subjects Count*	Key Performance Indicator of subjects with screen failure. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screen_Failed	Filtered data.
KPI: *Randomized Subjects Count*	Key Performance Indicator of randomized subjects. • **Type:** Tile chart. • **Count:** Subjects with EVENT_TYPE= – Randomized	Filtered data.
Overall Summaries	Lists subject counts. Total subjects, screen failed subjects and randomized subjects by study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_NAME – Total Subjects Count – Screen Failed Subjects Count – Randomized Subjects Count	Filtered data.

Subject Details
Use case: analyze screening and randomization details along with subject statuses.
Insights:

- Inform of subject metrics that could be relevant to supply management.

Visualizations:

Title	Description	Interactivity
KPI: *Total Subjects Count*	Key Performance Indicator of total subjects. • **Type:** Tile chart. • **Count:** Total subjects.	Filtered data.

Title	Description	Interactivity
KPI: *Screened Subjects Count*	Key Performance Indicator of total screened subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screening_Initiated	Filtered data.
KPI: *Randomized Subjects Count*	Key Performance Indicator of randomized subjects. • **Type:** Tile chart. • **Count:** Subjects with EVENT_TYPE= – Randomized	Filtered data.
KPI: *Screen Failed Subjects Count*	Key Performance Indicator of subjects with screen failure. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Screen_Failed	Filtered data.
KPI: *Discontinued Subjects Count*	Key Performance Indicator of subjects with screen failure. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Withdrawn	Filtered data.
KPI: *Completed Subjects Count*	Key Performance Indicator of randomized subjects. • **Type:** Tile chart. • **Count:** Subjects with STATE= – Complete	Filtered data.

Title	Description	Interactivity
Subject Details	Lists subjects with their state and state date details for every study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – SUBJECT_NUMBER – STATE – Screened Date – Screen Failed Date – Randomized Date – Discontinued Date – Completed Date	Filtered data.

Subjects Enrolment Summary
Use case: review the volume and cumulative counts of subjects by status and across countries.
Insights:

- Identify high amounts of screen failures or discontinued subjects to schedule audit visits and close monitoring of sites in the given countries.

Visualizations:

Title	Description	Interactivity
Total Sreened by Month	Represents total screened subjects count by month. • **Type:** Waterfall chart. • **X-Axis:** Month. • **Y-Axis:** Total screened subjects count.	This chart can be used as a filter.
Total Randomized by Month	Represents total randomized subjects count by month. • **Type:** Waterfall chart. • **X-Axis:** Month. • **Y-Axis:** Total randomized subjects count.	This chart can be used as a filter.

Title	Description	Interactivity
Total Completed by Month	Represents total completed subjects count by month. • **Type:** Waterfall chart. • **X-Axis:** Month. • **Y-Axis:** Total completed subjects count.	This chart can be used as a filter.
Total Discontinued by Month	Represents total discontinued subjects count by month. • **Type:** Waterfall chart. • **X-Axis:** Month. • **Y-Axis:** Total discontinued subjects count.	This chart can be used as a filter.
Enrollment Summary Details	Lists enrolment details for every study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_NAME – Month – Total Screened – Total Randomized – Total Discontinued – Total Completed	Filtered data.

Site Status
Use case: review status of different sites across countries for one or more studies.
Insights:

- Identify subject screening and activation timelines for sites.

Visualizations:

Title	Description	Interactivity
KPI: *Total Sites Count*	Key Performance Indicator of total sites for selected studies. • **Type:** Tile chart. • **Count:** Total sites.	Filtered data.
KPI: *Active Sites Count*	Key Performance Indicator of total active sites. • **Type:** Tile chart. • **Count:** sites with SITE_STATUS= – Active	Filtered data.

Title	Description	Interactivity
KPI: *New Sites Count*	Key Performance Indicator of total active sites. • **Type:** Tile chart. • **Count:** Sites with SITE_STATUS= – New	Filtered data.
KPI: *Retired Sites Count*	Key Performance Indicator of total active sites. • **Type:** Tile chart. • **Count:** Sites with SITE_STATUS= – Retired	Filtered data.
Sites by Status	Represents sites and their statuses. • **Type:** Donut chart. • **Count:** Total sites count. Different colors represent different site statuses.	This chart can be used as a filter.
Site Status by Studies	Represent sites and their statuses by study. • **Type:** Horizontal bar chart. • **X-Axis:** Total sites count. Different colors represent different site statuses. • **Y-Axis:** STUDY_TITLE.	This chart can be used as a filter.
Site Status by Countries	Represent sites and their statuses by study. • **Type:** Vertical stacked bar chart. • **X-Axis:** COUNTRY_NAME • **Y-Axis:** Total sites count. Different colors represent different site statuses.	This chart can be used as a filter.

Title	Description	Interactivity
Site Status Details	Lists subjects with their state and state date details for every study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – SITE_STATUS – First Screened – Firt Randomized – Site Activated Date – Site Retired Date – Total Sites Count – Active Sites Count – Retired Sites Count	Filtered data.

Unblinded Randomization
Use case: review randomization and treatment arm group distribution details.
Insights:

- Total number of site and subjects for a treatment arm.
- Evaluate possible need of randomization design update, including minimization cohorts or stratun groups definition and limits.

Visualizations:

Title	Description	Interactivity
Randomized Subjects Count by Treatment Arm	Represents total randomized subjects count by treatment arm in selected studies. • **Type:** Vertical stacked bar chart. • **X-Axis:** TREATMENT_ARM_DESCRIPTION. • **Y-Axis:** Total randomized subjects count.	This chart can be used as a filter.

Title	Description	Interactivity
Sites Count by Treatment Arm	Represents total randomized subjects count by treatment arm by site. • **Type:** Waterfall chart. • **X-Axis:** TREATMENT_ARM_TITLE. • **Y-Axis:** Sites count.	This chart can be used as a filter.
Unblinded Randomization Details	Lists unblinded randomization details for every randomized subject at every study and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – SITE_ID_NAME – SITE_NAME – SUBJECT_NUMBER – RAND_NUMBER – RANDOMIZATION_TYPE – RANDOMIZATION_TITLE – COHORT_NAME – TREATMENT_ARM_ID – TREATMENT_ARM_TITLE – RND_STATUS – KIT_NUMBER	Filtered data.

Site Overall and Monthly
Use case: review site activiy overview for a given month or the monthly trend.
Insights:

- Use site monthly metrics to make any required randomization or supply management adjustments.

Visualizations:

Title	Description	Interactivity
Sites Overview	Represents total subjects count by state over time by month. • **Type:** Line chart. • **X-Axis:** Visit month. • **Y-Axis:** Count of subjects by state. Different color represents different subject state: – Discontinued – Randomized – Screen Failed – Completed	This chart can be used as a filter.
Current Month Overview	Represents total subjects count by state for the current month. • **Type:** Pie chart. • **Count:** Total subjects by state. Different color represents different subject state: – Discontinued – Randomized – Screen Failed – Completed	This chart can be used as a filter.
Site Overall & Monthly Details	Lists subject state overall monthly details by site, country and study. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Screen Failed Subjects – Randomized subjects – Discontinued Subjects – Completed Subjects – Current Month – Visit Month	Filtered data.

Title	Description	Interactivity
Site Current Month Details	Lists subject state details for the current month by site, country and study. • **Type:** Listing table. • **Columns:** – Current Month – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Screen Failed Subjects – Randomized subjects – Discontinued Subjects – Completed Subjects	Filtered data.

Site Overall - Shipments
Use case: review shipment activity for a site on a monthly basis.
Insights:

- Increase or decrease shipments based on a site's supplies needs.

Visualizations:

Title	Description	Interactivity
Sites Overall (Monthly)	Represents total shipments count by kit status over time by month. • **Type:** Line chart. • **X-Axis:** Shipment month. • **Y-Axis:** Count of shipments by kit status. Different color represents different kit state: – Destroyed – In-Transit – Lost – Pending – Received	This chart can be used as a filter.

Title	Description	Interactivity
Sites Overall (Monthly) Shipment Details	Lists shipment details by kit staus by month for every site, country and study. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Shimpment Month – Shipment Destroyed Kits – Shipment In-Transit Kits – Shipment Lost Kits – Shipment Pending Kits – Shipment Received Kits	Filtered data.

Unblinded Shipment
Use case: review overll shipment history for a given site or depot.
Insights:

- Increase or decrease shipment activity based on history and actual site's or depot's needs.

Visualizations:

Title	Description	Interactivity
Shipments Count by Country	Represents total shipments by country. • **Type:** Pie chart. • **Count:** Shipments count. Different color represents different COUNTRY_NAME.	This chart can be used as a filter.
Shipments Count by Site	Represents total shipments count by site. • **Type:** Horizontal bar chart. • **X-Axis:** Shipments count. • **Y-Axis:** SITE_NAME.	This chart can be used as a filter.

Title	Description	Interactivity
Unblinded Shipment History Details	Lists subject state details for the current month by site, country and study. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Loation Type – SHIPMENT_NAME – SHIPMENT_STATUS – Shipment Date – Received Date – Shipment Days Outstanding – TRACKING_NUMBER – MANFACTURING_LOT_TITLE – Manufacturing Lot Expiration Date – MANFACTURING_LOT_DO_NOT_SHIP_DAYS – BLINDED_LOT_TITLE – Blinded Lot Expiration Date – BLINDED_LOT_DO_NOT_SHIP_DAYS	Filtered data.

Site Inventory
Use case: review site kits counts along with their statuses.
Insights:

- Identify high volume of damaged or missing kits to address any supply management failures.

Visualizations:

Title	Description	Interactivity
KPI: *Kits Dispensed*	Key Performance Indicator of total dispensed kits. • **Type:** Tile chart. • **Count:** Kits with KIT_STATUS= – Dispensed	Filtered data.

Title	Description	Interactivity
KPI: *Kits Damaged*	Key Performance Indicator of total damaged kits. • **Type:** Tile chart. • **Count:** Kits with KIT_STATUS= – Damaged	Filtered data.
KPI: *Kits Misallocated*	Key Performance Indicator of total misallocated kits. • **Type:** Tile chart. • **Count:** Kits with KIT_STATUS= – Misallocated	Filtered data.
KPI: *Kits Missing*	Key Performance Indicator of total missing kits. • **Type:** Tile chart. • **Count:** Kits with KIT_STATUS= – Missing	Filtered data.
Kits Dispensation Count by Site	Represents kits by status for every site. • **Type:** Vertical stacked bar chart. • **X-Axis:** SITE_NAME. • **Y-Axis:** Kits count by status. Different colors represent different kit statuses: – Dispensed – Damaged – Missing	This chart can be used as a filter.

Title	Description	Interactivity
Site Inventory Details	Lists kits counts by status for every study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Kits Dispensed – Kits Damaged – Kits Missing – Kits Quarantined – Kits Temporarily Unavailable – Kits Misallocated – Kits Not in Use – Kits in Transit – Kits Returned – Kits Dispensed	Filtered data.

Unblinded Visit Summary
Use case: review kits distribution on a site per visit.
Insights:

- Capture the number of kits being dispensed to a subject in a particular visit.
- Adapt inventory management based on dispensed kits to subjects at sites.

Visualizations:

Title	Description	Interactivity
Unblinded Visit Summary Details	Lists unblinded visit details for every subject, including randomization details, bu study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Site Active? – SUBJECT_NUMBER – EVENT_TITLE – Scheduled Visit? – VISIT_STATUS – VISIT_TYPE – Projected Visit Date – Actual Visit Date – RANDOMIZATION_TITLE – RANDOMIZATION_TYPE – TREATMENT_ARM_TITLE	Filtered data.

Unblinded Clinical Supplies Return
Use case: review kits being returned to depots.
Insights:

- Identify any issues with the supply management and resupply strategy that might be causing high volume of returned kits.

Visualizations:

Title	Description	Interactivity
KPI: *Total Sites Count*	Key Performance Indicator of total sites for selected studies. • **Type:** Tile chart. • **Count:** Total sites.	Filtered data.
KPI: *Subjects Count*	Key Performance Indicator of total subjects. • **Type:** Tile chart. • **Count:** Total subjects.	Filtered data.
KPI: *Total Kits Count*	Key Performance Indicator of total kits at selected studies and sites. • **Type:** Tile chart. • **Count:** Total kits.	Filtered data.

Title	Description	Interactivity
Total Kits by Kit Status	Represent kits and their statuses for all studies and sites. • **Type:** Vertical stacked bar chart. • **X-Axis:** Kit statuses. • **Y-Axis:** Total kits count. Different colors represent different site statuses.	This chart can be used as a filter.
Site Status Details	Lists kits unblinded details, including returned units, for every study, country and site. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – SUBJECT_NUMBER – EVENT_TITLE – KIT_NUMBER – KIT_STATUS – CONSERVED – MANFACTURING_LOT_TITLE – QUANTITY – UNITS_PER_KIT – RETURNED_UNITS – MISSING_UNITS – Balance Units.	Filtered data.

Unblinded Site and Depot Kit Status
Use case: review total number of kits in a site or depot along with their statuses.
Insights:

- Adapt supply management to actual site and depot inventory.

Visualizations:

Title	Description	Interactivity
KPI: *Total Inventory*	Key Performance Indicator of total inevntory for selected studies and sites. • **Type:** Tile chart. • **Count:** Total kits.	Filtered data.

Title	Description	Interactivity
KPI: *Kits Available*	Key Performance Indicator of total kits with available status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Available	Filtered data.
KPI: *Kits Returned*	Key Performance Indicator of total kits with returned status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Returned	Filtered data.
Kits Status by Site	Represent kits and their statuses for all studies and sites. • **Type:** Vertical bar chart. • **X-Axis:** SITE_NAME. • **Y-Axis:** Total kits count. Different colors represent different kit statuses: – Total Inventory – Kits Available – Kits Returned	This chart can be used as a filter.
Unblinded Site and Depot Kit Status	Lists kits unblinded details,for every site and depot. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – SITE_ID_NAME – SITE_NAME – Location Type – SUBJECT_NUMBER – RAND_NUMBER – TREATMENT_ARM_TITLE – KIT_NUMBER – KIT_TYPE_ID – KIT_DESCRIPTION – KIT_STATUS – Dispensation Date	Filtered data.

Unblinded Depot Inentory
Use case: analyze key performance indicators on depot inventory.
Insights:

- Adapt supply distribution based on depot's inventory.

Visualizations:

Title	Description	Interactivity
KPI: *Total Inventory*	Key Performance Indicator of total kits count. • **Type:** Tile chart. • **Count:** Total kits.	Filtered data.
KPI: *Kits Available*	Key Performance Indicator of total kits with available status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Available	Filtered data.
KPI: *Kits Received for Destruction*	Key Performance Indicator of total kits with received for destruction status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Received for destruction	Filtered data.
KPI: *Kits Missing*	Key Performance Indicator of total kits with missing status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Missing	Filtered data.
KPI: *Kits Pending for Destruction*	Key Performance Indicator of total kits with pending for destruction status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Pending for Destruction	Filtered data.
KPI: *Kits Returned*	Key Performance Indicator of total kits with returned status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Returned	Filtered data.

Title	Description	Interactivity
KPI: *Kits Not Dispensed to Subject*	Key Performance Indicator of total kits with not dispensed to subject status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Not Dispensed to Subject	Filtered data.
KPI: *Kits Temporarily Unavaiable*	Key Performance Indicator of total kits with temporarily unavailable status. • **Type:** Tile chart. • **Count:** Total kits with KIT_STATUS= – Temporarily Unavailable	Filtered data.
Unblinded Depot Inventory by Label Batch	Represents total inventory by manufacturing lot for selected studies and sites. • **Type:** Horizontal bara chart. • **X-Axis:** Total inventory. • **Y-Axis:** MANFACTURING_LOT_TITLE	This chart can be used as a filter.

Title	Description	Interactivity
Unblinded Depot Inventory Details	Lists inventory details and kits count by status for every depot. • **Type:** Listing table. • **Columns:** – STUDY_TITLE – COUNTRY_NAME – Depot ID – Depot Name – MANFACTURING_LOT_TITLE – MANFACTURING_LOT_EXPIRATION_DATE – KIT_TYPE_ID – KIT_DESCRIPTION – DEVICE_TYPE – Total Inventory – Kits Available – Kits Received for Destruction – Kits Missing – Kits Pending for Destruction – Kits Returned – Kits Not Dispensed to Subject – Kits Temporarily Unavailable	Filtered data.

Subject Data Analysis dashboard

The Subject Data Analysis dashboard offers you insights on a subject's journey through the different stages of a study by showcasing data related to demographics, events, adverse events, concomitant medications, as well as lab, and vitals data.

About access and filters

To properly view corresponding data in the Subject Data Analysis dashboard, you must have access to the Subject Form Items dataset. For more information see Permissions to access Oracle Clinical One Analytics datasets.

A dashboard is interactive so it displays any study data that you already have access to. To select what information to display you can use the following filters:

- IS_CURRENT (by default, this filter is set to Y)
- STUDY_MODE (by default, this filter is set to active)
- STUDY_TITLE
- COUNTRY_NAME

- SITE_NAME
- SUBJECT_NUMBER
- Date range

> **Tip:**
>
> Analyze data from your studies one by one. If multiple studies or sites are used in a dashboard filter there is a possibility that data doesn't appear in the different visualizations due to their default sizes.

You can use a chart as a filter, too. Click the Filter icon ( ) to the left of the visualization title. Click on any element of the chart with filter interactivity to filter out the remaining visualizations according to the selected data. To reverse the selection on the chart, click on any white space within the chart or use the Undo button ( ) in the upper right corner of the browser window.

> **Note:**
>
> If the selected filters point to data not present on another chart, it displays a message that states *No Data Found* .

Reports

The Subject Data Analysis Dashboard includes the following reports:

- Individual Subject Data
- AE (Adverse Event) & CM (Concomitant Medication) Data
- Lab Data

> **Note:**
>
> Data elements used in the visualizations are listed here with data element notation, upper cases with words separated by underscores. In contrast, custom calculation elements are listed using title case. These notations match with what you see in the dashboard template.

Individual Subject Data
Use cases

- A CRA who is interested in the data and finding the data in a study without difficulty.
- A physician who is overseeing the clinical study and wants to see whether the united individual subject information gets to another level.

Insights

- Get a centralized synopsis and particulars of an individual subject at a study and site level.
- Identify key data such as ethnicity, age, gender as part of a subject's demography.

- Review the visit schedule to help you monitor the progress of subjects in a clinical study or at a site.
- Review medical history, record, and physical examination parameters that are very important to relate a subject's condition to faster medical conclusions.
- Get access crucial information for sound decision making, such as a subject's vital signs.

Visualizations

Title	Description	Interactivity
Study Information (Listing Table)	• **Type**: Table chart • **Columns**: – STUDY_TITLE – STUDY_PHASE – THERAPEUTIC_AREA – BLINDING_TYPE – STUDY_VERSION	Filtered data.
Site Information (Listing Table)	• **Type**: Table chart • **Columns**: – SITE_ID_NAME – SITE_NAME – SITE_STATUS – SITE_STUDY_VERSION – SDV_GROUP_NAME – ADDRESS_COUNTRY – ADDRESS_CITY – TIMEZONE	Filtered data.
Subject Details (Listing Table)	• **Type**: Table chart • **Columns**: – SUBJECT_NUMBER – STATE – Total Visits – Completed Visits – Total Forms – Completed Forms	Filtered data.
Subject Information (Listing Table)	• **Type**: Table chart • **Columns**: – SUBJECT_NUMBER – Gender – Race – Date of Birth – Age – Date of Informed Consent	Filtered data.

Title	Description	Interactivity
Visit Schedule (Listing Table)	• **Type**: Timeline chart • **X-axis**: VISIT_START_DATE • **Y-axis**: EVENT_TITLE	Filtered data.
Medical History (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – Item Label – Value	Filtered data.
Medical History Records (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – # (serial number) – Condition – Ongoing? – Start date – Resolved date	Filtered data.
Physical Examination (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – # (serial number) – Body system – Evaluation	Filtered data.
Vital Sign Detailed Report (Listing Table)	• **Type**: Table chart • **Columns**: – SITE_NAME – Visit Seq. – Visit Name – Weight – Pulse – Respiratory rate – Temperature – Unit – Systolic – Diastolic	Filtered data.
Vital Signs	• **Type**: Line chart • **X-axis:** EVENT_TITLE. • **Y-axis:** Vital signs. All represented with a different color.	Filtered data.

AE (Adverse Event) & CM (Concomitant Medication) Data Use cases

- Physicians, medical reviewers, data monitors, and biostatisticians are engaged in analyzing safety data from clinical studies. They typically want to speed up the analysis of a subject's medical narrative when they experience a serious adverse event and they're on medication during the clinical study.

Insights

- Identify if a subject has experienced an adverse event, its seriousness, and the duration of that event, as well as any other relevant details.
- Identify whether a subject is on any concomitant medication and for how long they've been on a specific medication.
- Cross-checking data related to a subject's adverse events, their occurences and the prescribed medication. This helps identify the efficacy of the investigational product.

Visualizations

Title	Description	Interactivity
Adverse Events (Listing Table)	• **Type**: Table chart • **Columns**: – # (serial number) – Adverse Event – Severity – Start date – Ongoing? – End date – Any related medication? – Serious – Outcome – PT – SOC	Filtered data.
Prior and Concomitant Medications (Listing Table)	• **Type**: Table chart • **Columns**: – # (serial number) – Start date – Stop date – Route – Ongoing? – Medication name – Indication – Frequency – Form – Dose – Dose unit – ATC 1 – ATC 4	Filtered data.
Adverse Events	• **Type**: Scatter chart • **Y-axis:** Event Term, AE# • **X-axis:** AE Days	Filtered data.

Title	Description	Interactivity
Prior and Concomitant Medications	• **Type**: Scatter chart • **Y-axis**: Medication Name, CM# • **X-axis**: CM Days	Filtered data.

Lab Data

Use cases

- Physicians, medical reviewers, and data monitors need to identify a subject's medical conditions and monitor the progression and efficacy of a treatment. This custom report can help us diagnose, monitor, screen, and research a subject's medical condition.

Insights

- Identify signs or parameters of a subject's biochemistry, hematology, cardiac biomarkers, and more.
- Track the efficacy or progression of a subject's treatment.

Visualizations

Title	Description	Interactivity
Cardiac Biomarkers (Central Labs) (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – # (serial number) – Lab Test – Lab Result – Lab Unit – High Range – Low Range	Filtered data.
Biochemistry (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – # (serial number) – Lab Test – Lab Result – Lab Unit – High Range – Low Range	Filtered data.
Hematology (Listing Table)	• **Type**: Table chart • **Columns**: – Visit Seq. – Visit Name – # (serial number) – Lab Test – Lab Result – Lab Unit – High Range – Low Range	Filtered data.

Title	Description	Interactivity
Cardiac Biomarkers (Central Labs)	• **Type**: Stacked category chart • **X-axis:** EVENT_TITLE with different columns for each lab test number and name. • **Y-axis:** High Range, Low Range, Lab Result represented with different colors.	Filtered data.
Biochemistry	• **Type**: Stacked category chart • **X-axis:** EVENT_TITLE with different columns for each lab test number and name. • **Y-axis:** High Range, Low Range, Lab Result represented with different colors.	Filtered data.
Hematology	• **Type**: Stacked category chart • **X-axis:** EVENT_TITLE with different columns for each lab test number and name. • **Y-axis:** High Range, Low Range, Lab Result represented with different colors.	Filtered data.

- Required configuration for the Subject Data Analysis dashboard
  The Subject Data Analysis dashboard is closely related to the design of a study. This means that special configurations are needed in a form's design for some visualizations to work properly. These configurations include specific form names (`FORM_NAME`) and question names (`ITEM_NAME`).

Required configuration for the Subject Data Analysis dashboard

The Subject Data Analysis dashboard is closely related to the design of a study. This means that special configurations are needed in a form's design for some visualizations to work properly. These configurations include specific form names (`FORM_NAME`) and question names (`ITEM_NAME`).

Most of the visualizations in the Subject Data Analysis dashboard use custom calculations to specify which form and question is used to get data to display. For this reason, your form names, questions, and even code list values must match with the specified values in the dashboard template's custom calculations.

Review the list of requirements and make sure your study design complies with all of them. In case your study design doesn't meet a requirement, you can either update your study design to match the given configuration or modify the custom calculations used in the dashboard to match your study design. If you choose to modify the dashboard's custom calculations, keep in

mind that all impacted custom calculations must be updated, and updates can only be made on a modifiable copy of the Subject Data Analysis dashboard template. For more details, see Create a modifiable copy of a template.

> **Note:**
>
> Updating the custom calculations requires a basic understanding of programming. Reach out to your study manager for further assistance.

Required configurations for the Subject Data Analysis dashboard

> **Tip:**
>
> If your study doesn't use a question listed in this table, there is no need for you to modify anything. The impacted visualizations will still be part of the dashboard and show a *No Data Found* message, which you can simple ignore. If you prefer, you can also delete the given visualization from your copy to get rid of the empty spaces.

Individual Subject Data

You can customize some visualizations in the Individual Subject Data report, so that you don't have to modify your study's design. The tables in this section describe how to modify custom calculations for the following visualizations:

- Subject Information (Listing Table)
- Medical History Records (Listing Table)
- Physical Examination (Listing Table)
- Vital Signs Detailed Report (Listing Table)
- Vital Signs

Table 4-7 Subject Information (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be `'Demographics'`.	The form used in your study to collect demographic data must be called **`Demographics`**. **Note:** This form must contain all of the questions l	• Gender • Race • Date of Birth • Age • Date of Informed Consent	*Update to match with your current form name when it is not named as "Demographics".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME like 'Demographics'` 3. Replace `'Demographics'` with your current form name. • Keep the single quotes.

Table 4-7 (Cont.) Subject Information (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		i s t e d i n t h i s t a b l e .	
`ITEM_NAME` must contain the word `'Gender'`.	The form question used to collect data related to gender must have the word `'Gender'` in its name.	• Gender	*Update to match with your current question related to gender, when it doesn't contain the keyword "Gender".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Gender%'` 3. Replace `'%Gender%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-7 (Cont.) Subject Information (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Race'`.	The form question used to collect data related to race must have the word `'Race'` in its name.	• Race	*Update to match with your current question related to race, when it doesn't contain the keyword "Race".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Race%'` 3. Replace `'%Race%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-7 (Cont.) Subject Information (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Date of Birth'` or `'Age'`.	The form question used to collect data related to a subject's age or date of birth must have the words `'Date of Birth'` or `'Age'` in their names.	• Age • Date of Birth	*Update to match with your current questions related to age or the date of birth, when the questions don't contain the words "Date of Birth" or "Age".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Date of Birth%', or ITEM_NAME LIKE '%Age%' or ITEM_NAME LIKE '%Age_%'` 3. Replace `'%Date of Birth%'`, `'%Age%'`, or `'%Age_%'` with any keyword from your current questions. • Keep the single quotes and percentage signs (%).

Table 4-7 (Cont.) Subject Information (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Date of Informed Consent'`.	The form question used to collect data related to a subject's age or date of birth must have the words `'Date of Informed Consent'` in their names.	• Date of Informed Consent	*Update to match with your current question related to the date of the informed consent, when the question doesn't contain the words "Date of Informed Consent".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Date of Informed Consent%'` 3. Replace `'%Date of Informed Consent%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-8 Medical History Records (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be `'Medical History Records'`.	The form used in your study to collect data on a subject's medical history must be called **`Medical History Records`**.	• Condition • Ongoing? • Start Date • Resolved Date	*Update to match with your current form name when it is not named as "Medical History Records".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME like 'Medical History Records'` 3. Replace `'Medical History Records'` with your current form name. • Keep the single quotes.

Note: This form must contain all of the questionsl

Table 4-8 (Cont.) Medical History Records (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		`isstedinthistable.`	
`ITEM_NAME` must contain the string `'Condition'`.	The form question used to collect data on a subject's condition must contain the word `'Condition'`.	• Condition	*Update to match with your current question related to a subject's condition when the question doesn't contain the word "Condition".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Condition%'` 3. Replace `'%Condition%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-8 (Cont.) Medical History Records (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Ongoing'`.	The form question used to determine whether a subject's condition is ongoing or not must contain the word `'Ongoing?'`.	• Ongoing?	*Update to match with your current question related to a subject's condition when the question doesn't contain the word "Ongoing".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Ongoing%'` 3. Replace `'%Ongoing%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-8 (Cont.) Medical History Records (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Start Date'`.	The form question used to determine the start date of a subject's condition must contain the words `'Start Date'`.	• Start Date	*Update to match with your current question related to a subject's condition when the question doesn't contain the words "Start Date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Start Date%'` 3. Replace `'%Start Date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-8 (Cont.) Medical History Records (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Resolved Date'`.	The form question used to determine the day a subject's condition is resolved must contain the words `'Resolved Date'`.	• Resolved Date	*Update to match with your current question related to a subject's condition when the question doesn't contain the words "Resolved Date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Resolved Date%'` 3. Replace `'%Resolved Date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-9 Physical Examination (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must contain the word `'Physical Examination'`.	The form used in your study to collect data on a subject's physical exam must be called **`Physical Examination`**. **Note:** This form must contain all of the questions	• Body system • Evaluation	*Update to match with your current form name when it is not named as "Physical Examination".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `FORM_NAME LIKE 'Physical Examination' or CASE WHEN FORM_NAME = 'Physical Examination'` 3. Replace `'Physical Examination'` with any keyword from your current question. • Keep the single quotes.

Table 4-9 (Cont.) Physical Examination (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		listed in this table.	
`ITEM_NAME` must contain the string `'Body System'`.	The form question used to determine the examined body system of a subject must contain the words `'Body System'`.	• Body System	*Update to match with your current question related to a subject's analyzed body system when the question doesn't contain the words "Body System".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Body system%'` 3. Replace `'%Body system%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-9 (Cont.) Physical Examination (Listing Table)

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Evaluation'`.	The form question used to determine the type of evaluation of a subject must contain the word `'Evaluation'`.	• Evaluation	*Update to match with your current question related to a subject's analyzed body system when the question doesn't contain thr words "Evaluation".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Evaluation%'` 3. Replace `'%Evaluation%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be `'Vital Signs'`.	The form used in your study to collect data on a subject's vital signs must be called **`Vital Signs`**. **Note:** This form must contain all of the questions listi	• Weight • Pulse • Respiratory rate • Temperature • Unit • Systolic • Diastolic	*Update to match with your current form name when it doesn't contain the "Vital Signs"' string as part of it.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME LIKE 'Vital Signs' or CASE WHEN FORM_NAME = 'Vital Signs'` 3. Replace `'Vital Signs'` with any keyword from your current question. • Keep the single quotes.

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		stedinthistable.	
`ITEM_NAME` must contain the string `'Weight'`.	The form question used to determine a subject's weight must contain the word `'Weight'`.	• Weight	*Update to match with your current question related to a subject's weight when the question doesn't contain the word "Weight".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Weight%'` 3. Replace `'%Weight%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Pulse'`.	The form question used to determine a subject's pulse rate must contain the word `'Pulse'`.	• Pulse	*Update to match with your current question related to a subject's pulse rate when the question doesn't contain the word "Pulse".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Pulse%'` 3. Replace `'%Pulse%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Respiratory rate'`.	The form question used to determine a subject's respiratory rate must contain the words `'Respiratory rate'`.	• Respiratory rate	*Update to match with your current question related to a subject's respiratory rate when the question doesn't contain the words "Respiratory rate".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Respiratory rate%'` 3. Replace `'%Respiratory rate%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Temperature'`.	The form question used to determine a subject's temperature must contain the word `'Temperature'`.	• Temperature	*Update to match with your current question related to a subject's body temperature when the question doesn't contain the words "Temperature".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Temperature%'` 3. Replace `'%Temperature%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Unit'`.	The form question used to determine the unit of measurement of a subject's vital signs must contain the word `'Unit'`.	• Unit	*Update to match with your current question related to a subject's vital signs unit when the question doesn't contain the words "Unit".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Unit%'` 3. Replace `'%Unit%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Systolic'`.	The form question used to determine a subject's systolic blood pressure must contain the word `'Systolic'`.	• Systolic	*Update to match with your current question related to a subject's systolic blood pressure when the question doesn't contain the words "Systolic".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Systolic%'` 3. Replace `'%Systolic%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-10 (Cont.) Vital Signs Detailed Report (Listing Table) and Vital Signs

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Diastolic'`.	The form question used to determine a subject's diastolic blood pressure must contain the word `'Diastolic'`.	• Diastolic	*Update to match with your current question related to a subject's diastolic blood pressure when the question doesn't contain the words "Diastolic".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Diastolic%'` 3. Replace `'%Diastolic%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

AE (Adverse Event) and CM (Concomitant Medication) Data

You can customize some visualizations in the AE & CM Data report, so that you don't have to modify your study's design. The tables in this section describe how to modify custom calculations for the following visualizations:

- Adverse Events (Listing Table)
- Prior and Concomitant Medication (Listing Table)
- Adverse Events
- Prior and Concomitant Medication

Table 4-11 Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be `'Adverse Event'`.	The form used in your study to collect adverse events data must be called **`Adverse Event`**.	• Adverse Event • Severity • Start date • Ongoing? • End date • Any related medication? • Serious • Outcome • PT • SOC **Note:** This form must contain all of the questions li	*Update to match with your current form name when it is not named as "Adverse Event".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME like 'Adverse Event'` 3. Replace `'Adverse Event'` with your current form name. • Keep the single quotes.

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		stedinthistable.	
`ITEM_NAME` must contain the word `'Adverse Event'`.	The form question used to collect data on a subject's adverse event must contain the words `'Adverse Event'`.	• Adverse Event	*Update to match with your current question related to a subject's adverse event when the question doesn't contain the words "Adverse Event".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Adverse Event%'` 3. Replace `'%Adverse Event%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Severity'`.	The form question used to collect data on the severity of an adverse event must contain the words `'Severity'`.	• Severity	*Update to match with your current question related to the severity of an adverse event when the question doesn't contain the word "Severity".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Severity%'` 3. Replace `'%Severity%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Start date'`.	The form question used to collect data on the start date of an adverse event must contain the words `'Start date'`.	• Start Date	*Update to match with your current question related to the start date of an adverse event when the question doesn't contain the words "Start date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Start date%'` 3. Replace `'%Start date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Ongoing'`.	The form question used to collect data on whether an adverse event is ongoing or not must contain the words `'Ongoing?'`.	• Ongoing?	*Update to match with your current question related to whether an adverse event is ongoing or not even when the question doesn't contain the word "Ongoing".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Ongoing%'` 3. Replace `'%Ongoing%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'End Date'`.	The form question used to collect data on the end date of an adverse event must contain the words `'End Date'`.	• End date	*Update to match with your current question related to the end date of an adverse event when the question doesn't contain the words "End date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%End date%'` 3. Replace `'%End date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'Any related medication?'`.	The form question used to collect data on any related medication to an adverse event must contain the string `'Any related medication?'`.	• Any related medication?	*Update to match with your current question related to any medication being related to an adverse event when the question doesn't contain the string "Any related medication?".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Any related medication?%'` 3. Replace `'%Any related medication?%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Serious'`.	The form question used to collect data on the seriousness of an adverse event must contain the word `'Serious'`.	• Serious	*Update to match with your current question related to the seriousness of an adverse event when the question doesn't contain the string "Serious".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Serious%'` 3. Replace `'%Serious%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Outcome'`.	The form question used to collect data on the outcome of an adverse event must contain the word `'Outcome'`.	• Outcome	*Update to match with your current question related to outcome of an adverse event when the question doesn't contain the word "Outcome".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Outcome%'` 3. Replace `'%Outcome%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'PT'`.	The form question used to collect data on the PT must contain the acronym `'PT'`.	• PT	*Update to match with your current question related to physical therapy when the question doesn't contain the acronym"PT".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%PT%'` 3. Replace `'%PT%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-11 (Cont.) Adverse Events (Listing Table) and Adverse Events

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'SOC'`.	The form question used to collect data on the SOC must contain the acronym `'SOC'`.	• SOC	*Update to match with your current question related to the standard of care when the question doesn't contain the acronym"SOC".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%SOC%'` 3. Replace `'%SOC%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be `'Prior and Concomitant Medication'`.	The form used in your study to collect data on prior and concomitant medication for a subject must be called **`Prior and Concomitant Medication`**. **Note:** This form must contain all of the requestio	• Medication name • Start date • Stop date • Route • Ongoing? • Indication • Frequency • Form • Dose or unit • ATC 1 • ATC 4	*Update to match with your current form name when it is not named as "Prior and Concomitant Medication".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME like 'Prior and Concomitant Medication'` 3. Replace `'Prior and Concomitant Medication'` with your current form name. • Keep the single quotes.

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		nslistedinthistable.	

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Medication name'`.	The form question used to collect data on the name of a subject's medication must contain the words `'Medication name'`.	• Medication name	*Update to match with your current question related to the name of a subject's medication when the question doesn't contain the string "Medication name".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `AND LOWER(ITEM_NAME) LIKE '%medication name%'` 3. Replace `'%medication name%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Start date'`.	The form question used to collect data on the start date of a subject's administered medication must contain the words `'Start date'`.	• Start date • CM Day	*Update to match with your current question related to the start date of a subject's administered medication when the question doesn't contain the string "Start date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Start date%'` 3. Replace `'%Start date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Stop date'`.	The form question used to collect data on the stop date of a subject's administered medication must contain the words `'Stop date'`.	• Stop date	*Update to match with your current question related to the stop date of a subject's administered medication when the question doesn't contain the string "Stop date".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Stop date%'` 3. Replace `'%Stop date%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Route'`.	The form question used to collect data on route of administration of a medication must contain the word `'Route'`.	• Route	*Update to match with your current question related to the route of administration of a medication when the question doesn't contain the string "Route".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Route%'` 3. Replace `'%Route%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Ongoing?'`.	The form question used to collect data on whether the administration of a certain medication is ongoing or not must contain the word `'Ongoing?'`.	• Ongoing?	*Update to match with your current question related to whether the administration of a medication is ongoing or not when the question doesn't contain the string "Ongoing?".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Ongoing?%'` 3. Replace `'%Ongoing?%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Indication'`.	The form question used to collect data on the indication of a medication must contain the word `'Indication'`.	• Indication	*Update to match with your current question related to the indication of a medication when the question doesn't contain the string "Indication".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Indication%'` 3. Replace `'%Indication%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Frequency'`.	The form question used to collect data on a subject's frequency for taking medication must contain the word `'Frequency'`.	• Frequency	*Update to match with your current question related to a subject's frequency for taking medication when the question doesn't contain the string "Frequency".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Frequency%'` 3. Replace `'%Frequency%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Form'`.	The form question used to collect data on a subject's frequency for taking medication must contain the word `'Form'`.	• Form	*Update to match with your current question related to a form when the question doesn't contain the word"Form".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Form%'` 3. Replace `'%Form%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the word `'Dose'` or `'Dose unit'`.	The form question used to collect data on the dosage of a medication must contain the words `'Dose'` or `'Dose unit'`.	• Dose • Dose unit	*Update to match with your current question related to the dosage of a medication when the question doesn't contain the string "Dose" or 'Dose unit'.* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Dose%' or '%Dose unit%'` 3. Replace `'%Dose%' or '%Dose unit%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'ATC1'`.	The form question used to collect data on a subject's frequency for taking medication must contain the word `'ATC1'`.	• ATC1	*Update to match with your current question when the question doesn't contain the acronym"ATC1".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%ATC1%'` 3. Replace `'%ATC1%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-12 (Cont.) Prior and Concomitant Medication (Listing Table) and Prior and Concomitant Medication

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the string `'ATC4'`.	The form question used to collect data on a subject's frequency for taking medication must contain the word `'ATC4'`.	• ATC4	*Update to match with your current question when the question doesn't contain the acronym"ATC4".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%ATC4%'` 3. Replace `'%ATC4%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Lab Data

You can customize some visualizations in the Lab Data report, so that you don't have to modify your study's design. The table in this section describe how to modify custom calculations for the following visualizations:

- Cardiac Biomarkers (Central Labs) (Listing Table)
- Biochemistry (Listing Table)
- Hematology (Listing Table)
- Cardiac Biomarkers (Central Labs)
- Biochemistry
- Hematology

Table 4-13 Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`FORM_NAME` must be: • **`'Cardiac Biomarkers (Central Labs)'`** • **`Biochemistry`** • **`Hematology`**	The form used in your study to collect lab data must be called either: • **`'Cardiac Biomarkers (Central Labs)'`** • **`Biochemistry`** • **`Hematology`**	• Medication name • Start date • Stop date • Route • Ongoing? • Indication • Frequency • Form • Dose or unit • ATC 1 • ATC 4 **Note:** This form must contain all of the requestio	*Update to match with your current form name when it is not named as "Cardiac Biomarkers (Central Labs), "Biochemistry", or "Hematology".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `FORM_NAME`: `FORM_NAME like 'Cardiac Biomarkers (Central Labs)', 'Biochemistry', 'Hematology'` 3. Replace any of the form title instances mentioned in the code block above with your current form name. • Keep the single quotes.

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
		nslistedinthistable.	

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Lab Test'`.	The form question used to collect data on a subject's lab test must contain the words `'Lab Test'`.	• Lab Test	*Update to match with your current question related to a subject's lab test when the question doesn't contain the string "Lab Test".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Lab Test%'` 3. Replace `'%Lab Test%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Lab Result'`.	The form question used to collect data on a subject's lab results must contain the words `'Lab Result'`.	• Lab Result	*Update to match with your current question related to a subject's lab results when the question doesn't contain the string "Lab Result".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Lab Result%'` 3. Replace `'%Lab Result%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Lab Unit'`.	The form question used to collect data on the unit of measurement for a lab test must contain the word `'Lab Unit'`.	• Lab Unit	*Update to match with your current question related to a subject's lab unit when the question doesn't contain the string "Lab Unit".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Lab Unit%'` 3. Replace `'%Lab Unit%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'High Range'`.	The form question used to collect data on a lab test's high range value must contain the words `'High Range'`.	• High Range	*Update to match with your current question related to a lab test's high range value when the question doesn't contain the string "High Range".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%High Range%'` 3. Replace `'%High Range%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

Table 4-13 (Cont.) Lab data

Configuration requirement	Description	Impacted custom calculations	How to update the custom calculation
`ITEM_NAME` must contain the words `'Low Range'`.	The form question used to collect data on a lab test's low range value must contain the words `'Low Range'`.	• Low Range	*Update to match with your current question related to a lab test's low range value when the question doesn't contain the string "Low Range".* 1. On the data panel on the left, right-click the calculation under the *My Calculations* folder, and select **Edit Calculation...**. 2. In the Edit Calculation dialog, locate the line referring to `ITEM_NAME`: `ITEM_NAME LIKE '%Low Range%'` 3. Replace `'%Low Range%'` with any keyword from your current question. • Keep the single quotes and percentage signs (%).

5

Use cases

- A CRA creates a custom report on subject statuses
  A Clinical Research Associate (CRA) creates a custom report to view and export data related to subject statuses across studies.
- A data manager creates a custom report with visualizations
  A data manager creates a custom report, with data visualizations, to view a comparison of how many open queries exist at each site, the number of open queries in each form, as well as a custom table that offers additional data.

A CRA creates a custom report on subject statuses

A Clinical Research Associate (CRA) creates a custom report to view and export data related to subject statuses across studies.

Subject Status Export

Let's go through the required steps to create a custom tabular report with data related to subject statuses within a study in Oracle Clinical One Platform. The purpose of this custom report is to collect detailed and current data related to the statuses subjects have in a study.

To create this or any other report, you must have authoring access to Oracle Clinical One Analytics. See About your access to Oracle Clinical One Analytics.

1. Select a dataset to work with.
   For the purpose of this use case, select the **Subject dataset**.
2. From the Data Elements pane, expand the following folders and then drag and drop the following elements at the top of the canvas, to use them as filters for your custom report.

Folder to expand	Data element to use	Additional instructions
Study	**STUDY_ID_NAME**	In the filter dialog, select the studies you want to use to filter out the data on subject statuses from Oracle Clinical One Platform
Site	**SITE_ID_NAME**	Drag the data element onto the empty canvas.
Subject	**SUBJECT_NUMBER**	In the filter dialog, select the subject numbers you want to use to filter out the data.
Audit	**IS_CURRENT**	In the filter dialog, select **Y** if you want to only include currently opened queries or **N**, if you want to include all opened queries to ever be raised at in a study.

3. From the Data Elements pane, continue dragging and dropping the following data elements onto the **Rows** section in the Grammar Panel.

Folder to expand	Data element to use	Additional instructions
Study	• **STUDY_ID_NAME** • **STUDY_PHASE** • **THERAPEUTIC_AREA**	N/A
Site	• **ADDRESS_COUNTRY** • **SITE_ID_NAME**	N/A
Subject	• **SUBJECT_NUMBER** • **STATE** • **STATE_DATE**	N/A

4. In the upper right corner, click the **Share** icon and then click **File**.
5. On the File dialog, fill-in the following fields, and click **Save**:

Field	Description
Name	Enter a name for your custom report. For the purpose of this exercise, enter **Subject Status Export**.
Format	Choose the appropriate format for exporting this custom report. For the purpose of this exercise, because this custom report contains graphics, you can select either **CSV** or **Acrobat (PDF)**.
Include	Choose either **Active Canvas** or **All Canvas**.
Size	Choose the appropriate format size for your report.
Orientation	Choose either **Landscape** or **Portrait**.

A data manager creates a custom report with visualizations

A data manager creates a custom report, with data visualizations, to view a comparison of how many open queries exist at each site, the number of open queries in each form, as well as a custom table that offers additional data.

Open Queries report

Let's go through the required steps to create a custom report with visualizations on how many open queries exist by each site, in a study in Oracle Clinical One Platform. The purpose of this chart is to allow data reviewers to determine where to focus their efforts in closing open queries.

To create this or any other report, you must have authoring access to Oracle Clinical One Analytics. See About your access to Oracle Clinical One Analytics.

1. Select a dataset to work with.
   For the purpose of this use case, select the **Queries dataset**.
2. From the Data Elements pane, expand the the following folders and then drag and drop the following elements at the top of the canvas, to use them as filters for your custom report.

Folder to expand	Data element to use	Additional instructions
Study	**STUDY_ID_NAME**	In the filter dialog, select the study you want to use to filter out the data on queries from Oracle Clinical One Platform
Audit	**IS_CURRENT**	In the filter dialog, select **Y** if you want to only include currently opened queries or **N**, if you want to include all opened queries to ever be raised at in a study.
Query	**STATE**	In the filter dialog, select the **Opened** status.
Site	**SITE_ID_NAME**	Drag the data element onto the empty canvas.
Reference	**COUNT**	Drag the data element onto the **Values (X-Axis)** section in the Grammar Panel.

3. On the Grammar Panel, click the first row, and select the **Horizontal Bar** visualization.
4. On the right, select the **Visualizations** pane.
5. Select the **Horizontal Bar** visualization and drag it onto the canvas, next to the other visualization you just created.
6. Go back to the Data Elements pane and drag and drop the following data elements:

Folder to expand	Data element to use	Additional instructions
Form	**FORM_NAME**	Drag and drop the data element onto the empty box.
Reference	**COUNT**	Drag and drop the data element onto the **Values (X-Axis)** section in the Grammar Panel.

7. On the right, select the **Visualizations** again.
8. Select the **Table** visualization and drag it onto the bottom of the canvas, under the two horizontal stack visualizations you just created.

Folder to expand	Data element to use	Additional instructions
Site	**SITE_ID_NAME**	Drag and drop the data element onto the empty tabel.
Subject	• **SUBJECT_NUMBER**	Drag and drop the data element onto the **Rows** section, in the Grammar Panel.
Form	**FORM_NAME**	Drag and drop the data element onto the **Rows** section, in the Grammar Panel.
Query	• **HAS_QUERY** • **QUERY_COMMENT** • **QUERY_AGE**	Drag and drop the data elements onto the **Rows** section, in the Grammar Panel.
Item	• **ITEM_NAME** • **VALUE**	Drag and drop the data elements onto the **Rows** section, in the Grammar Panel.

9. In the top-right corner, click **Save**.

10. At the bottom of the right pane, select the **General** category, and customize the title as **Open Queries by Site**.
11. Select the **Labels Axis** category, click **Title**, select **Custom**, and enter user-friendly names for the axes included in your visualizations.
12. In the upper right corner, click the **Share** icon and then click **File**.
13. On the File dialog, fill-in the following fields, and click **Save**:

Field	Description
Name	Enter a name for your custom report. For the purpose of this exercise, enter **Open Queries report**.
Format	Choose the appropriate format for exporting this custom report. For the purpose of this exercise, because this custom report contains graphics, you can select either **Powerpoint (PPTX)**, **Acrobat (PDF)**, or **Image (PNG)**.
Include	Choose either **Active Canvas** or **All Canvas**.
Size	Choose the appropriate format size for your report.
Orientation	Choose either **Landscape** or **Portrait**.

Related Topics

- Add data to the visualization using Grammar Panel
- Create calculated data elements
  Create calculated data elements to use in your visualizations in fields that take only measure data.
- Sort data in visualizations
- Undo and redo edits
- Change visualization types
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters

6
Revision history

Date	Part number	Description
18-March-2025	G16753-04	Made the following updates: • Updated the following topics for the Electronic Health Record (EHR) data import: – Blinded Subject Events dataset – Queries dataset – Study Design dataset – Subject dataset – Subject Forms dataset – Subject Form Items dataset – Unblinded Subject Events dataset • Updated the Subject dataset with information related to undoing subject events. • Included a new topic for the new DH_Metrics dataset. For more information, see the Dataset descriptions.
28-February-2025	G16753-03	The following updates were applied to this version. 1. Updates were applied to complete the information about the permissions required for dashboard study roles. See the following: • Data Manager dashboard • Clinical Research Associate dashboard 2. Revised the permissions link to reflect the latest information. See the following: • Audit trail dashboard • Diversity & Inclusion dashboard • Subject Data Analysis dashboard • RTSM dashboard

Date	Part number	Description
21-February-2025	G16753-02	The following updates were applied to this version. 1. Corrected information that was mistakenly included for blinded randomization numbers in datasets. See the following: • Randomization folder in the Blinded Kits dataset • Kit folder in the Blinded Subject Events dataset • Kit folder in the Unblinded Subject Events dataset • Randomization folder in the Unblinded Kits dataset 2. The guide now includes a comment about the impact on DMW when forms contain more than 200 questions. For more information, see DMW 3.4.
17-January-2025	G16753-01	Original version of the document.

A

Form item output mapping in data extracts

As clinical data is extracted from Oracle Clinical One Platform to use in Oracle Clinical One Analytics and other downstream applications, form items get represented in four different columns: Raw, Formatted, Decode and the item itself.

> **Note:**
>
> There is a record created for every change applied in Oracle Clinical One Platform. Each record displays the value at the time of the change.

Raw: [*ItemReferenceCode*]_R
Alphanumeric value as entered in Oracle Clinical One Platform with no conversions. This includes data entry flags.

Formatted: [*ItemReferenceCode*]_F
Value as entered in Oracle Clinical One Platform converted to the question data type as per form design.

Decode: [*ItemReferenceCode*]_D
Decoded raw value, with additional considerations according to data type. If the question has a code value, it is populated in this field.

Item: [*ItemReferenceCode*]
Conatins either the formatted or decode value, depending on data type.

Table A-1 Column output according to data type

Data type	[*ItemReferenceCode*]_R	[*ItemReferenceCode*]_F	[*ItemReferenceCode*]_D	[*ItemReferenceCode*]
Text	Value as entered.	Value as entered.	`NULL`	Raw value: value as entered.
Number	Value as entered, excluding units if present.	Value as entered, excluding units if present.	Units if present, otherwise `NULL`.	Formatted value.
Date	Value as entered in alphanumeric format (no date format). • All available elements display, including unknown values. • Elements enetered as unknown display as `UNK`.	Complete date or date time using the format from form design in Oracle Clinical One Platform. • Only available elements display. • `UNK` time elements are omitted. • `NULL` for partial dates and time only items.	ISO 8601 date format, managing partial and full datetime value: *YYYY-MM-DD T HH: MM: SS* • Only available elements display. • `UNK` date and time elements are omitted.	Raw value: value as entered including unknown elements.

Table A-1 (Cont.) Column output according to data type

Data type	[*ItemReferenceCode*]_R	[*ItemReferenceCode*]_F	[*ItemReferenceCode*]_D	[*ItemReferenceCode*]
Codelist	Codelist label. ***Note**: For multi select questions, includes a pipe "|" separated list. For example "Asian|White".*	Codelist value. ***Note**: For multi select questions, includes a pipe "|" separated list. For example "A|W".*	Codelist code. ***Note**: For multi select questions, includes a pipe "|" separated list. For example "1|2".*	Decode value: Codelist code.
Data Entry flag	• *NA* for Not Applicable • *ND* for Not Done • *UNK* for Unknown • *Not Answered* for when the question is not answered	`NULL`	• *C48660* for Not Applicable • *C49484* for Not Done • *C17998* for Unknown • *-99999* for when the question is not answered	Decode value.

B

Data Management Workbench (DMW) extract data dictionary

Browse field descriptions of the DMW extract data by DMW version.

- DMW 3.4
  Browse field descriptions of the DMW 3.4 extract data by table.

DMW 3.4

Browse field descriptions of the DMW 3.4 extract data by table.

Clinical data extract common columns

The columns described in this section are common to all clinical data extract tables.

> **Note:**
>
> Forms created with more than two hundred (200) questions can impact the generation of DMW extract tables, resulting in a failure to integrate Oracle Clinical One Analytics datasets with DMW.

Column name	Data type	Description
TENANT	VARCHAR2(64 CHAR)	Tenant name
TENANT_ID	RAW(16 BYTE)	GUID tenant ID
TENANT_WID	NUMBER(38)	Numeric tenant ID
STUDY	VARCHAR2(64 CHAR)	Study name
STUDY_ID	RAW(16 BYTE)	GUID study ID
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_VERSION	VARCHAR2(32 CHAR)	The study version of a given record
COUNTRY	VARCHAR2(100 CHAR)	Site address country
COUNTRY_ID	RAW(16 BYTE)	GUID country ID
COUNTRY_WID	NUMBER(38)	Numeric country ID
INVESTIGATOR	VARCHAR2(100 CHAR)	Investigator associated with the given record
INVESTIGATOR_ID	RAW(16 BYTE)	GUID investigator ID
INVESTIGATOR_WID	NUMBER(38)	Numeric investigator ID
SITE	VARCHAR2(200 CHAR)	Site name

Column name	Data type	Description
SITE_ID	RAW(16 BYTE)	GUID site ID
SITE_WID	NUMBER(38)	Numeric site ID
VISIT	VARCHAR2(64 CHAR)	Visit (Event) Refname as defined in Oracle Clinical One Platform **Note:** This differs from Visit Title and Visit ID.
VISIT_ID	RAW(16 BYTE)	GUID visit ID
VISIT_WID	NUMBER(38)	Numeric visit ID
VISIT_DATE	DATE	Date on which the visit occurred
EVENT_INSTANCE_NUMBER	NUMBER	Event instance number for the visit
FORM	VARCHAR2(64 CHAR)	Form Refname as defined in Oracle Clinical One Platform
FORM_ID	RAW(16 BYTE)	GUID form ID
FORM_WID	NUMBER(38)	Numeric form ID
FORM_SECTION_ID	RAW(16 BYTE)	GUID form section ID
FORM_SECTION_WID	NUMBER(38)	Numeric form section ID
REPEAT_SEQUENCE_NUMBER	NUMBER	Usage dependent on form type: • **One-section repeating form type:** Numeric value to represent the Form Instance for Repeating Forms. • **Lab and two-section form types:** Sequential number to represent the Table (Repeating Section) row the Extract data pertains to.
UNSCHEDULED	NUMBER	Flag indicating if the visit where the form was collected was an unscheduled one
SUBJECT	VARCHAR2(500 CHAR)	Subject name
SUBJECT_ID	RAW(16 BYTE)	GUID subject ID
SUBJECT_WID	NUMBER(38)	Numeric subject ID
ENTERED_BY	VARCHAR2(255 CHAR)	User that created the record
ENTERED_ID	RAW(16 BYTE)	GUID user ID who entered the record
ENTERED_WID	NUMBER(38)	Numeric user ID who entered the record
ENTERED_DATE	TIMESTAMP(6)	Date of record entry

Column name	Data type	Description
LASTCHANGED_BY ***Note**: Changes made outside the form instance, such as updating a visit date or subject number, do not result in an update to LASTCHANGED_BY, LASTCHANGED_ID, LASTCHANGED_WID, and LASTCHANGED_DATE. This is because these elements provide information about changes made at the form level. The visit date and subject number are not associated with any form or visit. Such changes are tracked under the DH_TIMESTAMP, ensuring they get integrated with DMW.*	VARCHAR2(255 CHAR)	User that updated the record
LASTCHANGED_ID	RAW(16 BYTE)	GUID user ID who last updated the record
LASTCHANGED_WID	NUMBER(38)	Numeric user ID who last updated the record
LASTCHANGED_DATE	TIMESTAMP(6)	Indicates the date when a form instance changes, such as when a user updates clinical data or deletes a form or a form section.
DELETED	VARCHAR2(1)	Boolean value that indicates whether a record was deleted
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
VISIT_SEQ	NUMBER	Sequential number of a visit for a subject
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
REPEAT_FORM_NUMBER	NUMBER	**For two-section Forms:** Numeric value to represent the form instance

Note:

For **lab forms** this value is defaulted to 1 and for **repeating forms** this value is `NULL`.

Column name	Data type	Description
INNER_REPEAT	NUMBER	**For Lab and two-Section Form Designs:** Sequential number to represent the table (repeating section) row the extract data pertains to
OUTER_REPEAT	NUMBER	**For Repeating Forms (including one-section and two-section forms):** Sequential number to represent the form instance
NONREPEATING	VARCHAR2(1)	Column usage dependent on Form Type: • **For a given row in two-section Form Type:** – **Value = Y:** Indicates the given row is populated for only flat section data. All table (repeating section) columns remain blank. – **Value = N:** Indicates the given row is populated with both flat section data and data for a corresponding table (repeating section) row • **For 1 Section Form Type, for a given row:** – **Value = Y:** Indicates the Form in question is not a repeating form. – **Value = N:** Indicates the form in question is a repeating form.
ROW_ID	RAW(16 BYTE)	GUID generated in DataHub to uniquely identify a row in the Data Extract table
<ItemName>	VARCHAR2(4000 CHAR)	Item value collected in the form (1 column per item) **Note:** See column mapping details in Form item output mapping in data extracts.
<ItemName_R>	VARCHAR2(4000 CHAR)	Raw value of the item collected (1 column per item) **Note:** See column mapping details in Form item output mapping in data extracts.
<ItemName_F>	VARCHAR2(4000 CHAR)	Formatted value of the item collected (1 column per item) **Note:** See column mapping details in Form item output mapping in data extracts.

Column name	Data type	Description
<ItemName_D>	VARCHAR2(4000 CHAR)	Decoded value of the item collected (1 column per item)

> **Note:**
>
> See column mapping details in Form item output mapping in data extracts.

Table: DHVW_CODELISTS_V

Column name	Data type	Description
CODELIST_WID	NUMBER(38)	Numeric codelist ID
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_NAME	VARCHAR2(64 CHAR)	Study name
USER_WID	NUMBER(38)	Numeric user ID
USER_NAME	VARCHAR2(255 CHAR)	User name
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
CODELIST_ID	RAW(16 BYTE)	GUID of the codelist
VERSION_START	TIMESTAMP(6)	Timestamp of when the record was previously changed
VERSION_END	TIMESTAMP(6)	Timestamp of when the record was changed
OPERATION_TYPE	VARCHAR2(16 CHAR)	Type of operation: • CREATE • MODIFY • DELETE
USER_ID	RAW(16 BYTE)	GUID of the user
STUDY_ID	RAW(16 BYTE)	GUID of the study
REFNAME	VARCHAR2(64 CHAR)	System reference name of a codelist
TITLE	VARCHAR2(64 CHAR)	Codelist title
DESCRIPTION	VARCHAR2(4000 CHAR)	Codelist description
CODELIST_TYPE	VARCHAR2(16 CHAR)	Codelist type
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
OBJECT_VERSION_NUMBER	NUMBER	Version number of the codelist
STUDY_VERSION	VARCHAR2(32)	The study version of a given record
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change

Table: DHVW_CODELIST_ITEMS_V

Column name	Data type	Description
CODELISTITEM_WID	NUMBER(38)	Numeric codelist item ID
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_NAME	VARCHAR2(64 CHAR)	Study name
USER_WID	NUMBER(38)	Numeric user ID
USER_NAME	VARCHAR2(255 CHAR)	User name
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
CODELISTITEM_ID	RAW(16 BYTE)	GUID of the codelist item
VERSION_START	TIMESTAMP(6)	Timestamp of when the record was previously changed
VERSION_END	TIMESTAMP(6)	Timestamp of when the record was changed
OPERATION_TYPE	VARCHAR2(16 CHAR)	Type of operation: • CREATE • MODIFY • DELETE
USER_ID	RAW(16 BYTE)	GUID of the User
STUDY_ID	RAW(16 BYTE)	GUID of the study
CODELIST_ID	RAW(16 BYTE)	GUID of the codelist
CODELIST_WID	NUMBER(38)	Numeric codelist ID
CODELIST_NAME	VARCHAR2(64 CHAR)	Refname of the codelist
REFNAME	VARCHAR2(64 CHAR)	System reference name of a codelist
TITLE	VARCHAR2(64 CHAR)	Codelist title
DESCRIPTION	VARCHAR2(4000 CHAR)	Codelist description
ITEM_SEQ	NUMBER	Sequence of the item within the codelist
VALUEREF_ID	RAW(16 BYTE)	Reference ID of the String resource record (nls)
CODELIST_TYPE	VARCHAR2(16 CHAR)	Codelist type **Note:** Only STRING for now
CODE	VARCHAR2(64 CHAR)	Code value corresponding to the codelist item
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
OBJECT_VERSION_NUMBER	NUMBER	Version number of the codelist
STUDY_VERSION	VARCHAR2(32 CHAR)	The study version of a given record
REASON	VARCHAR2(255 CHAR)	User provided reason for record change

Column name	Data type	Description
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change
CL_CODE	VARCHAR2(255 CHAR)	The code corresponding to the codelist item.
CL_VALUE	VARCHAR2(32767 CHAR)	The value (for example, Plasma) associated to the CL_CODE.

Table: DHVW_DESIGN_DATASET_V

Column name	Data type	Description
MODIFIED_BY_ID	RAW(16 BYTE)	Numeric ID of the user who modified the design.
MODIFIED_BY_WID	NUMBER(38)	The unique numeric identifier of the user who modified the study.
CURRENT_STUDY_ROLE_ID	RAW(16 BYTE)	The ID associated with the study role assigned to the user who updated the given record. If the user study role changes, this field will show the current study role ID of the given user.
CURRENT_STUDY_ROLE_WID	NUMBER(38)	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.
CURRENT_STUDY_ROLE_NAME	VARCHAR2(100 CHAR)	Specifies the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.
STUDY_DESIGN_STATUS	VARCHAR2(16 CHAR)	Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active.
EVENT_ID	RAW(16 BYTE)	GUID of the event.
EVENT_WID	NUMBER(38)	A number that represents the unique identifier of an event.
EVENT_TITLE	VARCHAR2(64 CHAR)	The event's title, defined by the user when an event is created.

Column name	Data type	Description
EVENT_REFNAME	VARCHAR2(64 CHAR)	The events refname. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface.
EVENT_ID_NAME	VARCHAR2(16 CHAR)	The event's id as in Oracle Clinical One Platform.
VISIT_IS_REQUIRED	CHAR(1)	Indicates whether or not a visit is required.
VISIT_TYPE	VARCHAR2(32 CHAR)	Displays the type of visit: Screening, Randomization, Dispensation, Non-Dispensation, Optional, Withdrawal or Study Completion.
EVENT_TYPE	VARCHAR2(32)	Displays the type of event (visit started, visit completed).

Note:

This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version.

Column name	Data type	Description
IS_SCHEDULED_VISIT	CHAR(1)	Indicates whether the visit is scheduled or not.

Column name	Data type	Description
SCHEDULED_FROM_EVENT_NAME	VARCHAR2(64 CHAR)	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule.

Note:

If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening

Column name	Data type	Description
		Visit, as it is the first visit in the schedule.

Column name	Data type	Description
SCHEDULED_FROM_EVENT_REFNAME	VARCHAR2(64 CHAR)	Displays the EVENT_REFNAME of the Scheduled From Visit as defined in the Visit Schedule.

Note:

If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own refname. For example, SCREENING VISIT is displayed for the

Column name	Data type	Description
		Screening Visit, as it is the first visit in the schedule.
SCHEDULED_FROM_EVENT_ID	RAW(16 BYTE)	GUID of the event from which the given visit is scheduled from.
SCHEDULED_FROM_EVENT_WID	NUMBER	Numeric ID of the event from which the given visit is scheduled from
VISIT_WINDOW_AFTER_DAYS	NUMBER	Indicates how many days after the scheduled date and time the visit can occur.
VISIT_WINDOW_AFTER_HOURS	NUMBER	Indicates how many hours after the scheduled date and time the visit can occur.
VISIT_WINDOW_BEFORE_DAYS	NUMBER	Indicates how many days before the scheduled date and time the visit can occur, as entered by a study designer.
VISIT_WINDOW_BEFORE_HOURS	NUMBER	Indicates how many hours before the scheduled date and time the visit can occur, as entered by a study designer.
DELAY_DAYS	NUMBER	The number of days between the prior scheduled visit.
DELAY_HOURS	NUMBER	The number of hours between the prior scheduled visit (in addition to the DELAY_DAYS field).
VISIT_HOUR_SEQ_ORDER	NUMBER	The order in which subject visits occur, as configured in the study design.
VISIT_CREATION_ORDER	NUMBER	Numeric visit order that follows the visit schedule as it was created.
BRANCH_WID	NUMBER(38)	Indicates the unique numeric identifier of the branch.
BRANCH_TITLE	VARCHAR2(64 CHAR)	Indicates the branch title or name.
BRANCH_REFNAME	VARCHAR2(64 CHAR)	Indicates the REFNAME of the branch title or name.

Column name	Data type	Description
BRANCH_ID	RAW(16 BYTE)	A branch's ID as specified by a study designer.
IS_CYCLE_BRANCH	CHAR(1)	States whether the branch is cycled or not.
CYCLE_COUNT	NUMBER	Specifies the number of cycles in case the branch is cycled.
ASSIGN_SUBJECT_USING_TREATMENT_ARM	CHAR(1)	Indicates if subjects are assigned to the branch by Treatment arm.
ASSIGN_SUBJECT_USING_FORM_QUESTION	CHAR(1)	Indicates if subjects get assigned to branch by a form question.
BRANCH_ARM	VARCHAR2(32767 CHAR)	Specifies which treatment arm(s) correspond to the current branch, in case subjects are assigned to the branch by treatment arm.
BRANCH_FORM	VARCHAR2(64 CHAR)	Specifies which form contains the question used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_QUESTION	VARCHAR2(4000 CHAR)	Specifies which question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_ANSWER	VARCHAR2(4000 CHAR)	Specifies which exact answer to the selected question is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
BRANCH_VISIT	VARCHAR2(64 CHAR)	Specifies the visit containing the selected form and question that is used to assign subjects to the current branch, in case subjects are assigned to the branch by form question.
FORM_ID	RAW(16 BYTE)	GUID of the form.
FORM_WID	NUMBER	A number that represents the unique identifier of a form.
FORM_NAME	VARCHAR2(64 CHAR)	The name of the form, as specified by the study designer.
FORM_REFNAME	VARCHAR2(64 CHAR)	A form's reference name.
FORM_TYPE	VARCHAR2(14 CHAR)	Indicates the type of form: • One-section form • Two-section form • Lab form
FORM_IS_REPEATING	CHAR(1)	Indicates whether the form is repeating or not.
ALLOW_ADDITIONAL_ROWS	CHAR(1)	Indicates if this is a repeating form that allows additional rows.
SOURCE_DATAVIEW_WID	NUMBER	If it is a copied form, indicates the numeric identifier of the form it was copied from.

Column name	Data type	Description
SOURCE_DATAVIEW_NAME	VARCHAR2(64 CHAR)	If it is a copied form, indicates the original form it was copied from.
SOURCE_STUDY_WID	NUMBER	If it is a copied form, indicates the numeric identifier of the study it was copied from.
SOURCE_STUDY_NAME	VARCHAR2(64 CHAR)	If it is a copied form, indicates the name of the study it was copied from.
SOURCE_STUDY_VERSION	VARCHAR2(32 CHAR)	If it is a copied form, indicates the study version of the study it was copied from.
SOURCE_VERSION_START	TIMESTAMP(6)	If it is a copied form, indicates the date and time of when the copied data was entered.
RULE_COPY_STATUS	NUMBER	If it is a copied form, indicates the status of the source form rules copy.
ITEM_ID	RAW(16 BYTE)	GUID of the item.
ITEM_WID	NUMBER(38)	A number that represents the unique identifier of an item.
ITEM_NAME	VARCHAR2(4000 CHAR)	Indicates the title of the question, as entered by a study designer.
MEASURE_UNIT	VARCHAR2(64 CHAR)	Indicates the measure of unit specified by a study designer for a Number type of question.
QUESTION_TYPE	VARCHAR2(32 CHAR)	Indicates the type of question as defined by a study designer.
QUESTION_HINT	VARCHAR2(4000 CHAR)	Indicates information that a study designer provided as a hint to help answer a question.
FORMITEM_IS_REQUIRED	CHAR(1)	Indicates whether the question is required or not. Required questions must be answered in order to save the form that contains it.
READONLY	CHAR(1)	Indicates that the question is marked as read-only by a study designer.
SAS_VARIABLE	VARCHAR2(32 CHAR)	Indicates the SAS Variable of a form defined by a study designer.
SAS_LABEL	VARCHAR2(4000CHAR)	Indicates the SAS Label of a form defined by a study designer.
REFERENCE_CODE	VARCHAR2(64 CHAR)	Indicates a question's reference code.
ITEM_GROUP_ID	NUMBER(64 CHAR)	If this is a group question, indicates the group question ID.
ITEM_GROUP	VARCHAR2(64 CHAR)	If this is a group question, indicates the group question title.
GROUP_TYPE	VARCHAR2(32 CHAR)	Indicates if this is a group question.

Column name	Data type	Description
HIDDEN	CHAR(1)	Indicates whether a question is hidden or not, as marked by a study designer
VALIDATION_RULES	VARCHAR2(32767)	Specifies the question's validation rule if any. Validation rules types available depend on the type of question: • Text questions: – *Doesn't contain* • Date/Time and Date of Birth questions: – *After* – *On or After* – *Before* – *On or Before* – *On* – *Not On* – *Not Between* – *Range* • Number and Age questions: – *Greater Than* – *Greater Than or Equal To* – *Less Than* – *Less Than or Equal To* – *Is* – *Not Equal To* – *Not Between* – *Range* • Drop-down and check box questions – *Select at Least* – *Select at Most* – *Select Exactly* – *Answer Must Be* • Radio Button questions – *Answer Must Be*
RULE_ERROR	VARCHAR2(32767)	Reason for failure if validation status is failed or the rule validation failed
ACTION_RULES	VARCHAR2(32767 CHAR)	Details the action rule of a question which can be of the types: • *Show Question* • *Show Form* • *Show Visit* • *Link & Show Form*
CODE_QUESTION	VARCHAR2(32767 CHAR)	If the question has a Coding Question property, lists the following information: • *Dictionary* • *Coding Item Type* • *Tag for Central Coding*

Column name	Data type	Description
SDV	VARCHAR2(12 CHAR)	Specifies if the question has any SDV parameter and if it is of the type SDV for All Subjects or Critical Variables (Targeted SDV).
FORM_IS_ROLLOVER	CHAR(1)	Indicates whether the form is rollover or not.
FORMAT	VARCHAR2(40 CHAR)	Specifies the answer format. For example an specific date format, or the number of decimals after the point
ITEM_DATE_PARTIAL_REQUIRED	VARCHAR2(32 CHAR)	The partial date format allowed for the item. If a partial date is not allowed this value will be null.
ITEM_VALUES	VARCHAR2(32767)	The raw value of the form question value (can be an array in questions with decodes)
CODELIST_VALUES	VARCHAR2(32767)	Lists the codelist values added as answers to the current question.
VERSION_START	TIMESTAMP(6)	Indicates the date and time of when the data was changed.
VERSION_END	TIMESTAMP(6)	Indicates the date and time of when data was changed, if the data is not current.
DH_TIMESTAMP	TIMESTAMP(6)	A time stamp that indicates when the data became available in the dataset.
MODIFIED_BY	VARCHAR2(255 CHAR)	The user who last modify the study.
STUDY_ID	RAW(16 BYTE)	User entered ID of the study.
STUDY_WID	NUMBER(38)	A number that represents the unique identifier of the study.
STUDY_ID_NAME	VARCHAR2(64 CHAR)	A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number.
STUDY_TITLE	VARCHAR2(4000 CHAR)	A protocol's title as specified by the study manager.
STUDY_REFNAME	VARCHAR2(64 CHAR)	The STUDY_ID_NAME data element that is converted to uppercase and spaces are removed. This value never changes after created even if STUDY_ID_NAME changes.
THERAPEUTIC_AREA	VARCHAR2(64 CHAR)	Indicates the therapeutic area as specified by the study manager when they created the study.
STUDY_PHASE	VARCHAR2(64 CHAR)	A study's phase as indicated by the study manager when they created the study.

Column name	Data type	Description
BLINDING_TYPE	VARCHAR2(64 CHAR)	Indicates whether the study is an open-label type of study or a blinded study, as specified by the study manager when they created the study.
STUDY_VERSION	VARCHAR2(32 CHAR)	Indicates the study version number of the referencing data in a custom report.

Table: DHVW_FORMS_ASSOCIATIONS_V

Column name	Data type	Description
ID	RAW(16 BYTE)	Clinical One GUID for the form association.
FORMS_ASSOCIATION_WID	NUMBER(38)	Uniquely identifies a form association in DHTBD
VERSION_START	TIMESTAMP(6)	Indicates the date and time of when the data was changed.
VERSION_END	TIMESTAMP(6)	Indicates the date and time of when data was changed, if the data is not current.
OPERATION_TYPE	VARCHAR2(16 CHAR)	Audit trail field that represents the type of operation performed (for example, create or modify).
USER_ID	RAW(16 BYTE)	GUID of the user
USER_WID	NUMBER(38)	Indicates a user's numeric identifier.
USER_NAME	VARCHAR2(255 CHAR)	Audit trail field that represents the user who performed the action. The value for this column may represent a user's actual username or a user's email address, depending on how the user login was defined in Oracle Life Sciences IAMS.
OBJECT_VERSION_NUMBER	NUMBER	Audit trail field that represents the version number of the data.
SOFTWARE_VERSION_NUMBER	NUMBER	A number that represents an incremental increase every time a data point is modified.
REASON	VARCHAR2(255 CHAR)	Indicates a reason for changes in a subject's data. Populated by drop-down list.
COMMENT	VARCHAR2(2048 CHAR)	Required comment in a reason for change if ‘Other’ is selected. Populated as Rule Execution for calculated values.
STUDY_ID	RAW(16 BYTE)	User entered study ID.
STUDY_WID	NUMBER(38)	A number that represents the unique identifier of the study.
STUDY_NAME	VARCHAR2(64 CHAR)	Study name

Column name	Data type	Description
SUBJECT_ID	RAW(16 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Indicates a subject's numeric identifier.
SUBJECT_NUMBER	VARCHAR2(500 CHAR)	The number currently assigned to the subject in the system as identifier.
SITE_ID	RAW(16 BYTE)	User entered Site number/ID
SITE_WID	NUMBER(38)	A number that represents the unique identifier of a site.
SITE_NAME	VARCHAR2(200 CHAR)	Indicates the site's name as entered by a site manager when they created or last modified a site.
SRC_EVENT_ID	RAW(16 BYTE)	Source form event ID
SRC_EVENT_WID	NUMBER(38)	Source unique event Id assigned in DH to uniquely identify the event in DH
SRC_EVENT_NAME	VARCHAR2(64 CHAR)	Source form event name
SRC_EVENT_INSTANCE_NUM	NUMBER	Source form instance number - applies to unscheduled/repeating visits
SRC_FORM_ID	RAW(16 BYTE)	Source form ID
SRC_FORM_WID	NUMBER(38)	Source unique form Id assigned in DH to uniquely identify in DH
SRC_FORM_NAME	VARCHAR2(64 CHAR)	Source for name
SRC_REPEAT_SEQUENCE_NUMBER	NUMBER	Source repeat sequence number for repeating forms. Refers to the row instance number of all applicable form types with repeating data: • **Two-section forms:** unique numeric identifier of the row in the repeating section. • **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results. • **Repeating forms:** indicates the repeating form number.
SRC_STUDY_VERSION	VARCHAR2(100 CHAR)	Source study version
ASSOCIATED_EVENT_ID	RAW(16 BYTE)	The event ID for an associated event.
ASSOCIATED_EVENT_WID	NUMBER(38)	A number that represents the unique identifier of the event to which the form is assigned when a form association is present.
ASSOCIATED_EVENT_NAME	VARCHAR2(64 CHAR)	The name of the associated event.

Column name	Data type	Description
ASSOCIATED_EVENT_INSTANCE_NUM	NUMBER	The unique identifier for an associated event. **Note:** If the visit is not UnScheduleAbleVisit, this field will not be populated with any value.
ASSOCIATED_FORM_ID	RAW(16 BYTE)	The form ID that represents the associated form.
ASSOCIATED_FORM_WID	NUMBER(38)	A number that represents the unique identifier of the associated form, if present.
ASSOCIATED_FORM_NAME	VARCHAR2(64 CHAR)	The name of the associated form.
ASSOCIATED_REPEAT_SEQUENCE_NUM	NUMBER	When association is with a repeating form, indicates the associated sequence number.
ASSOCIATED_STUDY_VERSION	VARCHAR2(100 CHAR)	Indicates the study version of the associated form.
SRC_ITEM_ID	RAW(16 BYTE)	Source form item ID
SRC_ITEM_WID	NUMBER(38)	Source unique form item ID assigned in DH to uniquely identify in DH
SRC_ITEM_NAME	VARCHAR2(4000 CHAR)	Source form item name
SRC_FORM_SECTION_ID	RAW(16 BYTE)	Source form section ID
ASSOCIATED_FORM_SECTION_ID	RAW(16 BYTE)	The section ID of the associated form.

Column name	Data type	Description
SRC_REPEAT_FORM_NUM	NUMBER	Source repeat form number Refers to the form instance number of all applicable form types with repeating data: • **Two-section forms:** indicates the form instance number. • **Lab forms:** defaults to a value of 1. • **Repeating forms:** this value is null.
ASSOCIATED_REPEAT_FORM_NUM	NUMBER	When association is with a repeating form, indicates the associated repeating form number.
DH_TIMESTAMP	TIMESTAMP(6)	A time stamp that indicates when the data became available in the dataset.
IS_CURRENT	CHAR(1)	Audit trail field to display either current status or full audit trail of the data.
SRC_FORM_REFNAME	VARCHAR2(64 CHAR)	Source form refname
ASSOCIATED_FORM_REFNAME	VARCHAR2(64 CHAR)	Indicates the reference code of the associated form.
SRC_FORM_TYPE	NUMBER	Indicates the source form type, such as a two-section or lab form.
ASSOCIATED_FORM_TYPE	NUMBER	Indicates the form type of the associated form.
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.

Table: DHVW_QUERY_V

Column name	Data type	Description
QUERY_WID	NUMBER(38)	Numeric query ID
QUERY_ID	RAW(32 BYTE)	GUID of the query
VERSION_START	TIMESTAMP(6)	Version start
VERSION_END	TIMESTAMP(6)	Version end
OPERATION_TYPE	VARCHAR2(16 CHAR)	Type of operation: • CREATE • MODIFY • DELETE
USER_ID	RAW(32 BYTE)	GUID of the user
USER_WID	NUMBER(38)	Numeric user ID
USER_NAME	VARCHAR2(255 CHAR)	Oracle Clinical One Platform user name
OBJECT_VERSION_NUMBER	NUMBER	Change version number for the record

Column name	Data type	Description
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
STATE	NUMBER	The state of a given query row: • Answered • Closed • Deleted • Opened • Candidate
SUBJECT_ID	RAW(32 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Numeric subject ID
SUBJECT_NUMBER	VARCHAR2(500 CHAR)	Subject number
DATA_ELEMENT_ID	RAW(16 BYTE)	GUID of the data element
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(20 CHAR)	Comment for record change
QUERY_COMMENT	VARCHAR2(2048 CHAR)	Query comment provided by user for change
RULE_ID	RAW(32 BYTE)	GUID of the rule
FORM_ID	RAW(32 BYTE)	GUID of the form
FORM_WID	NUMBER(38)	Numeric form ID
FORM_NAME	VARCHAR2(64 CHAR)	Form name
EVENT_ID	RAW(32 BYTE)	GUID of the event
EVENT_WID	NUMBER(38)	Numeric event ID
EVENT_NAME	VARCHAR2(64 CHAR)	Name of the event for the current record
DATA_ELEMENT_VERSION_START	TIMESTAMP(6)	Timestamp of a given item's start date
EVENT_INSTANCE_NUMBER	NUMBER	Event instance number of the visit where the form with the query is collected
FORM_INSTANCE_NUMBER	NUMBER	Form repeat instance of the form where the query is present
ITEM_ID	RAW(32 BYTE)	GUID of the item
ITEM_WID	NUMBER(38)	Numeric item ID
ITEM_NAME	VARCHAR2(4000 CHAR)	Name of an item
SITE_ID	RAW(32 BYTE)	GUID of the site
SITE_WID	NUMBER(38)	Numeric site ID
SITE_NAME	VARCHAR2(200 CHAR)	Name of a site
STUDY_ID	RAW(16 BYTE)	GUID of the study
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_NAME	VARCHAR2(100 CHAR)	Study name
BRANCH_ID	RAW(32 BYTE)	GUID of the visit branch where the form with the query is collected
STUDY_ROLE_ID	RAW(32 BYTE)	GUID of the study role

Column name	Data type	Description
CREATOR_STUDY_ROLE_ID	RAW(32 BYTE)	GUID of the study role who created the query
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
DATA_ELEMENT_WID	NUMBER(38)	Numeric Data Element ID
STUDY_ROLE_WID	NUMBER(38)	Numeric ID of a study role
STUDY_ROLE_NAME	VARCHAR2(100 CHAR)	Name of a study role
CREATOR_STUDY_ROLE_WID	NUMBER(38)	Numeric ID of the study role who created the query
CREATOR_STUDY_ROLE_NAME	VARCHAR2(100 CHAR)	Name of the study role who created the query
DISCREPANCY_ID	NUMBER(38)	GUID of the query in DMW
IS_CURRENT	CHAR(1)	Boolean flag stating whether or not the record has an associated query
HAS_QUERY	CHAR(1)	Boolean flag stating whether a given record is the most recent version
HIDDEN	NUMBER(1)	Numeric value to represent whether the item is hidden or not
REPEAT_FORM_NUMBER	NUMBER	Numeric value to represent the instance number of a two-section form
IS_AUTO_QUERY	VARCHAR2(1 CHAR)	Indicates whether this is an automated query.
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
QUERY_TYPE	VARCHAR2(16 CHAR)	Indicates the query type.

Table: DHVW_RAND_KITS_DESIGN_DATASET_V

Column name	Data type	Description
STUDY_ID	RAW(16 BYTE)	Numeric ID value for study
STUDY_WID	NUMBER(38)	GUID of the study
STUDY_ID_NAME	VARCHAR2(64 CHAR)	Study ID name
STUDY_TITLE	VARCHAR2(4000 CHAR)	Title of the study
STUDY_REFNAME	VARCHAR2(64 CHAR)	Study ref name
THERAPEUTIC_AREA	VARCHAR2(64 CHAR)	Therapeutic area of the study
STUDY_PHASE	VARCHAR2(64 CHAR)	Phase of the study
BLINDING_TYPE	VARCHAR2(64 CHAR)	Blinding type of the study: • Blinded • Unblinded
STUDY_VERSION	VARCHAR2(32 CHAR)	Version of the study
MODIFIED_BY_ID	RAW(16 BYTE)	Numeric ID of the user name

Column name	Data type	Description
MODIFIED_BY_WID	NUMBER(38)	GUID of the username
MODIFIED_BY	VARCHAR2(255 CHAR)	Name of the user
STUDY_DESIGN_STATUS	VARCHAR2(16 CHAR)	Status of the study version
VERSION_START	TIMESTAMP(6)	Version start value of the study version
VERSION_END	TIMESTAMP(6)	Version end value of the study version
RAND_WID	NUMBER	GUID of the randomization
RAND_ID	RAW(16 BYTE)	Numeric ID for randomization
RANDOMIZATION_TITLE	VARCHAR2(64 CHAR)	Randomization title
RANDOMIZATION_DESCRIPTION	VARCHAR2(4000 CHAR)	Description of the randomization
RANDOMIZATION_TYPE	VARCHAR2(32 CHAR)	Type of randomization
COHORTTYPE	VARCHAR2(32 CHAR)	Type of cohorts
RERANDOMIZATION	NUMBER	Specifies if the study allows re-randomization
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
ARM_WID	NUMBER	Numeric ID of the treatment arm
ARM_ID	RAW(16 BYTE)	GUID of the treatment arm
TREATMENT_ARM_TITLE	VARCHAR2(64 CHAR)	Treatment arm title
TREATMENT_ARM_DESCRIPTION	VARCHAR2(4000 CHAR)	Treatment arm description
TREATMENT_ARM_ID	VARCHAR2(64 CHAR)	Unique numeric ID of the treatment arm
RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES	NUMBER	Specifies if randomization needs to restrict to available kit types
ASSIGNED_SKIPPED_RANDOMIZATION_NUMBERS	NUMBER	Specifies if the skipped randomization number has to be assigned
RANDOMIZATION_VERSION_START	TIMESTAMP(6)	Randomization version start date in study design
RANDOMIZATION_VERSION_END	TIMESTAMP(6)	Randomization version end date in study design
COHORT_ID	VARCHAR2(32767)	GUID of the cohort
COHORT_WID	VARCHAR2(32767)	Numeric ID of the cohort
COHORT_NAME	VARCHAR2(32767 CHAR)	Cohort name
VISIT_IS_REQUIRED	CHAR(1)	Specifies if the visit is mandatory
IS_SCHEDULED_VISIT	CHAR(1)	Specifies if the visit is scheduled or unscheduled

Column name	Data type	Description
SCHEDULED_FROM_EVENT_NAME	VARCHAR2(64 CHAR)	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. **Note:** If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule.
STUDYEVENT_ID	RAW(16 BYTE)	GUID of the visit in study design
STUDYEVENT_WID	NUMBER(38)	Numeric ID of the visit in study design
VISIT_TYPE	VARCHAR2(32 CHAR)	Visit type categorization: • ADVERSE_EVENT • DISPENSATION • NON_DISPENSATION • OPTIONAL • RANDOMIZATION • SCREENING • SUBJECT_COMPLETE • UNSCHEDULED • WITHDRAW
EVENT_TYPE	VARCHAR2(32)	Event type categorization: • Visit_Complete • Visit_Started • Visit_Date_Changed
DELAY_DAYS	NUMBER	Visit delay days
DELAY_HOURS	NUMBER	Visit delay hours
VISIT_WINDOW_BEFORE_DAYS	NUMBER	Number of days before the expected visit date when the visit could start
VISIT_WINDOW_BEFORE_HOURS	NUMBER	Number of hours before the expected visit date when the visit could start
VISIT_WINDOW_AFTER_DAYS	NUMBER	Number of days after the expected visit date when the visit could start
VISIT_WINDOW_AFTER_HOURS	NUMBER	Number of hours after the expected visit date when the visit could start
EVENT_TITLE	VARCHAR2(64 CHAR)	The event's title, defined by the user when an event is created.

Column name	Data type	Description
EVENT_REFNAME	VARCHAR2(64 CHAR)	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. **Note:** This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version.
EVENT_ID_NAME	VARCHAR2(16 CHAR)	Event/Visit ID name
VISIT_HOUR_SEQ_ORDER	NUMBER	Sequence of the visit based on schedule (number of hours)
KIT_WID	NUMBER(38)	GUID of the kit at study design
KIT_ID	RAW(16 BYTE)	Numeric ID of the kit at study design
DEVICE_TYPE	VARCHAR2(255)	Device type kit: • D2C • C2C
DEVICE_CONNECTION	VARCHAR2(255)	Whether the device is connected or non connected
CALCULATING_DOSES	NUMBER	Do kit has calculation does
DISTRIBUTION_SETTINGS	VARCHAR2(16 CHAR)	Indicates the type of distribution a kit has, as specified by the study designer. The following values can be displayed: • **Blinded:** if blinded users should never see the kit type description. • **Unblinded:** if blinded users should always see the kit type description. • **Unblinded Pharmacist:** if blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types.
KIT_TYPE_ID	VARCHAR2(64 CHAR)	Kit type ID at study design
TYPE	VARCHAR2(16 CHAR)	Type of the kit at study design
MINIMUM_KITS_TO_SHIP	NUMBER	Numeric value that represents the minimum kits to be shipped
UNITS_PER_KIT	NUMBER	Number of units in a kit
SINGLE_UNIT_DOSE_VALUE	NUMBER(20,2)	Dose value of single unit in a kit
SINGLE_UNIT_DOSE_UNITS	VARCHAR2(16 CHAR)	Dose unit of the kit
TITRATION	NUMBER	Specifies if the kit is a titration kit
KIT_VERSION_START	TIMESTAMP(6)	Version start of the kit at study design

Column name	Data type	Description
KIT_VERSION_END	TIMESTAMP(6)	Version end of the kit at study design
KIT_TYPE	VARCHAR2(23)	Type of the kit
CALCULATED_DOSE_TITLE	VARCHAR2(64 CHAR)	Calculation dose name of the kit
FORM_QUESTION_FOR_CALCULATED_DOSE	VARCHAR2(64 CHAR)	Question used for dosage calculation
VISIT_WHERE_FORM_IS_COLLECTED	VARCHAR2(64 CHAR)	Visit used for dosage calculation
PERCISION_FOR_EACH_DOSE	NUMBER	Dosage precision for calculated doses
ROUND_UP_FOR	NUMBER	Specifies if dosage calculations should be round up
DOSING_FREQUENCY	VARCHAR2(21 CHAR)	Specifies the frequency of doses in calculated doses
USE_LEFTOVER_UNITS_IN_NEXT_DOSE	NUMBER	Numeric field that represents if the use of left over kits/units in next dosage is allowed
KIT_MEASUREMENT	NUMBER(20,2)	Measure of the kit dosage used in dosage calculation
SUBJECT_MEASUREMENT	NUMBER(20,2)	Measurement of the subject reading

Table: DHVW_SUBJECT_FORMITEMS_V

Column name	Data type	Description
ID	RAW(16 BYTE)	GUID of the subject form item record
SUBJECT_EVENTINST_FORMITEM_WID	NUMBER(38)	Numeric ID of a subject form item record
VERSION_START	TIMESTAMP(6)	Timestamp of when the record was previously changed
VERSION_END	TIMESTAMP(6)	Timestamp for when the record was changed
OPERATION_TYPE	VARCHAR2(16 CHAR)	Type of operation: • CREATE • MODIFY • DELETE
USER_ID	RAW(16 BYTE)	GUID of the User
USER_WID	NUMBER(38)	Numeric user ID
USER_NAME	VARCHAR2(255 CHAR)	Oracle Clinical One Platform user name
OBJECT_VERSION_NUMBER	NUMBER	Change version number for the record
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change
TRANSACTION_START	DATE	*Reserved for future use*

Column name	Data type	Description
TRANSACTION_END	DATE	*Reserved for future use*
VALIDATION_STATUS	VARCHAR2(25 CHAR)	Status of a validation: • FAILED • RULE_VALIDATION_FAILED • SUCCESS
VALIDATION_FAILURE	VARCHAR2(4000 CHAR)	Validation failure message
STUDY_ID	RAW(16 BYTE)	GUID of the study
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_NAME	VARCHAR2(100 CHAR)	Study name
STUDY_VERSION	VARCHAR2(100 CHAR)	The study version of a given record
SUBJECT_ID	RAW(16 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Numeric subject ID
SUBJECT_NAME	VARCHAR2(500 CHAR)	Subject name
EVENT_ID	RAW(16 BYTE)	GUID of the event
EVENT_WID	NUMBER(38)	Numeric event ID
EVENT_NAME	VARCHAR2(64 CHAR)	Name of the event for the current record
FORM_ID	RAW(16 BYTE)	GUID of the form
FORM_WID	NUMBER(38)	Numeric form ID
FORM_NAME	VARCHAR2(64 CHAR)	The name of the form created in Oracle Clinical One Platform
FORM_REFNAME	VARCHAR2(64 CHAR)	System reference name of a form **Note:** This value is used to create the Clinical Data Extract table name in the database, which is then copied into Oracle DMW. Once a table is created for a form, the table name will not be recreated with a different name in Oracle DMW, even if the REFNAME is updated in Oracle Clinical One Platform.
FORM_SECTION_ID	RAW(16 BYTE)	GUID of the form section
REPEAT_SEQUENCE_NUMBER	NUMBER	Usage dependent on Form Type: • **One-section repeating form type:** Numeric value to represent the form instance for repeating forms. • **Lab and two-section form types:** Sequential number to represent the table (repeating section) row the extract data pertains to.
ITEM_ID	RAW(16 BYTE)	GUID of the item

Column name	Data type	Description
ITEM_WID	NUMBER(38)	Numeric item ID
ITEM_NAME	VARCHAR2(4000 CHAR)	The name of an item on a form
SITE_ID	RAW(16 BYTE)	GUID of the site
SITE_WID	NUMBER(38)	Numeric site ID
SITE_NAME	VARCHAR2(200 CHAR)	Site name
VARIABLE_ID	RAW(16 BYTE)	GUID of the variable
ORIGINATOR_ID	RAW(16 BYTE)	GUID of the originator
VENDOR_CODE	VARCHAR2(100 CHAR)	Populated and used by Oracle Clinical One Platform integrations
VALUE	VARCHAR2(4000 CHAR)	Response to the question (form item)
MEASURE_UNIT	VARCHAR2(64 CHAR)	Unit of measurement
NORMALIZED_VALUE	VARCHAR2(100 CHAR)	*Reserved for future use*
NORMALIZED_UNIT_ID	RAW(16 BYTE)	GUID of normalized unit
NUM_VALUE	NUMBER	Response if the value collected was of number type
FLOAT_VALUE	NUMBER	Response if the value collected was of float type
UTC_DATETIME_VALUE	TIMESTAMP(6)	Response in UTC if the value collected was of date time type
MONTH_VALUE	NUMBER(38)	Numeric value of the given month
DAY_VALUE	NUMBER(38)	Numeric value of the given day
YEAR_VALUE	NUMBER(38)	Numeric value of the given year
HOUR_VALUE	NUMBER(38)	Numeric value of the given hour
MINUTE_VALUE	NUMBER(38)	Numeric value of the given minute
SECOND_VALUE	NUMBER(38)	Numeric value of the given second
PARENT_ID	RAW(16 BYTE)	GUID of the parent record
PARENT_WID	NUMBER(38)	Numeric parent record ID
PARENT_NAME	VARCHAR2(4000 CHAR)	*Reserved for future use*
ROOT_ID	RAW(16 BYTE)	GUID of the root
ROOT_WID	NUMBER(38)	*Reserved for future use*
ROOT_NAME	VARCHAR2(4000 CHAR)	*Reserved for future use*
EVENT_INSTANCE_NUM	NUMBER	Event instance number for the visit
DATA_FLAG	RAW(16 BYTE)	GUID of the data flag (if existing, for example if the value was marked as not collected etc.)
ITEM_D	VARCHAR2(4000 CHAR)	Decoded response to the question
ITEM_R	VARCHAR2(4000 CHAR)	Raw value of the response to the question
ITEM_F	VARCHAR2(4000 CHAR)	Formatted response to the question
ITEM_TYPE	VARCHAR2(255 CHAR)	Type of question
PROPERTY_ID	RAW(16 BYTE)	GUID of the property

Column name	Data type	Description
PROPERTY_VERSION_START	TIMESTAMP(6)	Timestamp of when the record was previously changed
QUESTION_TYPE	VARCHAR2(32 CHAR)	The type of question asked: • Calculation • Choice • DateTime • Measurement • Number • Text • Label
QUESTION_HINT	VARCHAR2(4000 CHAR)	User provided hint to assist in answering a question
REQUIRED	NUMBER	Boolean value that denotes whether or not a question is required
READONLY	NUMBER(1)	Boolean value that denotes whether or not a question is read-only
SAS_VARIABLE	VARCHAR2(32 CHAR)	SAS Variable name associated with the question
SAS_LABEL	VARCHAR2(4000 CHAR)	SAS Label associated with the question
IS_CURRENT	CHAR(1)	Boolean flag stating whether a given record is the most recent version
IS_ROLLOVER	CHAR(1)	Indicator if the question is associated with rollover study
IS_REPEATING	CHAR(1)	Denotes whether an item has repeating entries
REFERENCE_CODE	VARCHAR2(64 CHAR)	Question reference code
HIDDEN	NUMBER(1)	Boolean value denoting whether an item is hidden
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
FREEZE	VARCHAR2(16 CHAR)	String value to represent the freeze status
VERIFIED	VARCHAR2(16 CHAR)	String value to represent the verified status
SIGNED	VARCHAR2(16 CHAR)	String value to represent the signed status
REPEAT_FORM_NUMBER	NUMBER	**For two-section Forms:** Numeric value to represent the form instance **Note:** For **lab forms** this value is defaulted to 1 and for **repeating forms** this value is `NULL`.
INNER_REPEAT	NUMBER	Sequential number for a form/item with repeating entries
OUTER_REPEAT	NUMBER	**For Repeating Forms (including one-section and two-section forms):** Sequential number to represent the form instance
EVENT_ID_NAME	VARCHAR2(16 CHAR)	The event's id as in Oracle Clinical One Platform.

Column name	Data type	Description
EVENT_TITLE	VARCHAR2(64 CHAR)	The event's title, defined by the user when an event is created.
HAS_QUERY	CHAR(1)	Indicates whether there is a query raised against a question or not, irrespective of the status.
LAB_ID	VARCHAR2(50 CHAR)	Indicates the associated lab ID, when the item is part of a lab form.
LAB_NAME	VARCHAR2(200 CHAR)	Indicates the associated lab name, when the item is part of a lab form.
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.

Table: DHVW_SUBJECT_VISITS_V

Column name	Data type	Description
SUBJECT_EVENT_INST_WID	NUMBER(38)	Numeric subject visit event ID
ID	RAW(16 BYTE)	GUID of the subject visit
VERSION_START	TIMESTAMP(6)	Timestamp of when the record was previously changed
VERSION_END	TIMESTAMP(6)	Timestamp of when the record was changed
OPERATION_TYPE	VARCHAR2(16 CHAR)	Categorization of the type of modification made to a given record: • CLEARED • CREATED • MODIFIED • REMOVED
USER_ID	RAW(16 BYTE)	GUID of the user
USER_WID	NUMBER(38)	Numeric user ID
USER_NAME	VARCHAR2(255 CHAR)	The user who modified the given record
OBJECT_VERSION_NUMBER	NUMBER	Sequential versioning of a given record
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change
STUDY_VERSION	VARCHAR2(100 CHAR)	The study version of a given record
SUBJECT_ID	RAW(16 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Numeric Subject ID
SUBJECT_NAME	VARCHAR2(64 CHAR)	Name of the subject
EVENT_ID	RAW(16 BYTE)	GUID of the event
EVENT_WID	NUMBER(38)	Numeric event ID
EVENT_NAME	VARCHAR2(64 CHAR)	Name of the event for the current record
SITE_ID	RAW(16 BYTE)	GUID of the site
SITE_WID	NUMBER(38)	Numeric site ID

Column name	Data type	Description
SITE_NAME	VARCHAR2(200 CHAR)	Name of a site
VISIT_STATUS	VARCHAR2(32 CHAR)	Status of a given visit: • COMPLETE • COMPLETE_ERR • INCOMPLETE • INCOMPLETE_ERR • INPROGRESS • NEW
VISIT_START_DATE	DATE	Timestamp of when a visit began
VISIT_TYPE	VARCHAR2(100 CHAR)	Visit type categorization: • ADVERSE_EVENT • DISPENSATION • NON_DISPENSATION • OPTIONAL • RANDOMIZATION • SCREENING • SUBJECT_COMPLETE • UNSCHEDULED • WITHDRAW
EVENT_TYPE	VARCHAR2(100)	Event type categorization: • Visit_Complete • Visit_Started • Visit_Date_Changed
STUDY_ID	RAW(16 BYTE)	GUID of the study
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_NAME	VARCHAR2(64 CHAR)	Study name
EVENT_INSTANCE_NUM	NUMBER	Event instance number for the visit
INVESTIGATOR	VARCHAR2(100 CHAR)	Investigator associated with a given visit
SUBJECT_NUMBER	VARCHAR2(500 CHAR)	Subject number
ADDRESS_STREET_1	VARCHAR2(150 CHAR)	Site address street 1
ADDRESS_STREET_2	VARCHAR2(150 CHAR)	Site address street 2
ADDRESS_CITY	VARCHAR2(100 CHAR)	Site address city
ADDRESS_STATE_OR_PROV_OR_CNTY	VARCHAR2(100 CHAR)	Site address state, province, or county
ADDRESS_POSTALCODE	VARCHAR2(20)	Site address postal code
ADDRESS_COUNTRY	VARCHAR2(100 CHAR)	Site address country
PROJECTED_VISIT_START_DATE	TIMESTAMP(6)	Projected date of visit start
PROJECTED_VISIT_END_DATE	TIMESTAMP(6)	Projected date of visit end

Column name	Data type	Description
PROJECTED_VISIT_DATE	TIMESTAMP(6)	Projected visit date
IS_REQUIRED	CHAR(1)	Boolean value indicating whether a visit is required
IS_SCHEDULED_VISIT	CHAR(1)	Boolean value indicating whether a visit is scheduled
SCHEDULED_FROM_EVENT_ID	RAW(16 BYTE)	GUID of the event from which the given visit is scheduled from
SCHEDULED_FROM_EVENT_WID	NUMBER(38)	Numeric ID of the event from which the given visit is scheduled from
SCHEDULED_FROM_EVENT_NAME	VARCHAR2(64 CHAR)	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule.
		Note: If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule.
DELAY_DAYS	NUMBER	Visit delay days
DELAY_HOURS	NUMBER	Visit delay hours
VISIT_WINDOW_BEFORE_DAYS	NUMBER	Number of days before the expected visit date when the visit could start
VISIT_WINDOW_BEFORE_HOURS	NUMBER	Number of hours before the expected visit date when the visit could start
VISIT_WINDOW_AFTER_DAYS	NUMBER	Number of days after the expected visit date when the visit could start
VISIT_WINDOW_AFTER_HOURS	NUMBER	Number of hours after the expected visit date when the visit could start
IS_CURRENT	CHAR(1)	Boolean flag stating whether a given record is the most recent version
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
COMPONENT_SEQ	NUMBER	Sequence of the visit based on schedule (number of hours)
FREEZE	VARCHAR2(16 CHAR)	String value to represent the freeze status
VERIFIED	VARCHAR2(16 CHAR)	String value to represent the verified status
SIGNED	VARCHAR2(16 CHAR)	String value to represent the signed status
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.

Table: DHVW_SUBJECTS_DATASET_V

Column name	Data type	Description
ID	RAW(16 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Numeric ID of the subject
DESCRIPTION	VARCHAR2(500 CHAR)	*This is a placeholder column that does not contain any data*
SUBJECT_NUMBER	VARCHAR2(500 CHAR)	Subject number
STUDY_ID	RAW(16 BYTE)	GUID of the study
STUDY_WID	NUMBER(38)	Numeric ID of the study
SITE_ID	RAW(16 BYTE)	GUID of the site
SITE_WID	NUMBER(38)	Numeric ID of the site
SITE_NAME	VARCHAR2(200 CHAR)	Name of the site
DOB	DATE	*Reserved for future use*
SCREENING_DATE	DATE	Date of the screening
STATE	VARCHAR2(100 CHAR)	Subject status
STATE_DATE	DATE	Date of the current status of the subject
SCREENING_FAILURE	VARCHAR2(255 CHAR)	Subject screening failure message
ENROLLMENT_FAILURE	VARCHAR2(255 CHAR)	Subject enrollment failure message
ENROLLMENT_OVERRIDE	VARCHAR2(255 CHAR)	Subject enrollment override message
INFORMED_CONSENT_DATE	DATE	*Reserved for future use*
GENDER	VARCHAR2(10 CHAR)	*Reserved for future use*
SUBJECT_TRANSFER_ID	RAW(16 BYTE)	GUID of the subject transfer
STUDY_VERSION	VARCHAR2(32 CHAR)	Version of the study
CODE_BREAK	VARCHAR2(2 CHAR)	Specifies if the subject undergoes a code break
EVENT_TYPE	VARCHAR2(100)	Event type categorization at the subject level: • Code_Break • Complete • Enrolled • New • Randomized • Screen_Failed • Screened • SubjectNumberChanged • Transferred • Undo_Complete • Undo_ScrFailed • Undo_Withdrawn • Withdrawn

Column name	Data type	Description
SITE_SERIAL_NUMBER	NUMBER	The serial number of the site
STUDY_SERIAL_NUMBER	NUMBER	*For internal use only.*Internal Clinical One study identifier
COUNTRY_NAME	VARCHAR2(100 CHAR)	Country name of the site
INVESTIGATOR	VARCHAR2(100 CHAR)	Investigator name
VERSION_START	TIMESTAMP(6)	Version start of the current subject record
VERSION_END	TIMESTAMP(6)	Version end of the current subject record
OPERATION_TYPE	VARCHAR2(16 CHAR)	Operation type of the current record: • Created • Modified • Deleted
USER_ID	RAW(16 BYTE)	GUID of the user who performed this action
USER_WID	NUMBER(38)	Numeric ID of the user who performed this action
USER_NAME	VARCHAR2(255 CHAR)	Name of the user
OBJECT_VERSION_NUMBER	NUMBER	Change version number for the record
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change
IS_CURRENT	CHAR(1)	Specifies if this is an active record or history record
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
TOTAL_VISITS	NUMBER	Total scheduled visits that are available for this subject based on site study version
TOTAL_FORMS	NUMBER	Total number of forms across the scheduled visits that are available for this subject based on site study version
COMPLETED_VISITS	NUMBER	Number of completed visits for a subject
TOTAL_FORMS_COMPLETED_VISITS	NUMBER	Number of forms that are present in the completed visit of the subject
COMPLETED_FORMS	NUMBER	Number of completed forms across the scheduled visits entered for the subject
STUDY_ID_NAME	VARCHAR2(64 CHAR)	Study ID name
STUDY_TITLE	VARCHAR2(4000 CHAR)	Title of the study
STUDY_REFNAME	VARCHAR2(64 CHAR)	Study ref name
STUDY_PHASE	VARCHAR2(64 CHAR)	Phase of the study
THERAPEUTIC_AREA	VARCHAR2(64 CHAR)	Therapeutic area of the study

Column name	Data type	Description
BLINDING_TYPE	VARCHAR2(64 CHAR)	Blinding type of the study: • Blinded • Unblinded
FROM_SITE_ID	RAW(16 BYTE)	GUID of the site from which the subject is transferred
FROM_SITE_WID	NUMBER(38)	Numeric ID of the site from which the subject is transferred
FROM_SITE_NAME	VARCHAR2(200 CHAR)	Site name from which the subject is transferred
OLD_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	Old subject number
SITE_ID_NAME	VARCHAR2(50 CHAR)	Site ID name
SITE_STATUS	VARCHAR2(50 CHAR)	Status of the site
ADDRESS_STREET_1	VARCHAR2(150 CHAR)	Primary site address1
ADDRESS_STREET_2	VARCHAR2(150 CHAR)	Primary site address2
ADDRESS_CITY	VARCHAR2(100 CHAR)	Primary site city
ADDRESS_STATE_OR_PROV_OR_CNTY	VARCHAR2(100 CHAR)	Primary site state
ADDRESS_POSTALCODE	VARCHAR2(20)	Primary site postal code
ADDRESS_COUNTRY	VARCHAR2(100 CHAR)	Primary site country
FAX	VARCHAR2(50 CHAR)	Primary site fax number
EMAIL	VARCHAR2(255 CHAR)	Primary site email address
PHONE	VARCHAR2(50 CHAR)	Primary site phone number
SHIPPING_ADDRESS_1	VARCHAR2(150 CHAR)	Site shipping addres1
SHIPPING_ADDRESS_2	VARCHAR2(150 CHAR)	Site shipping addres2
SHIPPING_CITY	VARCHAR2(100 CHAR)	Site shipping city
SHIPPING_STATE_OR_PROV_OR_CNTY	VARCHAR2(100 CHAR)	Site shipping country
SHIPPING_ZIP	VARCHAR2(20)	Site shipping postal code
SHIPPING_COUNTRY	VARCHAR2(100 CHAR)	Site shipping country
SHIPPING_FAX	VARCHAR2(50 CHAR)	Site shipping fax
SHIPPING_EMAIL	VARCHAR2(255 CHAR)	Site shipping email
SHIPPING_PHONE	VARCHAR2(50 CHAR)	Site shipping phone
SITE_STUDY_VERSION	VARCHAR2(100 CHAR)	Study version of the site

Column name	Data type	Description
DRUG_DESTRUCTION_CAPABLE	VARCHAR2(100 CHAR)	Specifies if site is capable for drug destruction
PI_PREFIX	VARCHAR2(100 CHAR)	Prefix value of principal investigator
ADD_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site is can add subjects
SCREEN_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can screen subjects
RANDOMIZE_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can randomize subjects
DISPENSE_TO_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can dispense to subjects
DEA_NUMBER	VARCHAR2(100 CHAR)	DEA registration number as defined by site manager
EXPIRATION	VARCHAR2(100 CHAR)	Expiration date of the DEA registration number as defined by the site manager
TIMEZONE	VARCHAR2(100 CHAR)	Site time zone
SHIPPING_ATTENTION	VARCHAR2(100 CHAR)	Shipping attention of the site
SDV_GROUP_NAME	VARCHAR2(255)	Source Data verification group name
INITIAL_SUBJECTS_COUNT	VARCHAR2(2048)	Initial subject count for SDV
INITIAL_SUBJECTS_SDV_TYPE	VARCHAR2(2048)	Specifies if only critical or all questions have to be verified for initial subject
REMAINING_SUBJECTS_PERCENTAGE	VARCHAR2(2048)	Value for percentage of remaining subject for SDV
REMAINING_SUBJECTS_SDV_TYPE	VARCHAR2(2048)	Specifies if only critical or all questions have to be verified for remaining subject
CURRENT_STUDY_ROLE_ID	RAW(16 BYTE)	The ID associated with the study role assigned to the user who updated the given record. If the user study role changes, this field will show the current study role ID of the given user.
CURRENT_STUDY_ROLE_NAME	VARCHAR2(100 CHAR)	Specifies the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.
CURRENT_STUDY_ROLE_WID	NUMBER(38)	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.
EXTERNAL_SOURCE_STATUS_DATE	TIMESTAMP(6)	Indicates the date on which the subject status was updated by an external source.
FREEZE	VARCHAR2(16 CHAR)	String value to represent the freeze status
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.
SIGNED	VARCHAR2(16 CHAR)	String value to represent the signed status
VERIFIED	VARCHAR2(16 CHAR)	String value to represent the verified status

Table: DHVW_UNBLD_KITS_DATASET_V

Column name	Data type	Description
STUDY_ID	RAW(16 BYTE)	GUID of the study
STUDY_WID	NUMBER(38)	Numeric study ID
STUDY_ID_NAME	VARCHAR2(64 CHAR)	Name of the study
STUDY_TITLE	VARCHAR2(4000 CHAR)	Title of the study
STUDY_REFNAME	VARCHAR2(64 CHAR)	Refname of the study
THERAPEUTIC_AREA	VARCHAR2(64 CHAR)	Therapeutic area of the study
STUDY_PHASE	VARCHAR2(64 CHAR)	Phase of the study
BLINDING_TYPE	VARCHAR2(64 CHAR)	Blinding type of the study: • Blind • Unblind
COUNTRY_NAME	VARCHAR2(100 CHAR)	Country name
DRUG_DESTRUCTION_CAPABLE	VARCHAR2(100 CHAR)	Drug destruction capability of the site
PI_PREFIX	VARCHAR2(100 CHAR)	Prefix value of principal investigator
ADD_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can add subjects
SCREEN_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can screen subject
RANDOMIZE_SUBJECTS	VARCHAR2(100 CHAR)	Specifies if site can randomize subject
DISPENSE_TO_SUBJECTS	VARCHAR2(100 CHAR)	specifies if site can dispense to subjects
DEA_NUMBER	VARCHAR2(100 CHAR)	DEA registration number as defined by the site manager
EXPIRATION	VARCHAR2(100 CHAR)	Expiration date of DEA registration number as defined by the site manager
TIMEZONE	VARCHAR2(100 CHAR)	Time zone of site
SHIPPING_ATTENTION	VARCHAR2(100 CHAR)	Shipping attention of the site
INVESTIGATOR	VARCHAR2(100 CHAR)	Investigator name
SDV_GROUP_NAME	VARCHAR2(255)	Source Data verification Group name
INITIAL_SUBJECTS_COUNT	VARCHAR2(2048)	Initial subject count for SDV
INITIAL_SUBJECTS_SDV_TYPE	VARCHAR2(2048)	Specifies if only critical or all questions have to be verified for the initial subject
REMAINING_SUBJECTS_PERCENTAGE	VARCHAR2(2048)	Value for percentage of remaining subject for SDV
REMAINING_SUBJECTS_SDV_TYPE	VARCHAR2(2048)	Specifies if only critical or all questions have to be verified for remaining subject

Column name	Data type	Description
ADDRESS_STREET_1	VARCHAR2(150 CHAR)	Primary site address1
ADDRESS_STREET_2	VARCHAR2(150 CHAR)	Primary site address2
ADDRESS_CITY	VARCHAR2(100 CHAR)	Primary site city
ADDRESS_STATE_OR_PROV_OR_CNTY	VARCHAR2(100 CHAR)	Primary site state
ADDRESS_POSTALCODE	VARCHAR2(20)	Primary site postal code
ADDRESS_COUNTRY	VARCHAR2(100 CHAR)	Primary site country
PHONE	VARCHAR2(50 CHAR)	Primary site phone number
FAX	VARCHAR2(50 CHAR)	Primary site fax number
EMAIL	VARCHAR2(255 CHAR)	Primary site email id
SHIPPING_ADDRESS_1	VARCHAR2(150 CHAR)	Site shipping addres1
SHIPPING_ADDRESS_2	VARCHAR2(150 CHAR)	Site shipping addres2
SHIPPING_CITY	VARCHAR2(100 CHAR)	Site shipping city
SHIPPING_COUNTRY	VARCHAR2(100 CHAR)	Site shipping country
SHIPPING_STATE_OR_PROV_OR_CNTY	VARCHAR2(100 CHAR)	Site or city
SHIPPING_ZIP	VARCHAR2(20)	GUID of the value for shipping
SHIPPING_PHONE	VARCHAR2(50 CHAR)	Site shipping phone
SHIPPING_FAX	VARCHAR2(50 CHAR)	Site shipping fax
SHIPPING_EMAIL	VARCHAR2(255 CHAR)	Site shipping email
SITE_STATUS	VARCHAR2(50 CHAR)	Site status
SITE_STUDY_VERSION	VARCHAR2(100 CHAR)	Site study version
SITE_ID	RAW(16 BYTE)	Numeric ID value for site
SITE_WID	NUMBER(38)	GUID of the value for site
SITE_NAME	VARCHAR2(200 CHAR)	Site name
SITE_ID_NAME	VARCHAR2(50 CHAR)	Site ID name
SITE_TYPE	VARCHAR2(50 CHAR)	Type of the site
SUBJECT_ID	RAW(16 BYTE)	GUID of the subject
SUBJECT_WID	NUMBER(38)	Numeric ID of the subject

Column name	Data type	Description
SUBJECT_NUMBER	VARCHAR2(500 CHAR)	Subject name
SUBJECT_STATE	VARCHAR2(100 CHAR)	State of the subject
RANDOMIZATION_TITLE	VARCHAR2(64 CHAR)	Randomization title
RANDOMIZATION_DESCRIPTION	VARCHAR2(4000 CHAR)	Randomization description
RANDOMIZATION_TYPE	VARCHAR2(32 CHAR)	Type of randomization
COHORT_ID	RAW(16 BYTE)	GUID of the cohort
COHORT_WID	NUMBER(38)	Numeric ID of the cohort
COHORT_NAME	VARCHAR2(64 CHAR)	Cohort name
RERANDOMIZATION	NUMBER	Specifies if it allows re-randomization
TREATMENT_ID	RAW(16 BYTE)	GUID of the treatment arm
TREATMENT_WID	NUMBER(38)	Numeric ID of the treatment arm
TREATMENT_ARM_TITLE	VARCHAR2(64 CHAR)	Treatment arm title
TREATMENT_ARM_DESCRIPTION	VARCHAR2(4000 CHAR)	Treatment arm description
TREATMENT_ARM_ID	VARCHAR2(64 CHAR)	Treatment arm ID name
RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES	NUMBER	Specifies if randomization needs to restrict to available kit types
ASSIGNED_SKIPPED_RANDOMIZATION_NUMBERS	NUMBER	Specifies if skipped randomization number has to be assigned
RAND_NUMBER	NUMBER	Randomization number
RND_STATUS	VARCHAR2(64 CHAR)	State of Randomization
RANDOMIZATION_DATE	TIMESTAMP(6)	Subject randomization date
MANFACTURING_LOT_TITLE	VARCHAR2(64 CHAR)	Manufacturing lot title name
BLINDED_LOT_TITLE	VARCHAR2(64 CHAR)	Blinded lot title name
MANFACTURING_LOT_SHORT_NAME	VARCHAR2(64 CHAR)	Manufacturing lot short name
BLINDED_LOT_SHORT_NAME	VARCHAR2(64 CHAR)	Blinded lot short name
MANFACTURING_LOT_EXPIRATION_DATE	DATE	Manufacturing lot expiration date
BLINDED_LOT_EXPIRATION_DATE	DATE	Blinded lot expiration date

Column name	Data type	Description
MANFACTURING_LOT_DO_NOT_SHIP_DAYS	NUMBER	Do-not-ship days for manufacturing lot
BLINDED_LOT_DO_NOT_SHIP_DAYS	NUMBER	Do-not-ship days for blinded lot
MANFACTURING_LOT_DO_NOT_COUNT_DAYS	NUMBER	Do-not-count days for manufacturing lot
BLINDED_LOT_DO_NOT_COUNT_DAYS	NUMBER	Do-not-count days for blinded lot
SHIPMENT_ID	RAW(16 BYTE)	GUID of the shipment
SHIPMENT_WID	NUMBER(38)	Numeric ID for the shipment
SHIPMENT_NAME	VARCHAR2(64 CHAR)	Shipment name
SHIPMENT_STATUS	VARCHAR2(64 CHAR)	Status of the shipment
SHIPMENT_CREATED_DATE	TIMESTAMP(6)	Shipment creation date
SHIPMENT_DATE	TIMESTAMP(6)	Shipment date
TRACKING_NUMBER	VARCHAR2(64 CHAR)	Shipment tracking number
VISIT_IS_REQUIRED	CHAR(1)	Specifies if visit is required or not
IS_SCHEDULED_VISIT	CHAR(1)	Specifies if visit is scheduled or not
SCHEDULED_FROM_EVENT_NAME	VARCHAR2(64 CHAR)	Displays the EVENT_TITLE (visit title) of the Scheduled From visit as defined in the Visit Schedule. **Note:** If a visit is not scheduled or it is the first visit in the schedule, then this element is populated with the visit's own title. For example, Screening Visit is displayed for the Screening Visit, as it is the first visit in the schedule.
VISIT_STATUS	VARCHAR2(32 CHAR)	Status of a given visit: • COMPLETE • COMPLETE_ERR • INCOMPLETE • INCOMPLETE_ERR • INPROGRESS • NEW
VISIT_START_DATE	DATE	Visit date

Column name	Data type	Description
VISIT_TYPE	VARCHAR2(100 CHAR)	Type of the visit
EVENT_TYPE	VARCHAR2(100)	Event type categorization: • Visit_Complete • Visit_Started • Visit_Date_Changed
PROJECTED_VISIT_START_DATE	TIMESTAMP(6)	Projected start date of this visit
PROJECTED_VISIT_END_DATE	TIMESTAMP(6)	Projected end date of this visit
PROJECTED_VISIT_DATE	TIMESTAMP(6)	Projected visit date
DELAY_DAYS	NUMBER	Delay days of the visit
DELAY_HOURS	NUMBER	Delay hours of the visit
VISIT_WINDOW_BEFORE_DAYS	NUMBER	Number of days before the expected visit date when the visit could start
VISIT_WINDOW_BEFORE_HOURS	NUMBER	Number of hours before the expected visit date when the visit could start
VISIT_WINDOW_AFTER_DAYS	NUMBER	Number of days after the expected visit date when the visit could start
VISIT_WINDOW_AFTER_HOURS	NUMBER	Number of hours after the expected visit date when the visit could start
EVENT_ID	RAW(16 BYTE)	GUID of the visit
EVENT_WID	NUMBER(38)	Numeric ID of the visit
EVENT_TITLE	VARCHAR2(64 CHAR)	The event's title, defined by the user when an event is created.
EVENT_REFNAME	VARCHAR2(64 CHAR)	The event's reference name. Displays a capitalized version of the (user entered) EVENT_TITLE with blank spaces removed. Oracle Clinical One Analytics generates this value, which is not displayed in the Oracle Clinical One Platform user interface. **Note:** This value does not change if the associated EVENT_TITLE is updated in a subsequent Study Version.
EVENT_ID_NAME	VARCHAR2(16 CHAR)	Visit ID name
VISIT_ORDER	NUMBER	Order of the visit in design
KIT_TYPE	VARCHAR2(255 CHAR)	Type of the kit
DEVICE_TYPE	VARCHAR2(255)	Device type kit: • D2C • C2C
DEVICE_CONNECTION	VARCHAR2(255)	Whether the device is connected or non connected

Column name	Data type	Description
CALCULATING_DOSES	NUMBER	Name of the calculated dose kit
DISTRIBUTION_SETTINGS	VARCHAR2(16 CHAR)	Indicates the type of distribution a kit has, as specified by the study designer. The following values can be displayed: • **Blinded:** if blinded users should never see the kit type description. • **Unblinded:** if blinded users should always see the kit type description. • **Unblinded Pharmacist:** if blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types.
KIT_DESIGN_ID	RAW(16 BYTE)	GUID of the kit at study design
KIT_DESIGN_WID	NUMBER(38)	Numeric ID of the kit at study design
KIT_TYPE_ID	VARCHAR2(64 CHAR)	Kit type ID as per study design
TRIAL_SUPPLY_TYPE	VARCHAR2(16 CHAR)	Indicates the supply type of the kit, as specified by the study designer. The following values can be displayed: • Blister • Pack • Bottle • Device • Syringe • Topical • Ointment • Vial • Inhaler • Infusion • Box • Other
MINIMUM_KITS_TO_SHIP	NUMBER	Minimum number of kits to ship
UNITS_PER_KIT	NUMBER	Number of units in a kit
SINGLE_UNIT_DOSE_VALUE	NUMBER(20,2)	Dose value of single unit in a kit
SINGLE_UNIT_DOSE_UNITS	VARCHAR2(16 CHAR)	Dose unit of the kit
CRA_VERIFIED	NUMBER	Specifies if kit is verified by CRA
BALANCE_UNITS	NUMBER	Balance number of units of a kit
TITRATION	NUMBER	Specifies if kit is a titration kit
INVENTORY_ID	RAW(16 BYTE)	Runtime GUID of the kit
INVENTORY_WID	NUMBER(38)	Number ID of kit at runtime
KIT_NUMBER	NUMBER	Kit number
SEQUENCE_NUMBER	NUMBER	Sequence number of the kit
KIT_DESCRIPTION	VARCHAR2(4000 CHAR)	Description of the kit
KIT_STATUS	VARCHAR2(64 CHAR)	Status of the kit

Column name	Data type	Description
DISPENSATION_DATE	TIMESTAMP(6)	Kit dispensation date
DOSAGE	NUMBER	Dosage of the kit
BAR_CODE	VARCHAR2(1000 CHAR)	Barcode of the kit
DISPENSATION_CONFIRMED	NUMBER	Specifies if kit dispensation is confirmed
MEASUREMENT	VARCHAR2(1000 CHAR)	Measurement of kit in dosage calculation
FREQUENCY	VARCHAR2(64 CHAR)	Frequency of the kit as per dosage calculation
RETURNED_UNITS	NUMBER	Number of units returned in the kit
MISSING_UNITS	NUMBER	Number of units missing in the kit
CONSERVED	VARCHAR2(16 CHAR)	Indicates whether a kit was conserved by a site user or not
QUANTITY	NUMBER	Kit quantity
INSTANCE_NUMBER	NUMBER	Indicates the repeat instance number of the visit
CALCULATED_DOSE_ID	RAW(16 BYTE)	GUID of dosage calculation
CALCULATED_DOSE_WID	NUMBER(38)	Numeric ID of dosage calculation
CALCULATED_DOSE_TITLE	VARCHAR2(64 CHAR)	Dosage calculation title
FORM_QUESTION_FOR_CALCULATED_DOSE	VARCHAR2(64 CHAR)	Question used for dosage calculation
VISIT_WHERE_FORM_IS_COLLECTED	VARCHAR2(64 CHAR)	Visit name used for dosage calculation
DOSE_PRECISION	NUMBER	Dosage precision for calculated doses
DOSE_ROUND_UP	NUMBER	Specifies if dosage calculations should be round up
DOSE_FREQUENCY	VARCHAR2(21 CHAR)	Specifies how many doses the subject must consume, as specified by the study designer
DOSE_LEFT_OVER_UNITS	NUMBER	Indicates whether leftover units from a previous dose can be used in a next dose, during the study conduct period, as specified by the study designer
KIT_MEASUREMENT	NUMBER(20,2)	Measure of the kit dosage used in dosage calculation
SUBJECT_MEASUREMENT	NUMBER(20,2)	Measurement of the subject reading
VERSION_START	TIMESTAMP(6)	Version start of the current kit record
VERSION_END	TIMESTAMP(6)	Version end of the current kit record
OPERATION_TYPE	VARCHAR2(16 CHAR)	Type of operation: • CREATE • MODIFY • DELETE
OBJECT_VERSION_NUMBER	NUMBER	Change version number for the record

Column name	Data type	Description
REASON	VARCHAR2(255 CHAR)	User provided reason for record change
COMMENT	VARCHAR2(2048 CHAR)	Comment for record change
USER_ID	RAW(16 BYTE)	GUID of the user who performed this action
USER_WID	NUMBER(38)	Numeric ID of the user who performed this action
USER_NAME	VARCHAR2(255 CHAR)	User name
IS_CURRENT	CHAR(1)	Specifies if this record is an active record or history record
VERIFIED_BY_ID	RAW(16 BYTE)	GUID of the user who verified the kit
VERIFIED_BY_WID	NUMBER(38)	Numeric ID of the user who verified the kit
VERIFIED_BY	VARCHAR2(255 CHAR)	User name who verified the kit
VERIFIED_DATE	TIMESTAMP(6)	Kit verified date
CONFIRMED_BY_ID	RAW(16 BYTE)	GUID of the user who confirmed the kit dispensation
CONFIRMED_BY_WID	NUMBER(38)	Numeric ID of the user who confirmed the kit dispensation
CONFIRMED_BY	VARCHAR2(255 CHAR)	User name who confirmed the kit dispensation
CONFIRMED_DATE	TIMESTAMP(6)	Kit confirmed date
SOFTWARE_VERSION_NUMBER	NUMBER	Internal on-disk version number for the record
DH_TIMESTAMP	TIMESTAMP(6)	Timestamp of when the record was written to Data Hub
BLOCK_NUMBER	VARCHAR2(512 CHAR)	Block number of the kit
CURRENT_STUDY_ROLE_ID	RAW(6 BYTE)	The ID associated with the study role assigned to the user who updated the given record. If the user study role changes, this field will show the current study role ID of the given user.
CURRENT_STUDY_ROLE_NAME	VARCHAR2(100 CHAR)	Specifies the role of the user who updated the given record. If the user's study role changes, this field will show the current study role of the given user.
CURRENT_STUDY_ROLE_WID	NUMBER(38)	Numeric identifier of the role of the user who updated the given record. If the user study role changes, this field will show the current study role of the given user.
ITEM_NUMBER	VARCHAR2(64 CHAR)	Numeric value used as a reference element for batch processing.
KIT_NUMBER	VARCHAR2(1024 CHAR)	Indicates a kit's number, as assigned in the system.

Note:

This field is part of the SAP system and populated via integration. This field does not display in Oracle Clinical One Platform.

Column name	Data type	Description
MATERIAL_ID	VARCHAR2(64 CHAR)	Alphanumeric identifier of the material of a given kit, used as a reference element for batch processing. **Note:** This field is part of the SAP system and populated via integration. This field does not display in Oracle Clinical One Platform.
PREVIOUS_SUBJECT_NUMBER	VARCHAR2(500 CHAR)	When a subject number change is applied, this field holds the number that was assigned to the subject before the change.