# Oracle® Health Sciences Clinical One Platform

## Analytics User Guide

Release 22.2
F56718-02
June 2022

ORACLE

Oracle Health Sciences Clinical One Platform Analytics User Guide, Release 22.2

F56718-02

# Contents

## 5 Revision history

# 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.

## Related resources

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

## Access to Oracle Support

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

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

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

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

## Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

1

# About your access to Oracle Clinical One Analytics

You can only access Oracle Clinical One Analytics if you have the right permissions assigned to your study role in Oracle Clinical One Platform. Additionally, in a dataset you only see the data for the sites that you are assigned in the study.

Work with your user administrator to make sure you are assigned at least one of the permissions listed below:

- *Run the Blinded Subject Events Dataset*
- *Run the Subject Dataset*
- *Run the Subject Form Items Dataset*
- *Run the Subject Forms Dataset*
- *Run the Unblinded Subject Events Dataset*
- *Run the Study Query Dataset*
- *Run the Unblinded Kits Dataset*
- *Run the Data Collection Design Dataset* (to access the Study Design Dataset)
- *Run the Kits and Randomization Design Dataset*

Depending on what study role and permissions you are assigned in the study, you can view and work with certain datasets in Oracle Clinical One Analytics. The table below lists every role that should get access to each dataset.

| Dataset | User roles |
|---|---|
| **Subject Form Items Dataset** | • Clinical Supply Manager<br>• Data Manager<br>• Medical Monitor<br>• Production Admin<br>• Rules Designer<br>• Statistician<br>• Study Manager<br>• View Only for Unblinded Support Users |
| **Unblinded Subject Events Dataset** | • Clinical Supply Manager<br>• View Only for Unblinded Support Users |
| **Subject Dataset** | • Clinical Supply Manager<br>• CRA<br>• Production Admin<br>• Statistician<br>• Study Manager<br>• View Only for Unblinded Support Users |

| Dataset | User roles |
|---|---|
| **Blinded Subject Events Dataset** | • Clinical Supply Manager<br>• CRA<br>• Data Manager<br>• Medical Monitor<br>• Production Admin<br>• Statistician<br>• Study Manager<br>• View Only for Unblinded Support Users |
| **Subject Forms Dataset** | • Clinical Supply Manager<br>• CRA<br>• Data Manager<br>• Medical Monitor<br>• Production Admin<br>• Statistician<br>• Study Manager<br>• View Only for Unblinded Support Users |
| **Queries Dataset** | • Clinical Supply Manager<br>• CRA<br>• Data Manager<br>• Medical Monitor<br>• Production Admin<br>• Rules Designer<br>• Statistician<br>• Study Manager<br>• View Only for Unblinded Support Users |
| **Unblinded Kits Dataset** | • Clinical Supply Manager<br>• Production Admin<br>• Statistician<br>• View Only for Unblinded Support Users |
| **Study Design Dataset** | • Study Designer<br>• View Study Design<br>• Data Manager<br>• User Administrator |
| **Kits and Randomization Design Dataset** | • Study Manager |

2

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

You must know that the data in the Oracle Clinical One Analytics application is refreshed every time that data is saved in the context of a visit, even though that visit may not yet be completed.

Specifically data is now refreshed whenever one of the following events takes place in Oracle Clinical One Platform:

- A new visit is started.
- The date is updated in the Visit Date field of a visit.
- Data is entered in a form and the form is saved.
- A form is saved.
- A question is updated after the form it belongs to was already completed.
- A query is created, updated, or closed.

> **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.

Lastly, you must know that Oracle Clinical One Analytics does not take data classifications into account. What that means for you is once a question is marked as Hidden in study design, you cannot view that question in any of the datasets, custom reports, or visualizations you will create. This is planned for a future release.

# 3
# Datasets

Oracle Clinical One Analytics let you use your study data in a multitude of ways, from visualizing it to exporting it in the right format for reading data, such as CSV or PDF. In turn, these new features allow you 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 that has not been tested and is reserved for a future release. If you run into any issues, contact Health Sciences Support.



## About datasets and visualizations

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 provieds 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 that you can use to create custom reports or visualizations that you can then export in a variety of formats, such as CSV, PPT, PDF, and PNG.

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**

- Add data to the visualization using Grammar Panel
- Create calculated data elements in a dataset
- Sort data in visualizations
- Undo and redo edits
- Refresh data in a project
- Adjust the Visualize Canvas Layout and properties
- Change visualization types
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters
- Drill in results
- Create data actions to connect visualization canvases
- Create data actions to connect external URLs from visualization canvases
- Create data actions to connect REST APIs from visualization canvases
- Invoke data actions from visualization canvases

# Select a dataset to work with

As an Oracle Clinical One Platform user, you don't have to create a custom dataset from scratch because they are already predefined in your Oracle Clinical One Analytics environment. However, you have control over what you choose to visualize or export from that dataset.

First, let's go through how you would get to the existing datasets before you begin your visualizations. Since you already have a set of predefined datasets, all you have to do is access the dataset that is most useful for your custom report or visualization, and begin your work.

1. On the Home page, click **Analytics**.
2. In Oracle Clinical One Analytics, in the datasets section, click any of the six datasets.

After following these steps, you can begin dragging and dropping data elements to create either a custom report or a data visualization. For more details, see Create a data visualization.

**Related Topics**

- Dataset descriptions
- Create a data visualization
  In Oracle Clinical One Analytics, you can visualize Oracle Clinical One Platform clinical data and add your visualizations into a dashboard that can be shared with analysts and statisticians on your study team.

- 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.

# Create a data visualization

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

Now that you have selected a dataset to work with, it is time you build a visualization.

**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. 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.

1. From the Data Elements pane, expand a folder, and then drag and drop one or more data elements onto the Visualize canvas.
2. Continue dragging and dropping data elements onto the Grammar Panel, as needed.

   The Grammar Panel contains sections that you can customize by associating with various data elements.
3. After including all of your required data elements, you can edit the visualization, including its colors, shapes, add filters, rename the visualization, or even its data elements, to give them user-friendly names.
4. After you are done with defining the details of your visualization, click **Save** or **Save As**, to save your work.
5. In the Save Project dialog, enter a name and a description for your custom report or visualization, and select a folder where you can save your work. You can either save it for personal use in **My Folders** or share it in **Shared Folders**.

**Related Topics**

- Add data to the visualization using Grammar Panel
- Create calculated data elements in a dataset
- Sort data in visualizations
- Undo and redo edits
- Adjust the Visualize Canvas Layout and properties
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters

# Dataset descriptions

- Queries dataset
  You can use a Queries dataset to analyze and visualize customized query data in Oracle Clinical One Analytics.
- Subject dataset
  You can use a Subject dataset to analyze and visualize customized subject data in Oracle Clinical One Analytics.
- Subject Forms dataset
  With the Subject Forms dataset you can analyze and visualize customized subject forms data in Oracle Clinical One Analytics.
- Subject Form Items dataset
  The Subject Form Items dataset allows you to export data related to questions in forms in a flexible manner and analyze and visualize this data in Oracle Clinical One Analytics.
- Blinded Subject Event dataset
  You can use the Blinded Subject Events dataset to analyze and visualize blinded subject event data in Oracle Clinical One Analytics.
- Unblinded Subject Event dataset
  You can use the Unblinded Subject Events dataset to analyze and visualize unblinded subject event data in Oracle Clinical One Analytics.
- Unblinded Kits dataset
  You can use an Unblinded Kits dataset to analyze and visualize customized supply data in Oracle Clinical One Analytics.
- Study Design dataset
- Kits and Randomization Design dataset
  You can use Kits and Randomization Design dataset to analyze and visualize customized data in Oracle Clinical One Analytics that will allow you to understand kit definitions, randomization definitions, and dispensation schedules.

## Queries dataset

You can use a Queries dataset to analyze and visualize customized query data in Oracle Clinical One Analytics.

**Modes**

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

**Roles that can run the report**

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

**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.

Browse descriptions of data elements included in this dataset:



## Study folder

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

**Table 3-1 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_MODE | Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active. |
| STUDY_TITLE | A protocol's title as specified by the study manager |
| STUDY_REFNAME | 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 | Indicates the therapeutic area 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_PHASE | A study's phase as indicated 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.

**Table 3-2 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 |
| 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 |
| 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 |

**Table 3-2 (Cont.) Data elements in the Site folder**

| Data element | Description |
|---|---|
| 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 |
| 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 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second 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 |

## Subject folder

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

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |

| Data Element | Description |
|---|---|
| SUBJECT_STATE | A subject's state |

## Event folder

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

**Table 3-3 Data elements in the Event folder**

| Data element | Description |
|---|---|
| VISIT_IS_REQUIRED | Indicates whether or not a visit is required |
| 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_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 (visit started, visit completed) |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| 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 | A visit or event's title as specified by a study designer |

**Table 3-3 (Cont.) Data elements in the Event folder**

| Data element | Description |
|---|---|
| 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 |

## Form folder

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

**Table 3-4 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 or not it is a rollover form |
| IS_REPEATING | Indicates whether or not it is a repeating form |
| FORM_STATUS | Indicates the status of a specific form in the system |
| FORM_REFNAME | A form's reference name |
| REPEAT_SEQUENCE_NUMBER | Refers to the row instance number of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** indicates the repeating form number. |
| REPEAT_FORM_NUMBER | • **Two section forms:** indicates the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** this value will be null. |
| OUTER_REPEAT | Refers to the *Form Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique identifier of the non-repeating section of the form, the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** unique numeric identifier of the repeating form. |
| INNER_REPEAT | Refers to the *Section Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** this value will be null. |

## Item folder

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

**Table 3-5 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) |
| 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) |
| 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 | If the question has a decode value, it is populated in this field |
| ITEM_R | The raw value of the form item value |
| ITEM_F | The formatted value of the form item value |
| 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. |
| IS_REQUIRED | Indicates whether or not the question requires an answer |
| READONLY | Indicates that the question is marked as read-only by a study designer |

**Table 3-5 (Cont.) Data elements in the Item folder**

| Data element | Description |
|---|---|
| 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 whether a question is hidden or not, as marked by a study designer |
| FREEZE | Indicates whether a question is frozen or not by a data manager or CRA |
| VERIFIED | Indicates whether a question is verified or not by a CRA.<br>Data element can be populated with the following values:<br>• VERIFIED: A question, form, or visit is verified.<br>• UNVERIFIED: A question, form, or visit is unverified. |
| SIGNED | Indicates whether a question is signed by a PI or not |

## Query (Required) folder

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

**Table 3-6 Data elements in the Query folder**

| Data element | Description |
|---|---|
| STATE | Indicates a query's status, whether it is Opened, Answered, Closed, or a Candidate query |
| QUERY_COMMENT | Indicates a comment associated with a query, as entered by the user who last modified the query |
| HAS_QUERY | Indicates whether there is a query raised against a question or not |
| ASSIGNED_ROLES | Indicates the roles that are assigned to receive a query |
| QUERYAGE | Indicates the number of days passed since a query was first opened |

## Audit folder

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

**Table 3-7 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 |
| COMMENT | 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.<br>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 Health IAMS. |
| IS_CURRENT | Audit trail field to display either current status or full audit trail of the data |

## Reference folder

This table describes data elements in the Reference folder.

**Table 3-8 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 | A number that represents the unique identifier of a subject. |
| 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 | Number that represents unique identifier of a form. |
| REPEAT_SEQUENCE_NUMBER | Indicates the number of repeats for a repeating form instance. |

**Table 3-8 (Cont.) Data elements in the Reference folder**

| Data element | Description |
|---|---|
| ITEM_WID | A number that represents the unique identifier of a question. |
| SOFTWARE_VERSION_NUMBER | A number that represents an incremental increase every time a data point is modified. |
| USER_WID | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| DH_TIMESTAMP | A timestamp that indicates when the data became available in the dataset. |
| SUBJECT_EVENTINST_FORMITEM_WID | Number the represents a unique identifier for a form item within a visit for a subject. |
| SUBJECT_EVENT_INST_WID | A number that represents the unique identifier of a subject event. |
| 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. |

# Subject dataset

You can use a Subject dataset to analyze and visualize customized subject data in Oracle Clinical One Analytics.

### Modes

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

### Roles that can run the report

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

### 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

Browse descriptions of data elements included in this dataset:

- Study folder
- Site folder
- Subject (Required) folder
- Event folder
- Audit folder

- Aggregations
- Reference folder

## Study folder

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

**Table 3-9 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 | 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 |
| 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.<br>Internal Clinical One study identifier. |

## Site folder

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

**Table 3-10 Data elements in the Site folder**

| Data element | Description |
|---|---|
| PI_PREFIX | Indicates the principal investigator's prefix, as configured by a site manager |
| SITE_STATUS | A site's status at the moment the report is run. For example, a site's status might be New, Active, or Retired at the time you are including this data in a report or dashboard |
| INVESTIGATOR | A Principal Investigator's Full Name as listed when the site manager created the site |

**Table 3-10 (Cont.) Data elements in the Site folder**

| Data element | Description |
|---|---|
| FROM_SITE_NAME | If a subject is transferred, this field is populated with the site the subject was transferred from |
| SITE_NAME | The name of the site |
| SITE_SERIAL_NUMBER | The serial number of the site |
| SITE_ID_NAME | Indicates the site ID as entered by a site manager when they created or last modified a site |
| ADD_SUBJECTS | Indicates whether a site is restricted from adding subjects, as configured by a site manager |
| 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 |
| 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 |
| SITE_STUDY_VERSION | The study version assigned to the site, as configured by a site manager |

**Table 3-10 (Cont.) Data elements in the Site folder**

| Data element | Description |
|---|---|
| DRUG_DESTRUCTION_CAPABLE | Indicates whether the site is drug destruction capable or not, as configured by the study or site 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 |
| 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 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second 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 |

**Table 3-10 (Cont.) Data elements in the Site folder**

| Data element | Description |
|---|---|
| SHIPPING_EMAIL | Email address associated with the shipping address |

## Subject (Required) folder

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

**Table 3-11 Data elements in the Subject folder**

| Data element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| OLD_SUBJECT_NUMBER | A subject's previously assigned number in the system |
| DOB | Indicates the date of birth.<br>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.<br>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.<br>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.<br>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.<br>Currently, this is a placeholder column that does not contain any data. This column is planned for a future release. |
| SUBJECT_TRANSFER_ID | The unique numeric identifier created if a subject is transferred |
| CODE_BREAK | Indicates whether a subject went through a Code Break event |

## Event folder

This table describes data elements in the Events folder.

**Table 3-12 Data elements in the Event folder**

| Data element | Description |
|---|---|
| EVENT_TYPE | Displays the type of event (visit started, visit completed) |

## Audit folder

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

**Table 3-13 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 |
| COMMENT | 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.<br>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 Health IAMS. |
| IS_CURRENT | Audit trail field to display either current status or full audit trail of the data |

## Aggregations

This table describes data elements in the Aggregations table.

**Table 3-14 Data elements in the Aggregations folder**

| Data element | Description |
|---|---|
| TOTAL_VISITS | The total number of visits in a study version. This count does not include unscheduled visits. |

**Table 3-14 (Cont.) Data elements in the Aggregations folder**

| Data element | Description |
|---|---|
| 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. |
| 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_COMPLETED_VISITS | The total number of completed forms associated with visits |
| 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. |

## Reference folder

This table describes data elements in the Reference folder.

**Table 3-15 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 | A number that represents the unique identifier of a subject. |
| SOFTWARE_VERSION_NUMBER | A number that represents an incremental increase every time a data point is modified. |
| USER_WID | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| 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. |
| DESCRIPTION | This is a placeholder column that does not contain any data. |
| COUNT | Represents the count of subjects. |

# Subject Forms dataset

With the Subject Forms dataset you can analyze and visualize customized subject forms data in Oracle Clinical One Analytics.

**Modes**

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

**Roles that can run the report**

Any user that's assigned the *Run the Subject Forms Dataset* permission can generate this report.

**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

Browse descriptions of data elements included in this dataset:



# Study folder

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

**Table 3-16 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_MODE | Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active. |
| STUDY_TITLE | A protocol's title as specified by the study manager |
| STUDY_REFNAME | 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 | Indicates the therapeutic area 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_PHASE | A study's phase as indicated 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 |

## Country folder

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

**Table 3-17 Data elements in the Country folder**

| Data element | Description |
|---|---|
| COUNTRY_WID | A number that represents the unique identifier of a country |
| COUNTRY_NAME | Indicates the full name of the site country, as specified by a site manager |

## Site folder

This table describes the 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_STREET_1 | A site's first address as entered by the site manager when they created or last modified the site |

| 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 |
| 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 |
| 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 |
| DEA_NUMBER | Indicates the DEA Registration Number as defined by a site manager |
| DRUG_DESTRUCTION_CAPABLE | Indicates whether the site is drug destruction capable or not, as configured by the study or site manager |
| 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 |
| 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 |
| 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 |
| 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 | 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 |

| Data Element | Description |
|---|---|
| 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 |
| SITE_NAME | The name of the site |
| SHIPPING_ADDRESS_1 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second 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_ATTENTION | Indicates the name of the person who will receive shipments at the site, as specified by a site manager |
| SHIPPING_EMAIL | Email address associated with the shipping address |
| SITE_STATUS | A site's status at the moment the report is run. For example, a site's status might be New, Active, or Retired at the time you are including this data in a report or dashboard |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |
| SITE_ID_NAME | Indicates the site ID as entered by a site manager when they created or last modified a site |
| SITE_STUDY_VERSION | The study version assigned to the site, as configured by a site manager |

## Subject folder

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

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| SUBJECT_STATE | A subject's state |

## Event folder

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

| Data Element | Description |
|---|---|
| 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_IS_REQUIRED | Indicates whether or not a visit is required |
| IS_SCHEDULED_VISIT | Indicates whether the visit is scheduled or not |
| SCHEDULED_FROM_EVENT_WID | A number that represents the unique identifier of the previously scheduled event |
| SCHEDULED_FROM_EVENT_NAME | The previous visit to this visit, as defined in the study design |
| 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 (visit started, visit completed) |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| 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, as entered by a study designer |

| Data Element | Description |
|---|---|
| VISIT_WINDOW_AFTER_HOURS | Indicates how many hours after the scheduled date and time the visit can occur, as entered by a study designer |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |

## Form (Required) folder

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

| Data Element | Description |
|---|---|
| FREEZE | Indicates whether a question is frozen or not by a data manager or CRA |
| VERIFIED | Indicates whether a question is verified or not by a CRA.<br>Indicates whether a question is verified or not by a CRA.<br>Data element can be populated with the following values:<br>• VERIFIED: A question, form, or visit is verified.<br>• UNVERIFIED: A question, form, or visit is unverified. |
| SIGNED | Indicates whether a question is signed by a PI or not |
| FORM_NAME | The name of the form, as specified by the study designer |
| FORM_REFNAME | A form's reference name |
| REPEAT_SEQUENCE_NUMBER | Refers to the row instance number of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** indicates the repeating form number. |
| REPEAT_FORM_NUMBER | • **Two section forms:** indicates the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** this value will be null. |
| OUTER_REPEAT | Refers to the *Form Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique identifier of the non-repeating section of the form, the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** unique numeric identifier of the repeating form. |

| Data Element | Description |
|---|---|
| INNER_REPEAT | Refers to the *Section Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** this value will be null. |
| FORM_STATUS | Can be valid or invalid. Invalid form status indicates there are items within the form with a validation failure |
| IS_REPEATING | Indicates whether or not it is a repeating form |
| IS_ROLLOVER | Indicates whether the form contains a rollover type of question |

## Form association folder

| Data element | Description |
|---|---|
| ASSOCIATED_EVENT_INSTANCE_NUM | The unique identifier for an associated event. |
| 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. |

**Note:**

If the visit is not *UnScheduleAble Visit*, this field will not be populated with any value.

## Audit folder

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

| Data Element | Description |
|---|---|
| IS_CURRENT | Audit trail field to display either current status or full audit trail of the data |

| 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 the 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 |

## Aggregations folder

This table describes the data elements included 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 | A number that represents the unique identifier of a subject. |
| EVENT_WID | A number that represents the unique identifier of an event. |
| SUBJECT_EVENT_INST_FORM_WID | A number that represents the unique identifier of a subject form associated with a specific visit. |
| FORM_WID | A number that represents the unique identifier of a form. |
| USER_WID | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| 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. |
| 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. |

| Data Element | Description |
|---|---|
| COUNT | Represents the count of forms. |

# Subject Form Items dataset

The Subject Form Items dataset allows you to export data related to questions in forms in a flexible manner and analyze and visualize this data in Oracle Clinical One Analytics.

### Modes

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

### Roles that can run the report

Any user that's assigned the *Run the Subject Form Items Dataset* permission can generate this report. The study roles that are assigned this permission include:

### 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:

- How many subjects have an incomplete form at a specific site for a particular visit
- 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
- All subjects with a specified tumor size.
- Show all skipped and scheduled visits for a subject.
- Show all missing forms and questions for a subject.
- Build a report to project how much data will be collected at a site over a period of time to schedule monitoring visits.
- Identify information to create a schedule of when forms should be started for a subject.

Browse descriptions of data elements included in this dataset:

- Study folder
- Site 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 3-18 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_MODE | Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active. |
| STUDY_TITLE | A protocol's title as specified by the study manager |
| STUDY_REFNAME | 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 | Indicates the therapeutic area 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_PHASE | A study's phase as indicated 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.

| Data element | Description |
|---|---|
| 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 |
| 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 |

| Data element | Description |
|---|---|
| SHIPPING_ADDRESS_1 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second 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 |
| SITE_NAME | Indicates the site's name as entered by a site manager when they created or last modified a site |
| INVESTIGATOR | A Principal Investigator's Full Name as listed when the site manager created the site |
| DRUG_DESTRUCTION_CAPABLE | Flag that defines if the kit type is destructible at the site or not |
| PI_PREFIX | The principal investigator's prefix at the site |
| ADD_SUBJECTS | Flag that enables or prevents site users from adding subjects at one or multiple sites |
| SCREEN_SUBJECTS | Flag that enables or prevents site users from screening subjects at one or multiple sites |
| RANDOMIZE_SUBJECTS | Flag that enables or prevents site users from randomizing subjects at one or multiple sites |
| 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 |
| DEA_NUMBER | The DEA registration number |
| 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 |
| 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 | Number of initial subjects included in the SDV strategy |

| Data element | Description |
|---|---|
| INITIAL_SUBJECTS_SDV_TYPE | Type of Source Data Verification: All Questions or Critical Questions |
| 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 |
| 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 |
| SITE_ID_NAME | Indicates the site ID as entered by a site manager when they created or last modified a site |
| SITE_STUDY_VERSION | The study version assigned to the site, as configured by a site manager |
| SITE_STATUS | Indicates the status of a site whether it is New, Active, or Retired. |

## Subject folder

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

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| SUBJECT_STATE | A subject's state |

## Event folder

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

| Data Element | Description |
|---|---|
| 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 |
| EVENT_INSTANCE_NUM | Indicates the unscheduled visit instance number as designed by the study designer |
| VISIT_IS_REQUIRED | Indicates whether or not a visit is required |
| IS_SCHEDULED_VISIT | Indicates whether the visit is scheduled or not |

| Data Element | Description |
|---|---|
| SCHEDULED_FROM_EVENT_WID | A number that represents the unique identifier of the previously scheduled event |
| SCHEDULED_FROM_EVENT_NAME | The previous visit to this visit, as defined in the study design |
| VISIT_STATUS | Indicates a visit's status in the system<br>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.<br>. |
| 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 (visit started, visit completed) |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| 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, as entered by a study designer |
| VISIT_WINDOW_AFTER_HOURS | Indicates how many hours after the scheduled date and time the visit can occur, as entered by a study designer |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |

## Form folder

This table describes the data elements included in the 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 |

| Data Element | Description |
|---|---|
| FORM_STATUS | Can be valid or invalid. Invalid form status indicates there are items within the form with a validation failure |
| IS_ROLLOVER | Indicates whether or not it is a rollover question |
| IS_REPEATING | Indicates whether or not the form is repeating |
| REPEAT_SEQUENCE_NUMBER | Refers to the row instance number of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** indicates the repeating form number. |
| REPEAT_FORM_NUMBER | • **Two section forms:** indicates the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** this value will be null. |
| OUTER_REPEAT | Refers to the *Form Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique identifier of the non-repeating section of the form, the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** unique numeric identifier of the repeating form. |
| INNER_REPEAT | Refers to the *Section Repeat* values of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** this value will be null. |

## Item (Required) folder

This table describes the data elements included in the Item (Required) 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 |
| MONTH_VALUE | If the question type is Date/Time, this field is populated with the month value (1-12) |

| Data Element | Description |
|---|---|
| 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) |
| 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) |
| UTC_DATETIME_VALUE | Indicates the date and time in UTC for a Date/ Time type of question |
| ITEM_D | If the question has a decode value, it is populated in this field |
| ITEM_R | The raw value of the form item value |
| ITEM_F | The formatted value of the form item value |
| ITEM_TYPE | The form item's question type |
| ITEM_WID | A number that represents the unique identifier of a question |
| 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 |
| NUM_VALUE | If the question type is a calculation, measurement, or number, this field is populated with that number |
| VALIDATION_STATUS | Indicates if a form item passed validation. For example, if the question was entered correctly and a rule was not broken. |
| VALIDATION_FAILURE | Reason for failure if validation status is failed or the rule validation failed |
| QUESTION_TYPE | Indicates the format of the question |
| QUESTION_HINT | Indicates information that can be provided as a hint to help answer a question. |
| 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 |
| SECOND_VALUE | If the question type is Date/Time, this field is populated with the second value (0-59) |
| VALUE | The raw value of the form question value (can be an array in questions with decodes) |
| REFERENCE_CODE | A form's reference code |
| HIDDEN | Indicates whether or not is hidden |
| NORMALIZED_VALUE | Currently not populated |
| FREEZE | Indicates whether a question is frozen or not by a data manager or CRA |

| Data Element | Description |
|---|---|
| VERIFIED | Indicates whether a question is verified or not by a CRA.<br>Data element can be populated with the following values:<br>• VERIFIED: A question, form, or visit is verified.<br>• UNVERIFIED: A question, form, or visit is unverified. |
| SIGNED | Indicates whether a question is signed by a PI or not |

## Audit folder

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

**Table 3-19 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 |
| COMMENT | 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.<br>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 Health 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 included in the Reference folder.

| Data Element | Description |
|---|---|
| PARENT_WID | Currently not populated. |
| STUDY_WID | A number that represents the unique identifier of the study. |

| Data Element | Description |
|---|---|
| SITE_WID | A number that represents the unique identifier of a site. |
| SUBJECT_WID | A number that represents the unique identifier of a subject. |
| EVENT_WID | A number that represents the unique identifier of an event. |
| ROOT_WID | Currently not populated. |
| USER_WID | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| FORM_WID | A number that represents the unique identifier of a form. |
| SUBJECT_STATE | A subject's state. |
| SCHEDULED_FROM_EVENT_WID | A number that represents the unique identifier of the previously scheduled event. |
| DH_TIMESTAMP | A timestamp that indicates when the data became available in the dataset. |
| SUBJECT_EVENT_INST_FORM_WID | A number that represents the unique identifier of a subject form associated with a specific visit. |
| COUNT | Represents the count of items. |

# Blinded Subject Event dataset

You can use the Blinded Subject Events dataset to analyze and visualize blinded subject event data in Oracle Clinical One Analytics.

### Modes

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

### Roles that can run the report

Any user that's assigned the *Run the Blinded Subject Event Dataset* permission can generate this report.

### 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?

Browse descriptions of data elements included in this dataset:

- Study folder

## Study folder

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

**Table 3-20 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_MODE | Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active. |
| STUDY_TITLE | A protocol's title as specified by the study manager |
| STUDY_REFNAME | 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 | Indicates the therapeutic area 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_PHASE | A study's phase as indicated 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 |

## Country folder

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

**Table 3-21 Data elements in the Country folder**

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

## Site folder

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

| Data element | Description |
|---|---|
| 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 |
| 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 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second 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 |
| SITE_NAME | Indicates the site's name as entered by a site manager when they created or last modified a site |
| INVESTIGATOR | A Principal Investigator's Full Name as listed when the site manager created the site |
| DRUG_DESTRUCTION_CAPABLE | Flag that defines if the kit type is destructible at the site or not |
| PI_PREFIX | The principal investigator's prefix at the site |
| ADD_SUBJECTS | Flag that enables or prevents site users from adding subjects at one or multiple sites |

| Data element | Description |
|---|---|
| SCREEN_SUBJECTS | Flag that enables or prevents site users from screening subjects at one or multiple sites |
| RANDOMIZE_SUBJECTS | Flag that enables or prevents site users from randomizing subjects at one or multiple sites |
| 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 |
| DEA_NUMBER | The DEA registration number |
| 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 |
| 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 | Number of initial subjects included in the SDV strategy |
| INITIAL_SUBJECTS_SDV_TYPE | Type of Source Data Verification: All Questions or Critical Questions |
| 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 |
| 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 |
| SITE_ID_NAME | Indicates the site ID as entered by a site manager when they created or last modified a site |
| SITE_STUDY_VERSION | The study version assigned to the site, as configured by a site manager |
| SITE_STATUS | Indicates the status of a site whether it is New, Active, or Retired. |

## Subject folder

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

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| SUBJECT_STATE | A subject's state |

## Event folder

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

| Data element | Description |
|---|---|
| FREEZE | Indicates whether a question is frozen or not by a data manager or CRA |
| VERIFIED | Indicates whether a question is verified or not by a CRA.<br>Data element can be populated with the following values:<br>• VERIFIED: A question, form, or visit is verified.<br>• UNVERIFIED: A question, form, or visit is unverified. |
| SIGNED | Indicates whether a question is signed by a PI or not |
| IS_REQUIRED | Indicates whether the visit is required or not. |
| 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_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 (visit started, visit completed) |
| EVENT_INSTANCE_NUM | Indicates the unscheduled visit instance number as designed by the study designer |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| DELAY_DAYS | The number of days between the prior scheduled visit |

| Data element | Description |
|---|---|
| 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 |
| EVENT_REFNAME | The event's reference name |
| EVENT_ID_NAME | The event's id |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |

## Kit folder

This table describes the data elements in the Kit folder.

**Table 3-22 Data elements in the Kit folder**

| Data element | Description |
|---|---|
| RAND_NUMBER | Unique number for randomization |
| KIT_NUMBERS | Indicates a kit's number |

## Audit folder

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

**Table 3-23 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 |

**Table 3-23 (Cont.) Data elements in the Audit folder**

| Data element | Description |
|---|---|
| COMMENT | 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.<br>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 Health IAMS. |
| IS_CURRENT | Audit trail field to display either current status or full audit trail of the data |

## Aggregations folder

This table describes the data elements in the Aggregations folder.

**Table 3-24 Data elements in the Aggregations folder**

| Data element | Description |
|---|---|
| FORM_TOTAL_COUNT | Count of all forms |
| FORM_COMPLETED_COUNT | Count of completed forms |

## 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. |
| SUBJECT_WID | A number that represents the unique identifier of a subject. |
| 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 | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| 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. |

# Unblinded Subject Event dataset

You can use the Unblinded Subject Events dataset to analyze and visualize unblinded subject event data in Oracle Clinical One Analytics.

### Modes

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

### Roles that can run the report

Any user that's assigned the *Run the Unblinded Subject Event Dataset* permission can generate this report.

### 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?

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) |

| Data element | Description |
|---|---|
| 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 |
| 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 |


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


## Study folder

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

**Table 3-25 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_MODE | Indicates the study mode used in the referencing data in a custom report, such as Testing, Training, or Active. |
| STUDY_TITLE | A protocol's title as specified by the study manager |
| STUDY_REFNAME | 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 |

**Table 3-25 (Cont.) Data elements in the Study folder**

| Data element | Description |
|---|---|
| THERAPEUTIC_AREA | Indicates the therapeutic area 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_PHASE | A study's phase as indicated 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 |

## Country folder

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

**Table 3-26 Data elements in the Country folder**

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

## Site folder

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

| Data element | Description |
|---|---|
| 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 |
| 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 | A site's first shipping address as entered by the site manager when they created or last modified the site |
| SHIPPING_ADDRESS_2 | A site's second shipping address as entered by the site manager when they created or last modified the site |

| Data element | Description |
|---|---|
| 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 |
| SITE_NAME | Indicates the site's name as entered by a site manager when they created or last modified a site |
| INVESTIGATOR | A Principal Investigator's Full Name as listed when the site manager created the site |
| DRUG_DESTRUCTION_CAPABLE | Flag that defines if the kit type is destructible at the site or not |
| PI_PREFIX | The principal investigator's prefix at the site |
| ADD_SUBJECTS | Flag that enables or prevents site users from adding subjects at one or multiple sites |
| SCREEN_SUBJECTS | Flag that enables or prevents site users from screening subjects at one or multiple sites |
| RANDOMIZE_SUBJECTS | Flag that enables or prevents site users from randomizing subjects at one or multiple sites |
| 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 |
| DEA_NUMBER | The DEA registration number |
| 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 |
| 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 | Number of initial subjects included in the SDV strategy |
| INITIAL_SUBJECTS_SDV_TYPE | Type of Source Data Verification: All Questions or Critical Questions |
| 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 |

| Data element | Description |
|---|---|
| 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 |
| SITE_ID_NAME | Indicates the site ID as entered by a site manager when they created or last modified a site |
| SITE_STUDY_VERSION | The study version assigned to the site, as configured by a site manager |
| SITE_STATUS | Indicates the status of a site whether it is New, Active, or Retired. |

## Subject folder

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

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| SUBJECT_STATE | A subject's state |

## Event (Required) folder

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

| Data element | Description |
|---|---|
| FREEZE | Indicates whether a question is frozen or not by a data manager or CRA |
| VERIFIED | Indicates whether a question is verified or not by a CRA.<br>Data element can be populated with the following values:<br>• VERIFIED: A question, form, or visit is verified.<br>• UNVERIFIED: A question, form, or visit is unverified. |
| SIGNED | Indicates whether a question is signed by a PI or not |
| IS_REQUIRED | Indicates whether the visit is required or not. |
| 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 |

| 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 (visit started, visit completed) |
| EVENT_INSTANCE_NUM | Indicates the unscheduled visit instance number as designed by the study designer |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| 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 |
| EVENT_REFNAME | The event's reference name |
| EVENT_ID_NAME | The event's id |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |

## Kit folder

This table describes the data elements in the Kit folder.

| Data element | Description |
|---|---|
| KIT_NUMBER | A unique number assigned to the individual kits (serialized kit distribution) |
| KIT_TYPE_SRC_ID | A kit type's ID as entered by a study designer when the kit was created |

| Data element | Description |
|---|---|
| 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 |
| TREATMENT_NAME | Indicates the treatment arm title as entered by a study designer |
| RAND_NUMBER | Unique number for the randomization |
| 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 |

## Audit folder

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

**Table 3-27 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 |

**Table 3-27 (Cont.) Data elements in the Audit folder**

| Data element | Description |
|---|---|
| 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 |
| COMMENT | 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.<br>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 Health IAMS. |
| IS_CURRENT | Audit trail field to display either current status or full audit trail of the data |

## Aggregations folder

This table describes the data elements in the Aggregations folder.

**Table 3-28 Data elements in the Aggregations folder**

| Data element | Description |
|---|---|
| FORM_TOTAL_COUNT | Count of all forms |
| FORM_COMPLETED_COUNT | Count of completed forms |

## 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. |
| 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 | A number that represents the unique identifier of a subject. |
| 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. |

| Data element | Description |
|---|---|
| USER_WID | A number that represents the unique identifier of a user in Oracle Clinical One Platform. |
| 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 cohorts's numeric identifier. |
| COUNT | Represents the count of unblinded events. |

# Unblinded Kits dataset

You can use an Unblinded Kits dataset to analyze and visualize customized supply data in Oracle Clinical One Analytics.

### Modes

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

### Roles that can run the report

Any user that's assigned the *Run the Unblinded Kits Dataset* permission can work with this dataset and generate custom reports.

### 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 a study.
- 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.

Browse description of data elements included in this dataset:

- Study folder
- Site folder
- Country folder
- Subject folder
- Event folder
- Randomization folder
- Lot folder
- Shipment folder

- Kit (Required) folder
- Calculated dose folder
- Audit folder
- Reference folder

## Study folder

This table describes the elements in the Study folder.

**Table 3-29 Data elements in the Study folder**

| Data element | Description |
|---|---|
| STUDY_MODE | Indicates the study mode used in 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 | 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 |
| 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.

| Data element | Description |
|---|---|
| ADD_SUBJECTS | This is a flag that can be either turned on or off by a site manager. The flag enables or prevents site users from adding subjects at one or multiple sites.<br>This data element is only available for sites. |
| ADDRESS_CITY | For a site, this data element indicates a site's city as entered by the site manager when they created or last modified the site.<br>For a depot, this data element indicates a depot's city as entered by the clinical supply manager when they created or last modified the depot. |

| Data element | Description |
|---|---|
| ADDRESS_COUNTRY | For a site, this data element indicates 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.<br>For a depot, this data element indicates a depot's country as entered by the clinical supply manager when they created or last modified the depot. The field displays the country ISO code. |
| ADDRESS_POSTALCODE | Indicates the ZIP postal code associated with a site or depot address. |
| ADDRESS_STATE_OR_PROV_OR_CNTY | For a site, it indicates a site's state, province, or county as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates a depot's state, province, or country as entered by the clinical supply manager when they created or last modified the depot. |
| ADDRESS_STREET_1 | For a site, it indicates the first address as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates the first address as entered by the clinical supply manager when they created or last modified the depot. |
| ADDRESS_STREET_2 | For a site, it indicates the secondary address as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates the secondary address as entered by the clinical supply manager when they created or last modified the depot. |
| DEA_NUMBER | Indicates a site's DEA registration number. This data element is only available for sites. |
| DISPENSE_TO_SUBJECTS | This is a flag that can be either turned on or off by a site manager. The flag enables or prevents site users from dispensing kits, devices, or performing dose changes for subjects at one or multiple sites.<br>This data element is only available for sites. |
| DRUG_DESTRUCTION_CAPABLE | Indicates whether a depot or a site can destroy the kit type at their organization. |
| EMAIL | For a site, it indicates the email address of the site as entered by the site administrator when they created or last modified the site.<br>For a depot, it indicates the email address of the depot as entered by the clinical supply manager when they created or last modified the depot. |

| Data element | Description |
|---|---|
| EXPIRATION | Indicates the expiration date of the DEA Registration Number as defined by a site manager.<br>This data element is only available for sites. |
| FAX | For a site, it indicates the contact fax number as entered by the site administrator when they created or last modified the site.<br>For a depot, it indicates the contact fax number as entered by the clinical supply manager when they created or last modified the depot. |
| INITIAL_SUBJECTS_COUNT | Indicates the number of initial subjects included in the source data verification (SDV) strategy, as specified by the study manager.<br>This data element is only available for sites. |
| INITIAL_SUBJECTS_SDV_TYPE | Indicates the type of source data verification that must be performed by a Clinical Research Associate (CRA): All Questions or Critical Questions.<br>This data element is only available for sites. |
| PHONE | For a site, it indicates the contact phone number as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates the contact phone number as entered by the clinical supply manager when they created or last modified the depot. |
| PI_PREFIX | Indicates a principal investigator's prefix at the site.<br>This data element is only available for sites. |
| RANDOMIZE_SUBJECTS | This is a flag that can be either turned on or off by a site manager. The flag enables or prevents site users from randomizing subjects at one or multiple sites.<br>This data element is only available for sites. |
| REMAINING_SUBJECTS_PERCENTAGE | Indicates the number of remaining subjects included in the source data verification (SDV) strategy, as specified by the study manager.<br>This data element is only available for sites. |
| REMAINING_SUBJECTS_SDV_TYPE | Indicates the type of source data verification that a Clinical Research Associate (CRA) must perform for the remaining subjects at a site: All Questions or Critical Questions.<br>This data element is only available for sites. |
| SCREEN_SUBJECTS | This is a flag that can be either turned on or off by a site manager. The flag enables or prevents site users from screening subjects at one or multiple sites.<br>This data element is only available for sites. |

| Data element | Description |
|---|---|
| SDV_GROUP_NAME | Indicates the name of the source data verification (SDV) strategy, as entered by the study manager. |
| SHIPPING_ADDRESS_1 | For a site, it indicates a site's first shipping address as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates a depot's first shipping address as entered by the clinical supply manager when they created or last modified the depot. |
| SHIPPING_ADDRESS_2 | For a site, it indicates a site's secondary shipping address as entered by the site manager when they created or last modified the site.<br>For a depot, it indicates a depot's secondary shipping address as entered by the clinical supply manager when they created or last modified the depot. |
| SHIPPING_ATTENTION | Indicates the name of the person who will receive shipments at the site, as specified by a site manager.<br>This data element is only available for sites. |
| SHIPPING_CITY | Indicates the city associated with the shipping address, as entered by the site manager when they created or last modified the site. |
| SHIPPING_COUNTRY | Indicates the country associated with the shipping address, as entered by the site manager when they created or last modified the site.<br>This data element is only available for sites. |
| SHIPPING_EMAIL | Indicates the email address associated with the shipping address, as entered by the site manager when they created or last modified the site.<br>This data element is only available for sites. |
| SHIPPING_FAX | Indicates the fax number associated with the shipping address, as entered by the site manager when they created or last modified the site.<br>This data element is only available for sites. |
| SHIPPING_PHONE | Indicates the phone number associated with the shipping address, as entered by the site manager when they created or last modified the site.<br>This data element is only available for sites. |
| SHIPPING_STATE_OR_PROV_OR_CNTY | Indicates the state, province, or county associated with the shipping address, as entered by the site manager when they created or last modified the site.<br>This data element is only available for sites. |

| Data element | Description |
|---|---|
| SHIPPING_ZIP | Indicates the ZIP postal code associated with the shipping address, as entered by the site manager when they created or last modified the site. |
| SITE_NAME | For a site, it indicates a site's name as entered by a site manager when they created or last modified a site.<br>For a depot, it indicates a depot's name as entered by a clinical supply manager when they created or last modified a depot. |
| SITE_ID_NAME | For a site, it indicates the site ID as entered by a site manager when they created or last modified a site.<br>For a depot, it indicates the depot ID as entered by a clinical supply manager when they created or last modified a depot. |
| SITE_STATUS | For both a depot and a site, this data element indicates its status whether it is New, Active, or Retired. |
| SITE_STUDY_VERSION | Indicates the study version assigned to the site, as configured by a site manager.<br>This data element is only available for sites. |
| SITE_TYPE | Indicates an organization's type, whether it is a site or a depot. |
| TIMEZONE | Indicates the time zone the site or depot is currently placed on as specified by a site manager or a clinical supply manager. |

## Country folder

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

**Table 3-30 Data elements in the Country folder**

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

## Subject folder

| Data Element | Description |
|---|---|
| SUBJECT_NUMBER | A subject's assigned number in the system |
| SUBJECT_STATE | A subject's state |

## Event folder

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

| Data element | Description |
|---|---|
| VISIT_IS_REQUIRED | Indicates whether the visit or event in the study is required or not, as specified by the study designer when they created the visit or event. |
| 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_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 (visit started, visit completed) |
| PROJECTED_VISIT_DATE | Date when the next scheduled dispensation should take place in the study |
| PROJECTED_VISIT_START_DATE | Date when the next scheduled dispensation should start in the study |
| PROJECTED_VISIT_END_DATE | Date when the next scheduled dispensation should end in the study |
| 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 |
| EVENT_REFNAME | The event's reference name |
| EVENT_TITLE | The event's title |
| VISIT_ORDER | The order in which subject visits occur, as configured in the study design |

## Randomization folder

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

| Data element | 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:<br>• **Blinded**: if blinded users should never see any of the titles of the treatment arms used in the randomization design.<br>• **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:<br>• **None**: this indicates that the study has no cohorts<br>• **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.<br>• **Demography**: this indicates that the study contains population groups according to demographic criteria, such as age. |
| RE_RANDOMIZATION | Indicates whether the study designer chose to use the current randomiation 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. |

| Data element | Description |
|---|---|
| RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES | Indicates the option that a study designer chose (Yes or No) when configuring this setting.<br>• **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.<br>• **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. |
| ASSIGN_SKIPPED_RANDOMIZATION_NUMBERS | Indicates the option that a study designer chose (Yes or No) when configuring this setting.<br>• **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.<br>• **No**: indicates that skipped randomization numbers are never assigned to subjects. |
| RAND_NUMBER | Indicates the randomization number assigned to each subject in a 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:<br>• **New**: If they're newly enrolled in the study at the time that you are creating a report using this data element.<br>• **Screened**: If they're screened in the study at the time that you are creating a report using this data element.<br>• **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 during which a subject has been randomized in the study. |

## Lot folder

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

| Data element | Description |
|---|---|
| MANUFACTURING_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. |
| BLINDED_LOT_SHORT_NAME | Indicates an alternative blinded lot label, as specified by the clinical supply manager when they created the blinded lot.<br>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. |
| MANUFACTURING_LOT_SHORT_NAME | Indicates an alternative manufacturing lot label, as specified by the clinical supply manager when they created the manufacturing lot.<br>A manufacturing lot short name can be used when your organization's labeling conventions differ from the lot name supplied by the depot. |
| MANUFACTURING_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. |
| MANUFACTURING_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. |
| MANUFACTURING_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.

| Data element | 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:<br>• Pending<br>• In Transit<br>• Received<br>• Cancelled<br>• Lost<br>• Confirmed<br>• Invalid<br>• Pending Destruction<br>• Received for Destruction<br>• Destroyed |
| SHIPMENT_CREATED_DATE | Indicates the date a shipment was created, whether it is a:<br>• **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).<br>• **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 Project Manager). 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. |
| TRACKING_NUMBER | Indicates a shipment's tracking number, as specified by the depot user. |

## Kit (Required) folder

This table describes the data elements included in the Kit (Required) 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:<br>• Investigation Product<br>• Device<br>• Kit Type Titration<br>For more information on these kit types, see the following topics:<br>• Define the kits for investigational products<br>• Define the kits for devices<br>• 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:<br>• Activity Watch<br>• Blood Pressure Monitor<br>• Glucose Monitor<br>• Weight Scale<br>• ECG Reader<br>• Spirometer<br>• Mobile App<br>• Smart Pill Bottle<br>• Pulse Oximeter<br>• Wearable Patch<br>• 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:<br>• No Connection<br>• Device to Cloud<br>• Cloud to Cloud<br>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.<br>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:<br>• **Blinded**: if blinded users should never see the kit type description.<br>• **Unblinded**: if blinded users should always see the kit type description.<br>• **Unblinded Pharmacist**: if blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types |

| 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:<br>• Blister Pack<br>• Bottle<br>• Device<br>• Syringe<br>• Topical Ointment<br>• Vial<br>• Inhaler<br>• Infusion<br>• Box<br>• Other |
| MINIMUM_KITS_TO_SHIP | Indicates the minim number of kits to include in each shipment to meet pacakinging 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.<br>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. |
| 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. |
| TITRATION | Indicates if a kit type is part of a kit type titration or not. Values can be 1 or 0. |
| KIT_STATUS | Indicates a kit's status in the study's inventory.<br>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. |
| 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 barcode as generated by the sysem. |
| DISPENSATION_CONFIRMED | Indicates whether a kit's dispensation was confirmed by a site user or not |

| Data element | Description |
|---|---|
| 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 or not |
| 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 dispenstion 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 |

## 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 reference code of the question that is selected by the study designer to be used in calculating the appropriate dose. |

| Data element | Description |
|---|---|
| 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_PRECISION | Indicates the number of places after the decimal point that each dose should be calculated in, as specified by the study designer. |
| DOSE_ROUND_UP | Indicated for the rounding is performed to reach the dose precision, as specified by the study designer. |
| DOSE_FREQUENCY | Indicates how many doses the subject must consume, as specified by the study designer. |
| 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. |
| KITS_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. |

## Audit folder

**Table 3-31 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 |
| COMMENT | 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.<br>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 Health IAMS. |

**Table 3-31 (Cont.) 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 |

## Reference folder

This table describes the 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. |
| EVENT_WID | A number that represents the unique identifier of an event. |
| TREATMENT_ARM_WID | A number that represents the unique identifier of a treatment arm. |
| SHIPMENT_WID | A number that represents the unique identifier of a shipment. |
| KIT_TYPE_WID | A number that represents the unique identifier of a kit type. |
| KIT_DESIGN_WID | Indicates the numeric identifier of a kit's design. |
| INVENTORY_WID | Indicates the numeric identifier of the study's inventory. |
| 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. |
| SUBJECT_WID | Indicates a subject's numeric identifier. |
| COHORT_WID | Indicates a cohort's numeric identifier. |
| CALCULATED_DOSE_WID | Indicates the numeric identifier of a kit containing calculated doses. |
| USER_WID | Indicates a user's numeric identifier. |
| COUNT | Represents the count of kits. |

# Study Design dataset

You can use Study Design dataset to analyze and visualize data collection design data in Oracle Clinical One Analytics that will allow you to identify differences between study versions and across modes.

**Modes**

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

> **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 will be available to the following study roles:
>
> - Template - Study Designer
> - Template - View Study Design
> - Template - Data Manager
> - Template - User Administrator

**Roles that can run the report**

Any user that is assigned the *Run the Data Collection Design Dataset* permission can generate this report.

The study roles that are assigned this permission include:

- Template - Study Designer

**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

Browse description of data elements included in this dataset:

- Study folder
- Branch folder
- Event folder
- Form folder
- Item folder

- Reference folder

## Study folder

This table describes the data elements included 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 | 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 | Indicates the therapeutic area as specified by the study manager when they created the study |
| STUDY_PHASE | A study's phase as indicated 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. |
| 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 |
| MODIFIED_BY | The user who last modify the study. |

## 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 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. |

| Data element | Description |
|---|---|
| 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 in the Event folder

| Data element | Description |
|---|---|
| VISIT_IS_REQUIRED | Indicates whether or not a visit is required |
| 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 |

| Data element | Description |
|---|---|
| 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 folder

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

| Data element | Description |
|---|---|
| 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. |
| 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. |
| REPEAT_SEQUENCE_NUMBER | Refers to the row instance number of all applicable form types with repeating data:<br>• **Two section forms:** unique numeric identifier of the row in the repeating section.<br>• **Lab forms:** unique numeric identifier of the row in the repeating section that captures lab tests and results.<br>• **Repeating forms:** indicates the repeating form number. |
| REPEAT_FORM_NUMBER | • **Two section forms:** indicates the form instance number.<br>• **Lab forms:** defaulted to a value of 1.<br>• **Repeating forms:** this value will be null. |

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

## Item folder

This table describes the data elements included in the 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_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:<br>• Text questions:<br>– *Doesn't contain*<br>• Date/Time and Date of birth questions:<br>– *After*<br>– *On or After*<br>– *Before*<br>– *On or Before*<br>– *On*<br>– *Not On*<br>– *Not Between*<br>– *Range*<br>• Number and Age questions:<br>– *Greater Than*<br>– *Greater Than or Equal To*<br>– *Less Than*<br>– *Less Than or Equal To*<br>– *Is*<br>– *Not Equal To*<br>– *Not Between*<br>– *Range*<br>• Drop-down and checkboxes questions<br>– *Select at Least*<br>– *Select at Most*<br>– *Select Exactly*<br>– *Answer Must Be*<br>• Radio Buttons questions:<br>– *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:<br>• *Show Question*<br>• *Show Form*<br>• *Show Visit*<br>• *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:<br>• Dictionary<br>• Coding Item Type<br>• Tag for Central Coding |
| FORMAT | Specifies the answer format. For example an specific date format, or the number of decimals after the point |

## 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 | Indicates the unique numeric identifier of the form. |
| ITEM_WID | Indicates the unique numeric identifier of the form item. |
| MODIFIED_BY_WID | The unique numeric identifier of the user who last modify the study. |

# Kits and Randomization Design dataset

You can use Kits and Randomization Design dataset to analyze and visualize customized data in Oracle Clinical One Analytics that will allow you to understand kit definitions, randomization definitions, and dispensation schedules.

### Modes

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

### Roles that can run the report

Any user that is assigned the *Run the Kits and Randomization Design Dataset* permission can generate this report.

The study roles that are assigned this permission include:

- Template - Study Designer

### 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

Browse description of data elements included in this dataset:

- Study folder

## Study folder

This table describes the data elements included 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 | 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 | Indicates the therapeutic area as specified by the study manager when they created the study |
| STUDY_PHASE | A study's phase as indicated 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. |
| 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 |
| MODIFIED_BY | The user who last modify the study. |

## Randomization folder

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

| Data element | 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:<br>• **Blinded**: if blinded users should never see any of the titles of the treatment arms used in the randomization design.<br>• **Unblinded**: if blinded users should always see the titles of the treatment arms used in the randomization design. |
| COHORT_NAME | Indicates the cohort name in case cohorts are used in the randomization design. |
| COHORTTYPE | Indicates the type of cohort selected by a study designer when creating a randomization design:<br>• **None**: this indicates that the study has no cohorts<br>• **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.<br>• **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 **Yes** or **No**. |
| 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. |

| Data element | Description |
|---|---|
| RESTRICT_RANDOMIZATION_TO_AVAILABLE_KIT_TYPES | Indicates the option that a study designer chose (Yes or No) when configuring this setting.<br>• **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.<br>• **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. |
| ASSIGN_SKIPPED_RANDOMIZATION_NUMBERS | Indicates the option that a study designer chose (Yes or No) when configuring this setting.<br>• **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.<br>• **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 in the Event folder

| Data element | Description |
|---|---|
| VISIT_IS_REQUIRED | Indicates whether or not a visit is required |
| 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 |

| Data element | Description |
|---|---|
| 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 |

## Kit folder

This table describes the data elements included 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:<br>• Investigation Product<br>• Device<br>• Kit Type Titration<br>For more information on these kit types, see the following topics:<br>• Define the kits for investigational products<br>• Define the kits for devices<br>• 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:<br>• Activity Watch<br>• Blood Pressure Monitor<br>• Glucose Monitor<br>• Weight Scale<br>• ECG Reader<br>• Spirometer<br>• Mobile App<br>• Smart Pill Bottle<br>• Pulse Oximeter<br>• Wearable Patch<br>• Other |

| Data element | Description |
|---|---|
| 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:<br>• No Connection<br>• Device to Cloud<br>• Cloud to Cloud<br>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.<br>The values following values can be displayed: Yes or No. |
| DISTRIBUTION_SETTINGS | Indicates the type of distribution a kit has, as specified by the study designer. The following values can be displayed:<br>• **Blinded**: if blinded users should never see the kit type description.<br>• **Unblinded**: if blinded users should always see the kit type description.<br>• **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 a kit type's identifier, as specified by the study designer. For example, A. |
| TYPE | Indicates the supply type of the kit, as specified by the study designer. The following values can be displayed:<br>• Blister Pack<br>• Bottle<br>• Device<br>• Syringe<br>• Topical Ointment<br>• Vial<br>• Inhaler<br>• Infusion<br>• Box<br>• Other |
| MIN_KITS_TO_SHIP | Indicates the minim number of kits to include in each shipment to meet pacakaging 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.<br>For more information on this value, see Define the kits for investigational products. |
| SINGLE_UNIT_DOSE_VALUE | Indicates the amount of units in one single dose. |

| Data element | Description |
|---|---|
| SINGLE_UNIT_DOSE_UNITS | Indicates the unit in which the kit dose is measured. |
| TITRATION | Indicates whether a kit type titration is designed in the study or not. |
| 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 tht each dose should be calculated in, as specified by the study designer. |
| ROUND_UP_FOR | Indicated for the rounding is performed to reach the dose precision, as specified by the study designer.<br>In the dataset, a decimal value for a round-up number is displayed as a whole number. 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), the following numbers are displayed in this dataset:<br>• For the dose precision, the number 4 is displayed (this value represents the number of zeros after the decimal point of the round up number).<br>• 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. |
| KITS_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.

| Data element | Description |
|---|---|
| STUDY_WID | A number that represents the unique identifier of the study. |
| RAND_WID | Indicates the numeric identifier of the randomization design. |
| COHORT_WID | Indicates a cohort's numeric identifier. |
| 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. |
| KIT_WID | Indicates the numeric identifier of a kit. |
| MODIFIED_BY_WID | The unique numeric identifier of the user who modified the study. |

# 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 collected detailed and current data related to the statuses subjects in a study have.

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**<br>• **STUDY_PHASE**<br>• **THERAPEUTIC_AREA** | N/A |
| **Site** | • **ADDRESS_COUNTRY**<br>• **SITE_ID_NAME** | N/A |
| **Subject** | • **SUBJECT_NUMBER**<br>• **STATE**<br>• **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**. |

| Field | Description |
|---|---|
| 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.

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**<br>• **QUERY_COMMENT**<br>• **QUERY_AGE** | Drag and drop the data elements onto the **Rows** section, in the Grammar Panel. |
| **Item** | • **ITEM_NAME**<br>• **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 in a dataset
- Sort data in visualizations
- Undo and redo edits
- Refresh data in a project
- Adjust the Visualize Canvas Layout and properties
- Change visualization types
- Adjust visualization properties
- Apply color to visualizations
- Create and apply filters

4

# Projects and reports



## Access saved projects in Oracle Clinical One Analytics

Oracle Clinical One Analytics let you save visualization projects to continue your work in different sessions. Through the Projects page, you can access saved projects and reports 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 Data page. Other type content, including saved projects and reports, is available through the main menu.

1. Click on the menu icon (

   

   ) located at the top left corner of the screen.

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

   > **Tip:**
   >
   > You can use the available Search and Sort By filters to easly locate your work.
4. Click on the desired project or report to open, or click on the actions menu (

) to the left to see other options.

# Standard report templates in Oracle Clinical One Analytics

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

- 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 by saving the template to their own or a shared folder.

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:<br><br>**STUDY_ID_NAME**<br>A study ID as specified by the study manager when they created the study, such as a protocol acronym and protocol number<br><br>**STUDY_DESIGN_STATUS**<br>Indicates the study mode used in the referencing data in a custom report, such as *Testing*, *Approved*, or *Archived*.<br><br>**Note:**<br>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.<br><br>**STUDY_VERSION**<br>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.<br>**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.<br>**N** indicates no difference between versions exists. |
| VISIT_IS_REQUIRED | Indicates whether or not a visit is required |
| 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.<br>**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. |

| Data element | Description |
|---|---|
| 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 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.<br>**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:<br>• Text questions:<br>– *Doesn't contain*<br>• Date/Time and Date of birth questions:<br>– *After*<br>– *On or After*<br>– *Before*<br>– *On or Before*<br>– *On*<br>– *Not On*<br>– *Not Between*<br>– *Range*<br>• Number and Age questions:<br>– *Greater Than*<br>– *Greater Than or Equal To*<br>– *Less Than*<br>– *Less Than or Equal To*<br>– *Is*<br>– *Not Equal To*<br>– *Not Between*<br>– *Range*<br>• Drop-down and checkboxes questions<br>– *Select at Least*<br>– *Select at Most*<br>– *Select Exactly*<br>– *Answer Must Be*<br>• Radio Buttons questions:<br>– *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:<br>• *Show Question*<br>• *Show Form*<br>• *Show Visit*<br>• *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:<br>• Dictionary<br>• Coding Item Type<br>• Tag for Central Coding |
| FORMAT | Specifies the answer format. For example an specific date format, or the number of decimals after the point |

# 5 Revision history

| Date | Part number | Description |
|---|---|---|
| June 2021 | F56718-01 | Updated the month of the publication. |
| June 2021 | F56718-02 | Original version of the document. |