18 Help Index

***This page is currently in draft form and subject to change.**

Approved for publication by Riley Bianchi. Signed on 2022-05-02 4:36PM

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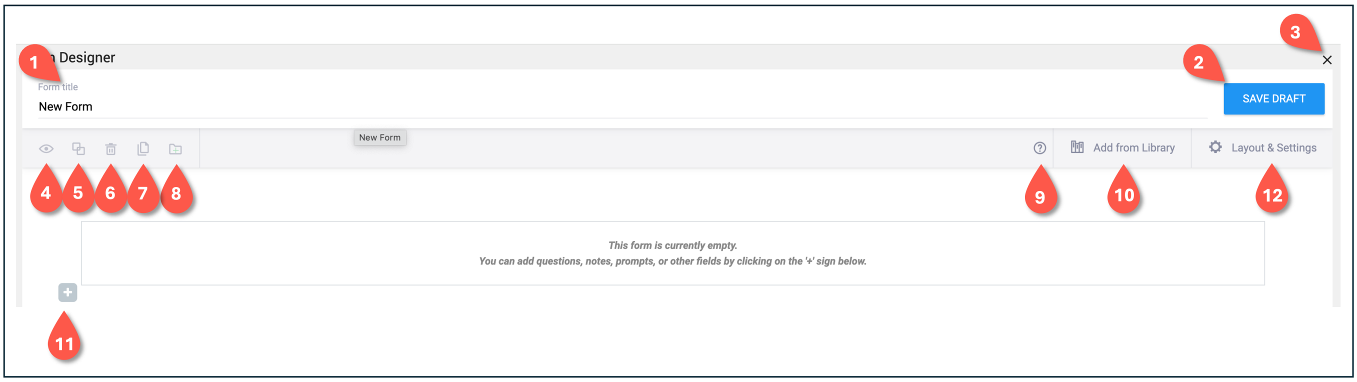
18.1 Form Designer

For full details of the functionality included in Form Designer, review **Using Form Designer**.



1. **Form Title**

    1. **The title of the Form can be updated from what was initially entered when the Form Card was created.**

2. **Save Draft**

    1. Save Draft saves the Form.

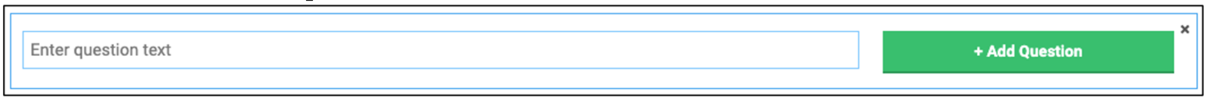
3. **Close Form Designer**

    1. Exit Form Designer by clicking the **X**.

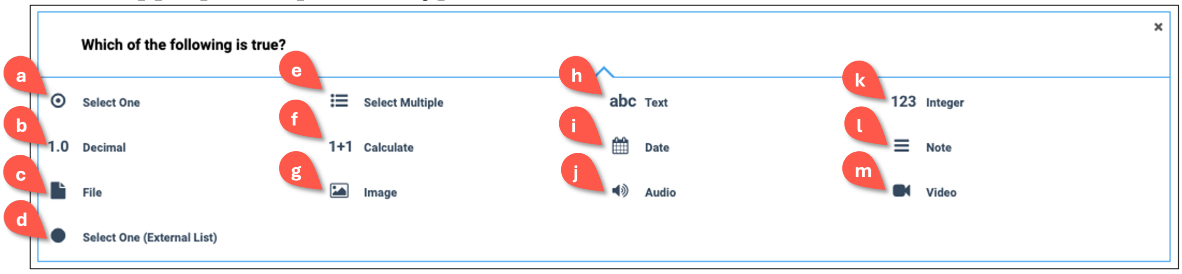
4. **Preview Form**

    1. Once Items have been created, the Form can be viewed as it will be seen by users in Study Runner. Simple validation of fields can be done within the Preview, with the exception of any Items utilizing cross-form logic.

5. **Create Group with Selected Questions**
    1. Once Items have been created, Layout Groups can be created by clicking on this icon.
6. **Delete Selected Items**
    1. Once Items have been created, they can be removed by clicking the trash can icon.
7. **Duplicate Selected Questions**
    1. Once Items have been created, they can be duplicated by clicking on this icon.
8. **Add Selected Questions to Library**
    1. Once Items have been created, they can be added to the Library by clicking on this icon.
9. **Help**
    1. Access the Form Designer Help page by clicking the question mark icon.
10. **Add an Item**
    1. Click the **+** to add an item to the Form
    2. Enter the text for the question and click **+ Add Question**.

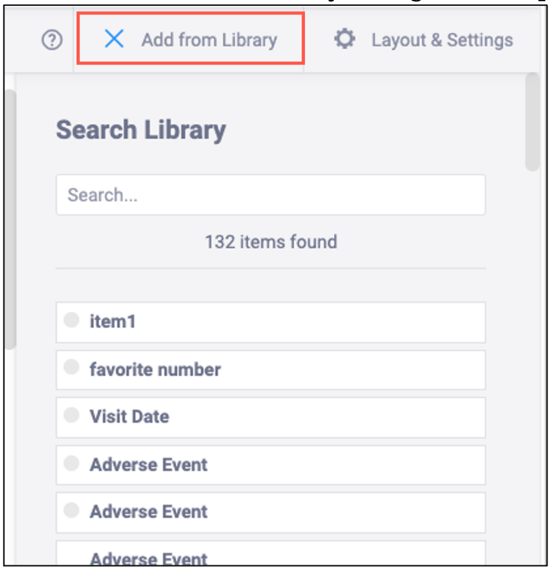


    3. Select the appropriate question type.

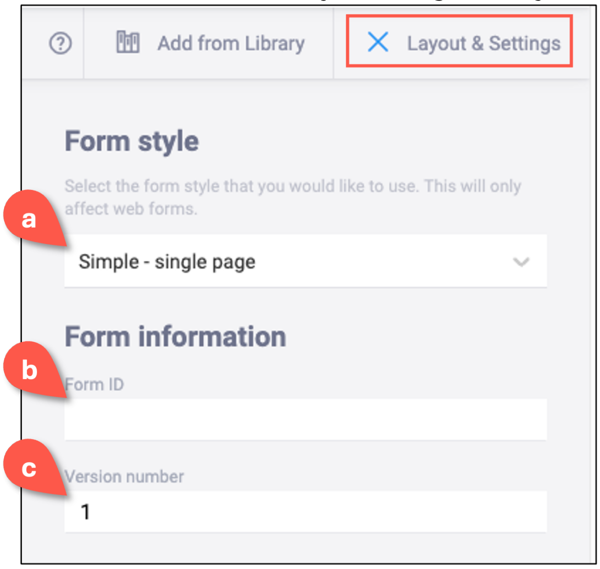


        a. **Select One:** Allows the user to select one response from a list defined in the Form. The Form Designer user defines the list of response options.
        b. **Decimal:** Allows the user to enter a decimal value.
        c. **File:** Allows the user to attach a file.
        d. **Select One (external list):** Allows the user to select one response from a list defined in an external file. The Form Designer user uploads the file containing the list of response options.
        e. **Select Multiple:** Allows the user to select one or more responses from a list defined in the Form.
        f. **Calculate:** Calculates a value and does not display it to the user by default.
        g. **Image:** Allows the user to attach a .png or .gif file.
        h. **Text:** Allows the user to enter a text value up to **3,999** characters.
        i. **Date:** Allows the user to enter a date value.
        j. **Audio:** Allows the user to attach an audio file.
        k. **Integer:** Allows the user to enter an integer value.
        l. **Note:** Displays a message to the user without collecting a value.
        m. **Video:** Allows the user to attach a video file.

11. **Add from Library**

    1. Search for Items that have previously been saved in the Library. Drag and drop the appropriate Item into Form Designer. 

12. **Layout and Settings**

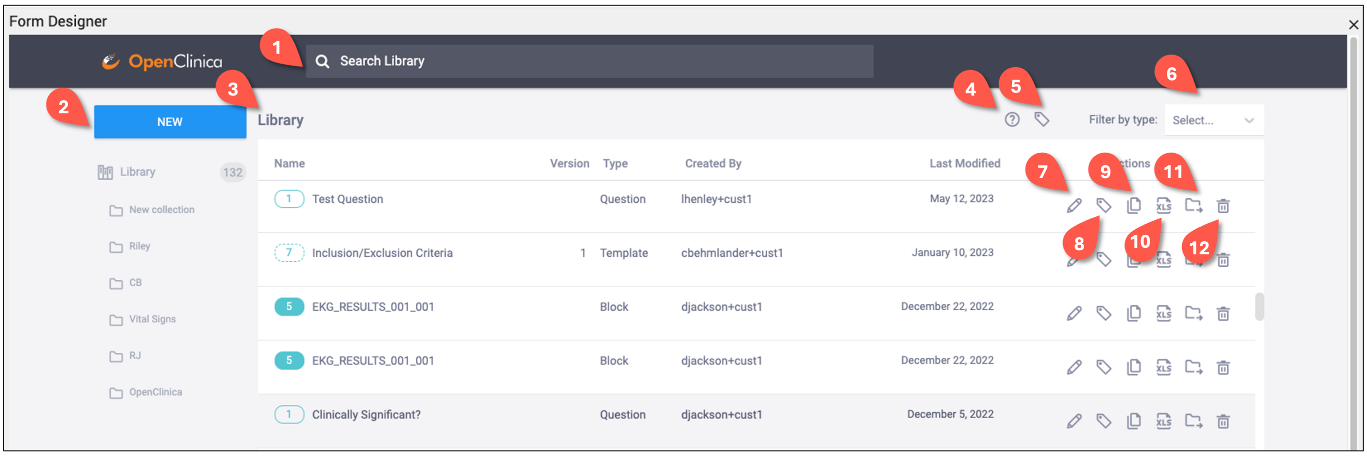
    1. Update the Form style and Form information by clicking on **Layout and Settings**.


        1. There are four options for Form style:
            - **Simple - single page:** Items appear in rows on a single page.
            - **Grid - single page:** Items appear together as a group but can have multiple questions appearing in the same row as columns; this is defined in the individual question settings.
            - **Simple - multiple pages:** Items appear in rows with the other items in their groups on, each group on a separate page.
            - **Grid - multiple pages:** The same as **Grid - single page** but each group of items will be displayed on its own page.
        2. Update the Form ID.
        3. Update the Form Version. Updating the form and not changing the form version will overwrite the given form version once it has been added to the Study.

1. **Expand / Collapse Questions**
    1. Click the icon to expand or collapse all questions on the Form.
2. **Settings**
    1. Selecting **Settings** allows the user to modify the following:
        a. **Question Options** - Specific options available to be modified depend on the type of question selected. For specific information on the required and optional fields for each question type, see the **Form Designer** column within the **Form Designer and Form Template Fields** in the **Using Form Designer** article.
        b. **Skip Logic** - Condition under which the question is skipped. Skip Logic can be added via the user interface by selection the question response that triggers the given question to be skipped, or manually in XLSForm code.
        c. **Validation Criteria** - Condition under which an a response is considered invalid. Validation criteria can be added via the user interface by selection the question response that triggers the validation as well as the constraint message, or manually in XLSForm code.
3. **Delete Question**
    1. The question can be removed by clicking the trash can icon.
4. Duplicate Question
    1. The question can be duplicated by clicking this icon.
5. Add Question to Library
    1. The question can be added to the Library by clicking on this icon.

18.1.1 Library Management

For full details of the functionality included in Library Management, review **Content Library.**



1. **Search Library**
    1. Enter text to search for an item.
2. **New**
    1. Create a new single question, a block of questions, or a full Form Template to add to the library.
        - Question - a single item.
        - Template - a complete form template that can either be created/edited in the form design studio or uploaded with a form template.
        - Upload - a form definition file can be uploaded. Regardless of the number of items, uploads will be saved as templates in the Library.
        - Collection - a folder designed to hold Questions, Blocks (groups of Questions) and Templates.
3. **Collections**
    1. Library objects can be organized into Collections to make it easier to manage the Library.
4. **Library Contents**
    1. Displays the Library contents, filtered if applicable.
5. **Help**
    1. Displays the Help page for Library Management.
6. **Show All Labels**
    1. Displays labels with their associated Library objects.
7. **Filter by Type**
    1. Filter the list by the type of item (**Question**, **Block**, or **Template**).
8. **Edit**
    1. Edit the Library object within the question form as you normally would within Form Designer.

9. **Labels**
    1. Can be used to further categorize Library objects beyond Collections.
10. **Clone**
    1. Duplicate the Library object.
11. **Download XLS**
    1. Download the XLS file of the Library object. The XLS is in the format of the form definition file regardless of whether the Library object is a question, block, or template.
12. **Manage Collection**
    1. Add the Library object to a collection by clicking this icon and selecting the collection the item should be added to. If there are no available collections, the selection box will say none available.
13. **Delete**
    1. Delete the Library object.

18.2 Study Runner

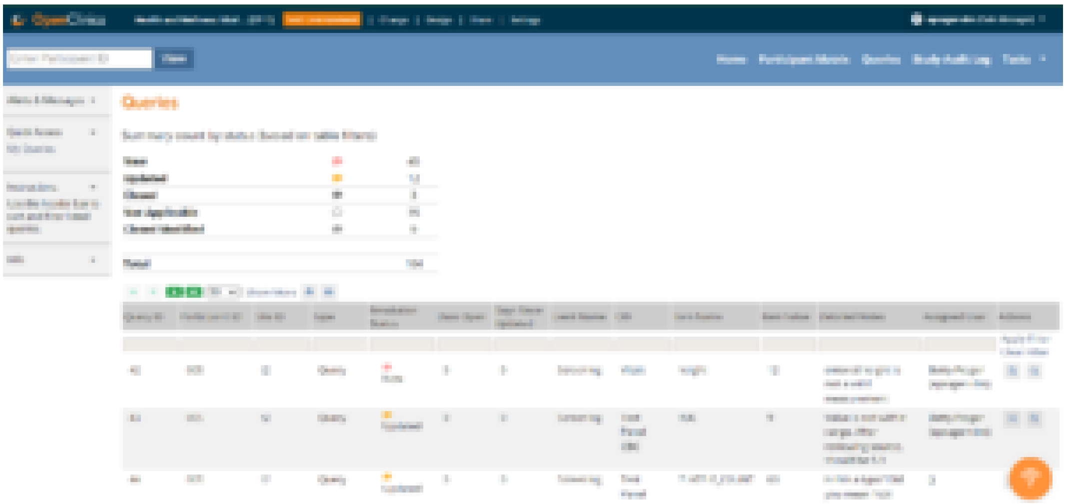
When users are entering data for testing or real world data collection, users will access OpenClinica via Study Runner. Study Runner is made up of many other paged such as the Participant Matrix, Queries Table, Data Review Tables, in addition to all Participant Details Pages and data. To access Study Runner the first step is to publish a study. Usually, studies will be published to **TEST** first . In addition to letting you use Study Runner features, publishing to **Test** generates OIDs that can be used for edit checks. To learn more about publishing to test and accessing study runner review section **5.1 Publishing Your Study.** The following sections make up OpenClinica's Study Runner environment.

***This page is currently in draft form and subject to change.**

18.2.1 Submit Data

18.2.1.1 Queries

The Queries page is the central point for reviewing all notes (queries, annotations, and reasons for change) entered within a study or site. You can sort and filter these notes by Query ID, Participant ID, Note Type, Resolution Status, Days Open, Assigned User, CRF, and more.

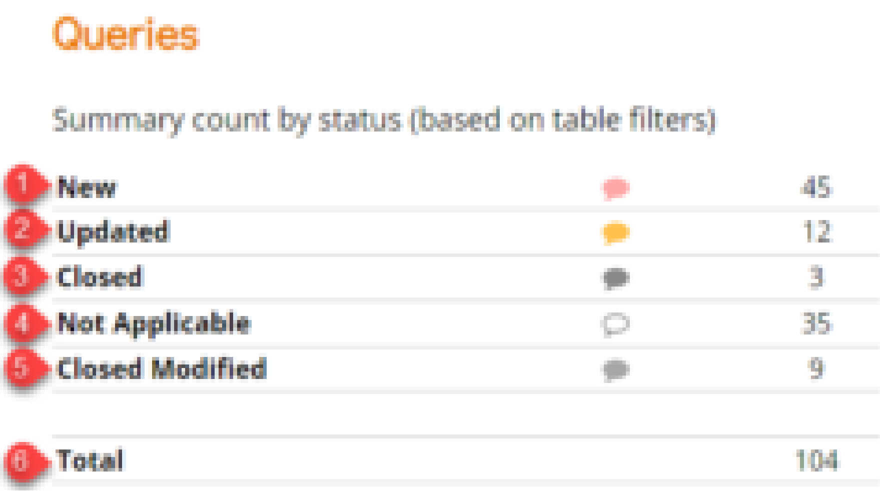


The following are definitions for the 3 types of notes found in Queries page:

Definitions:
• **Queries** are inquiries or alerts about potential incorrect or missing data. Each query has a workflow status to ensure it is reviewed and acted on.
• **Annotations** are notes on a Form that do not contain clinical data and are usually used for keeping track of user workflow.
• **Reasons for Change** are notes added by a user when modifying data on a form that has already been marked as Complete. They explain why there was a data change.

How are queries created?
Queries can be created manually by a user when entering data within a form or automatically by the system due to a pre-configured edit check within a form.
How do I close a query?
A data manager or monitor user can close a query when updating the query note within the form. This can be done by viewing the record as a whole or viewing only the query. If you are a Data Manager or Monitor you can find additional information about your role and queries below.

The Summary Table

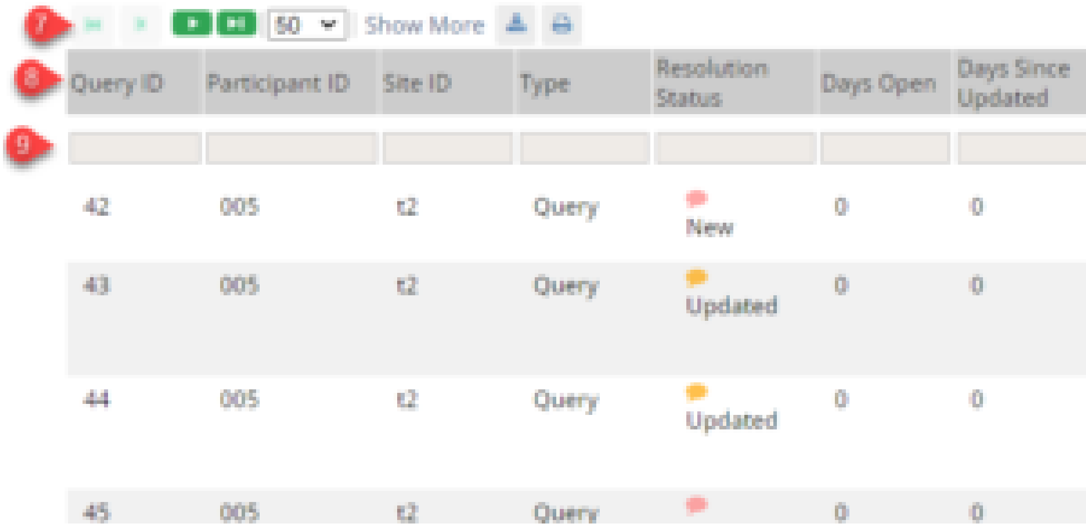


The summary table contains the types of query resolutions statuses and total of each resolution status shown in the Query table. These numbers reflect the breakdown of the total number of items on the current Queries table. Apply filters to the Queries table both the total number of rows and the Summary Table total will represent the filtered table view.
1: New - This status indicated that a query has been added by either a site user (e.g., a comment/annotation), data manager, or monitor, or was auto-generated by OpenClinica based on built-in edit checks. In the summary table this row represents the number of queries in the current

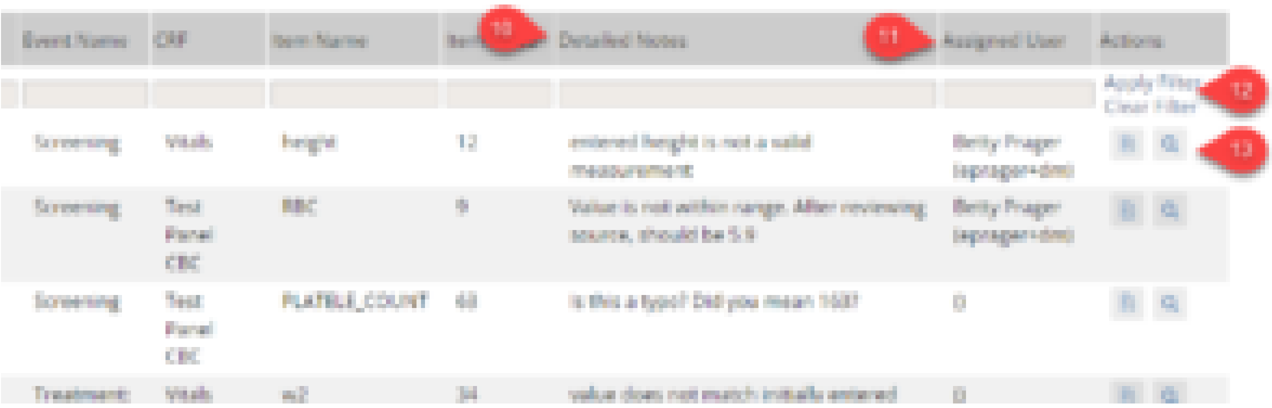
queries table view that have the resolution status of new.
2: Updated - This status indicated that either a site user, data manager, or monitor has added information to the query. In the summary table this row represents the number of queries in the current queries table view that have the resolution status of updated.
3: Closed - This status indicated that the query is considered resolved by the data manager or monitor. In the summary table this row represents the number of queries in the current queries table view that have the resolution status of closed.
4: Not Applicable - This resolution status is given to Annotations and Reasons for Change. In the summary table this row represents the number of Annotations and/or Reason for Change shown in the current queries table view. Their resolution status is always Not Applicable and they have N/A in the Query ID column .
5: Closed Modified - This resolution status means the data was changed after the query was closed.
6: Total - The total number of New, Updated, Closed, Not Applicable, and Closed Modified Resolutions Statuses within the current queries table. In other words the total number of queries, annotations , and reason for change shown in the current queries table view.

The Queries Table

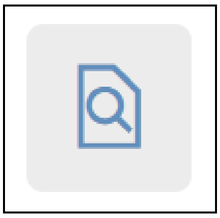
The Queries table displays queries, annotations, and reasons for change. This table can be filtered to show only queries, only annotations, only reasons for change, and combinations of the 3 types. This table can also be printed or downloaded.



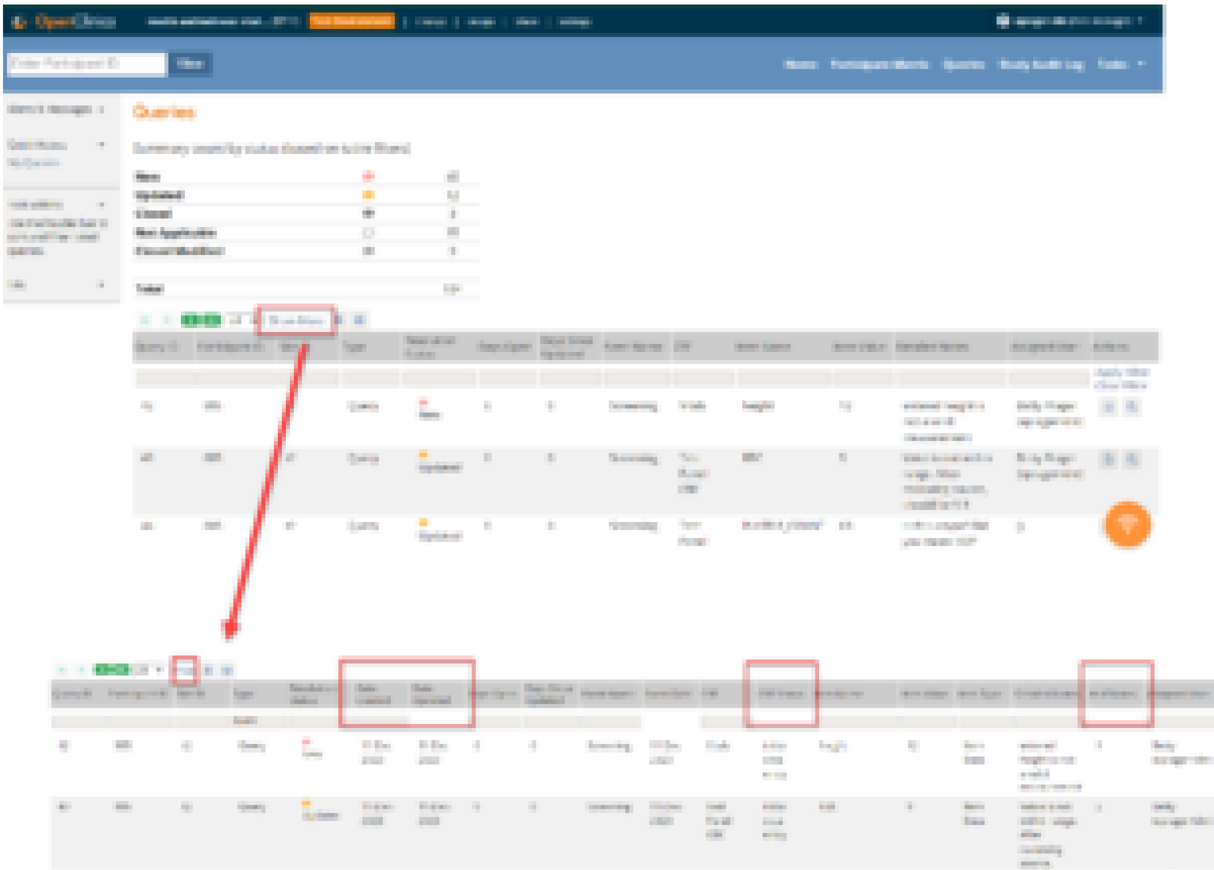
7: The drop down box can be used to set the number of rows per page to 15, 25, 50, or 100 based on the total number of results in the queries table. If the number of rows per page is set to 50 and the total number of results in the table is 135, the green arrows can be used to move between pages of the queries table.
8: This row of the queries table shows the headers for each column. For example, the first column of this row shows the Query ID, this is a unique number that is assigned to any query when it is created. If the queries table is set to show only annotations or reasons for change this Query ID column will only contain N/A values. Other column headers are: ParticipantID, SiteID, Type, Resolution Status, Days Open, Days Since Updated, Event Name, CRF, Item Name, Item Value, Detailed Notes, Assigned User, Actions .
9: This row of the queries table is used to filter different columns based on information specific to the header for each column. You can change the view of the Queries screen to filter any column that includes a gray filter box.
Examples of filters:



10: Details about each query, annotation, or reason for change are listed in the Detailed Notes column.
11: This column indicates if the query has been assigned to a user. In some cased the user is sent an email when a query is assigned to them. When there is no assigned user there will be no user name between the () parenthesizes.
12: Under the Actions column you can Apply and Clear Filters.
13: Under the Actions column any row below the filter row will have 2 actions. First the "View Query Within Record" action and second the "View Query Only" action.

Icon	View	Description
	View Query Only	This option displays a mini version of the form contain only the item in question along with its queries and item history. You can add a query note, reassign the query, and you have the option of emailing the assigned user. All users with access to queries can update the query; but only Data Managers and Monitors have access to close the query. This option does not allow changing the item value.
	View Query Within Record	This option displays the full form initially focused directly on the selected query. All users with access to queries can to update the query, but only Data Managers and Monitors have access to close the query. The rest of the form is also available for review. This provides reviewers with more context when reviewing specific item data issues. Note that for users with permission to edit the record, the form will be opened in edit mode allow any data value on the form to be updated.

You can click Show More at the top of the table to show more columns. The Show More text will then be replaced by Hide. If you click Hide the additional columns will be hidden from the table view and Show More will reappear.
Additional columns that will display when Show More is select are:
Date Created
Date Updated
Event Date
CRF Status
Item Type
# of Notes
Originator - This is where you can see if a user created the query or if it was auto generated by an edit check. If it was auto generated the Originator will be System.



If you would like to learn more about Queries and how they relate to a specific user type:
[Queries and Clinical Research Coordinators (CRC)]()
[Queries and Data Managers (DMs)]()
[Queries and Monitors.]()

18.2.2 Monitor and Manage Data

18.2.3 Extract Data

18.2.4 Reports

18.3 Study Designer

Approved for publication by Riley Bianchi. Signed on 2022-08-04 4:53PM

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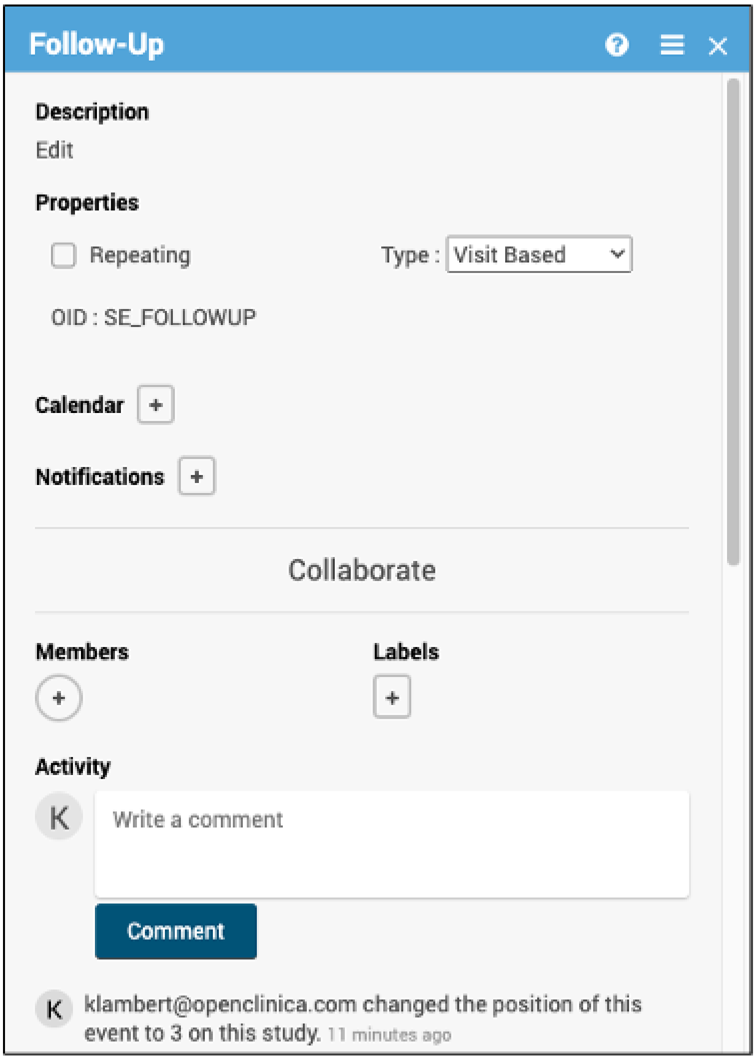
18.3.1 Events

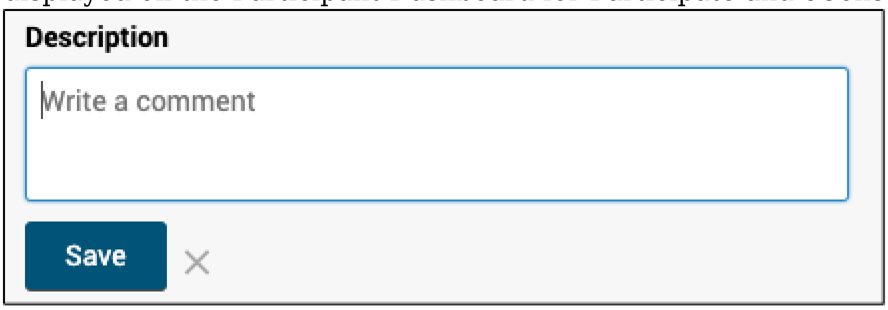
Once users have created a study event, they can configure the event by accessing the Event Card. On the Event Card, users are able to update event name, description and properties, as well as set up automatic event scheduling and notifications.



Description / Properties

Clicking on the Event name will make the field editable. The user can update the Event name as needed, and **Save**. Updating the Event name will change the name of the event that appears within Study Runner. This does not change the Event OID that was assigned at the time of Event creation.

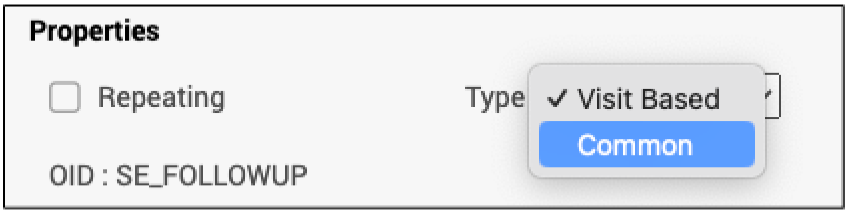
Clicking on **Edit** under **Description** will allow the user to add or update the Event description as needed. This is optionally displayed on the Participant Dashboard for Participate and eConsent events.



There are two main types of events:

- **Visit-Based:** An event that is scheduled to occur within the study and is associated with a visit date. These visits are associated with a schedule that is outlined in the study protocol, and each visit has a specific set of forms that are collected.

- **Common:** An event that isn't necessarily associated with a visit but may occur any time throughout the study, such as an Adverse Event. They can additionally be defined as:
    - **Repeating**: Used when the event needs to have multiple instances of the event, such as with an Adverse Event.
    - **Non-Repeating**: Used when the event will only occur once, such as Early Termination.



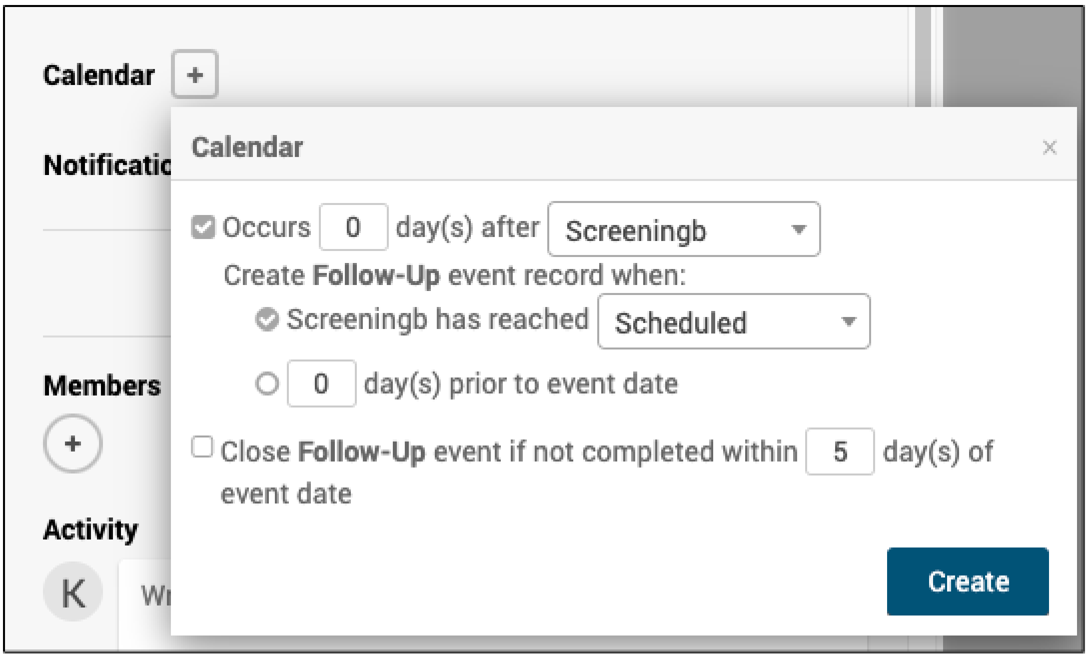
Calendar Configurations

Calendaring allows the user to define automated Event scheduling based on the status of other study Events.

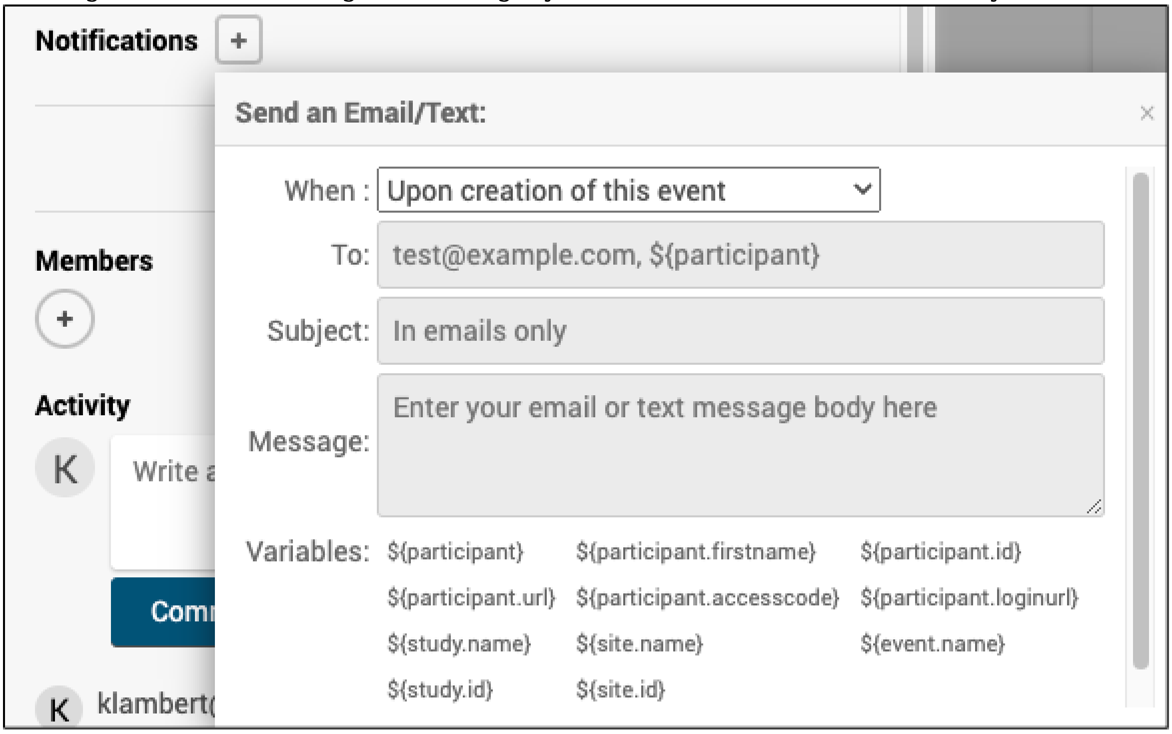
Users can choose when to create and also when to close events:

- **Occurs [x] day(s) after [Triggering Event]**: Schedules this Event for a specific number of days after another study Event, which are shown in the dropdown menu.
    - **Create *[this Event]* event record when**: Only one of the following can be selected:
        - **[Triggering Event] has reached [status]**: Schedules this Event when the Triggering Event has reached a specific status. The options are Scheduled, Data Entry Started, or Completed.
        - **[x] day(s) prior to event date**: Schedules this Event a specific number of days before the Event date.

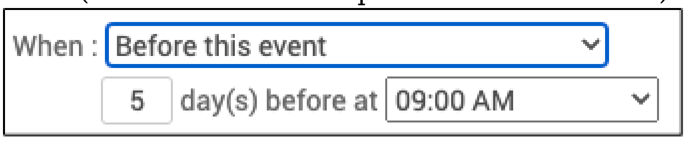
- **Close *[this Event]* event if not completed within [x] day(s) of event date**: Once an Event is scheduled, whether automatically or manually, the user can elect to close it automatically if it has not been completed within [x] days.

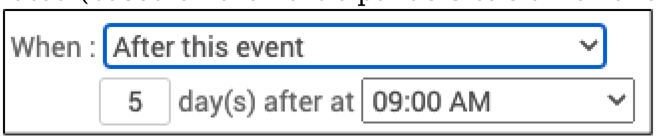


Calendar Notifications

The user can also configure notifications to be sent upon Event status change. Notifications can be scheduled to send to one or more static email addresses or to the Participant. **Important Note**: Using Calendaring notifications alongside the legacy OC4 rules within the same study is not 

supported.

- **When**: The timing for the notification to be sent
  - *Upon creation of this event:* Notification will be sent as soon as the event has been created.
  - *Before this event:* Notification will be sent [x] days prior to the event date at the time designated (based on the Participant's Site's time zone).
    - 

  - *After this event:* Notification will be sent [x] days after the event date at the time designated (based on the Participant's Site's time zone).
    - 

  - *This event is complete:* Notification will be sent as soon as the event has been completed.
- **To**: Notification can be sent to one contact, or a comma-separated list of multiple contacts. The following types of contact information can be entered:
  - Email address
  - ${participant}: When the study has the Participate module activated, will send the notification to the contact information entered into OpenClinica for a Participant. This will send an email and a text message if the Participant has both an email address and a phone number.
- **Subject**: The subject is used as the subject for email notifications only, and can be customized using Variables.
- **Message**: The message can be customized using Variables.

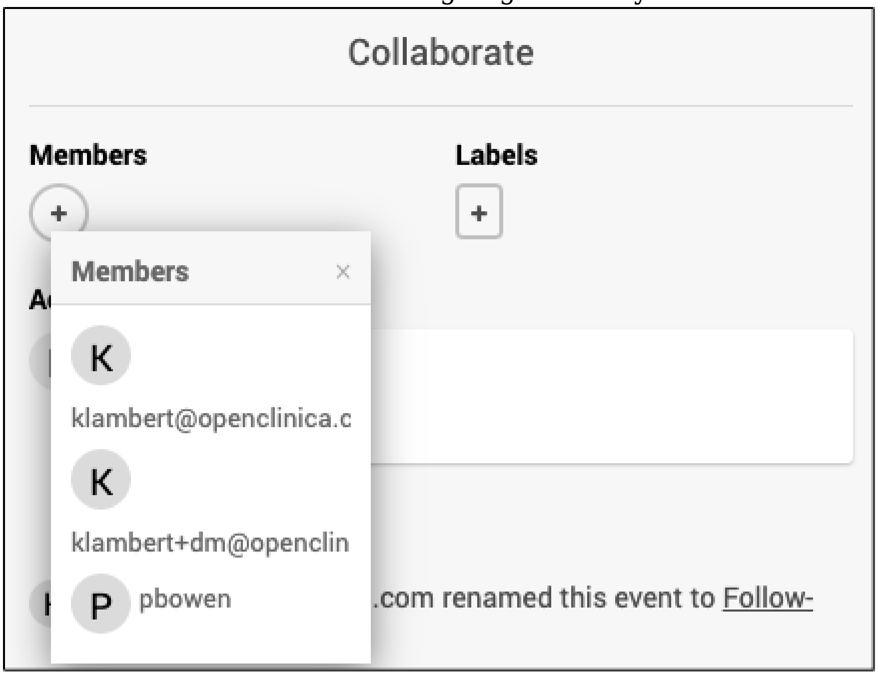
Variables refer to specific study data and can be inserted into Subject and Message to customize the message.

Parameter	Description	To	Message	Subject
${participant.firstname}	The Participant First Name		X	
${participant.loginurl}	The Participant URL with Automatic Login		X	
${participant.url}	The Participant URL without Automatic Login		X	
${study.name}	The Name of the Study, as Defined in OpenClinica		X	X
${participant.accesscode}	The Single-Use Code the Participant Must Use to Access OpenClinica Participate		X	
${event.name}	The Name of the Event, as Specified in OpenClinica		X	X
${participant}	The Participant Contact Information, as Provided When the Participant was Connected to the Study. (This Could be a Mobile Number for SMS Notification, an Email Address, or Both); OpenClinica Automatically Sends the Notification	X		
${participant.id}	Participant ID		X	X
${site.id}	Site ID		X	X
${site.name}	Site Name		X	X
${study.id}	Study ID		X	X

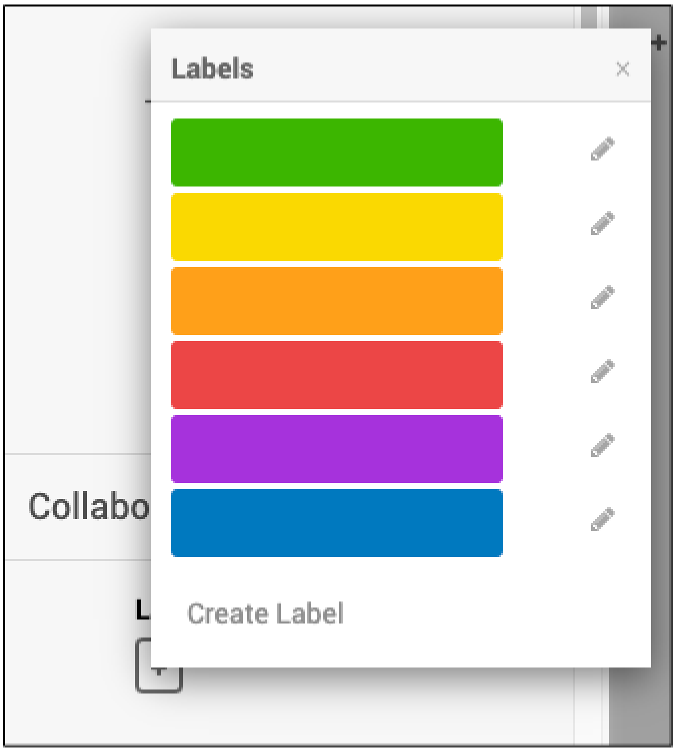
Collaborate

Members

Shows the users involved in designing the study who can be associated with specific Events.

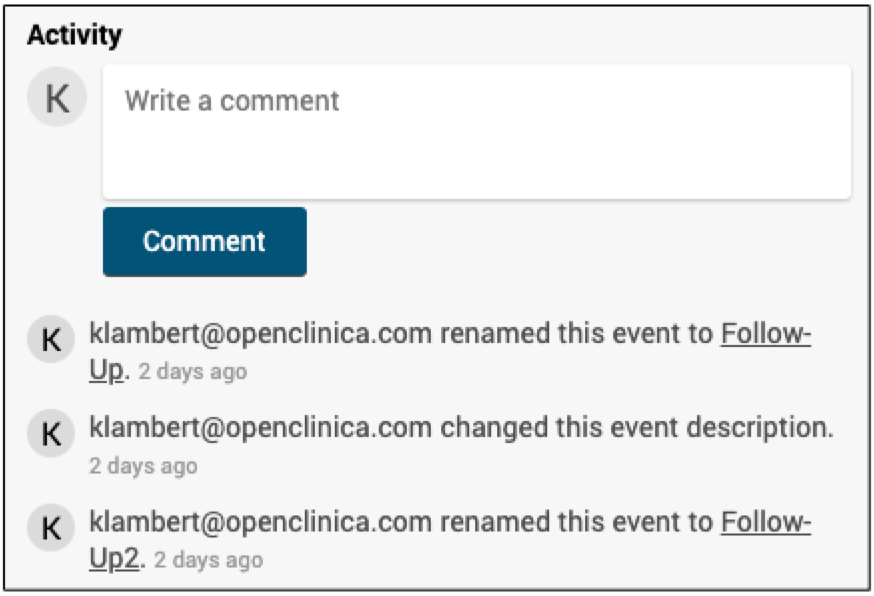


Labels

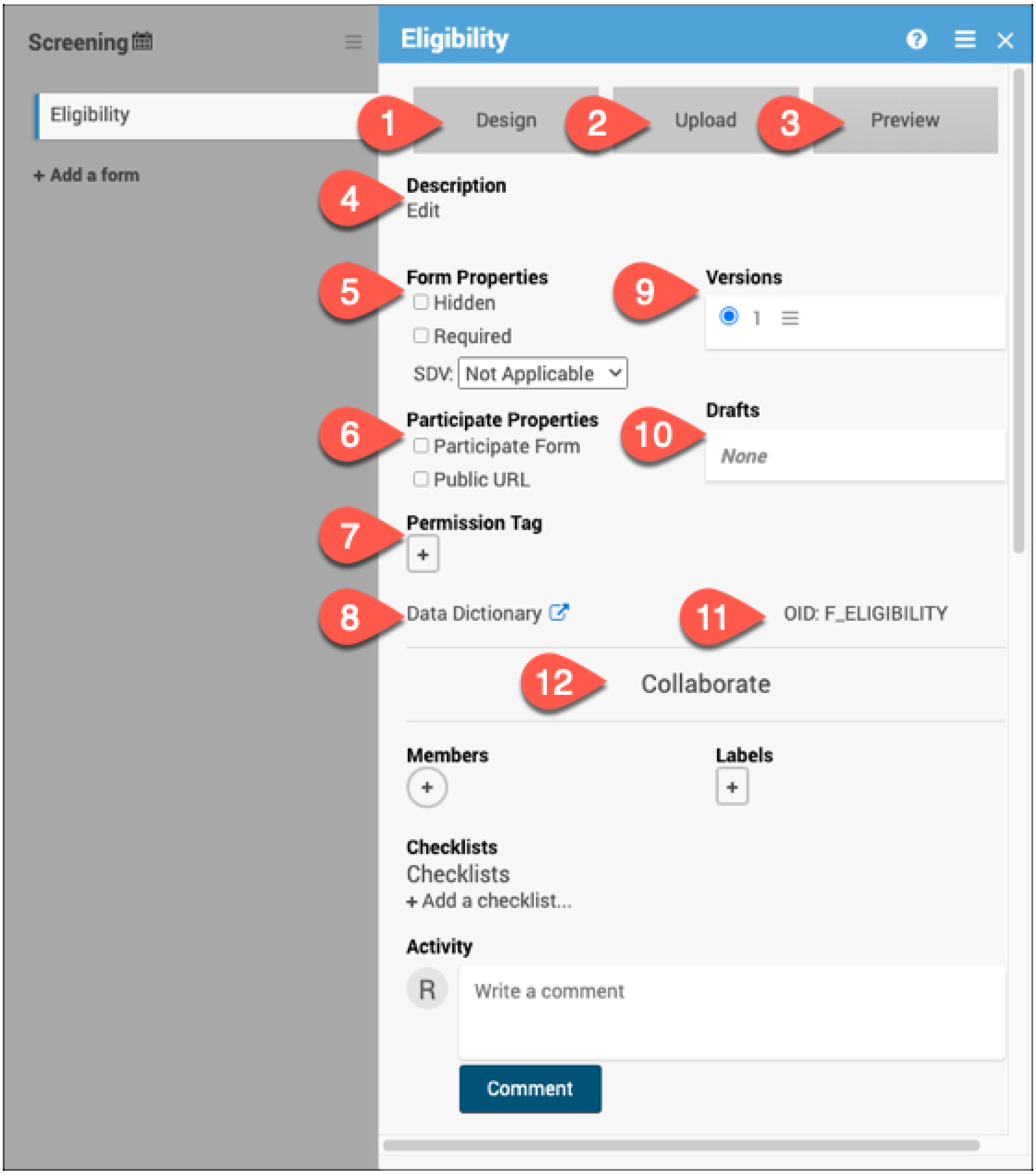
A Label is a color or color with text that can be used to represent groups of Events. Labels can be used to help facilitate building a study but have no functional implications. For example, a label can be added for events that require review. 

Activity

The **Activity Log** displays design-related actions that have been taken on the Event. It also displays the user who performed the action and when the action was performed. A **Comment** is text that allows users in Study Designer to communicate with collaborators. This text remains in the Activity Log for the event.



18.3.2 Form Card



1. Design

Click **Design** to use Form Designer to create or make changes to your form instead of or in addition to using the Form Template. **[Using Form Designer]**

2. Upload

Click **Upload** to use the Form Template to create or make changes to your form instead of or in addition to using Form Designer. **[Using the Form Template]**

3. Preview

Use **Preview** to preview the default version of the form for data entry. The button will change to *Preview (as a Participant)* if it is marked as a Participate form.

[OpenClinica Participate]

4. Description

Add, edit, or remove a brief description for the form.

5. Form Properties

Use the Form Properties section to mark a form as Hidden or Required. Here you can also set the SDV status for the form. **Form Properties** **Source Data Verification (Monitor)** **Source Data Verification (Data Manager)**

6. Participate Properties

*This section will only appear if the Participate module is activated for your study. Here, you can specify if the form is a Participate form (where participants will fill out the form), if it will have a Public URL, and if the form will be offline capable.

Design Participate Forms

7. Permission Tag

Use Permission Tags to determine which User Roles can access data from specific Forms in Study Runner. **Permission Tags** **User Access & Sharing**

8. Data Dictionary

The Data Dictionary gives you form-specific information including form metadata, form properties, and item metadata (such as Item OID, Item Group Name, Item Group OID, Item Type, and Insight Table). The Data Dictionary is available via a link on each form card in Study Designer and can be downloaded as a CSV file to view outside of Study Designer.

Locating Object Identifiers in a Study

9. Versions

This section displays all available versions of the form and indicates the default version. Click on the menu next to the version name to display all available actions for the version. **Publishing Your Study** **Publish History** **Form Migration**

10. Drafts

Drafts will display the pending version of the form. Click the menu to view all actions for the draft including saving the draft as a version.

11. OID

Quickly view the form OID to reference for different form functions. **Locating Object Identifiers in a Study**

12. Collaborate

The Collaborate section includes multiple features to facilitate collaboration with colleagues while building your study. **Members** **Labels** **Checklists** **Activity** **Comments**

Additional Resources for Form Cards

Designing Forms

Use this section to get started designing forms within your study, learn about events, and understand the basics with form templates.

Design a Study

Events & Forms

Logic and Functions

Use this section to go beyond the basics with your forms by using functions and logic. **Form Logic** **Functions**

Example Forms

Use this section to view sample CDISC CDASH-compliant eCRF templates that can be customized or imported as-is to the OpenClinica EDC platform.

Form Library (CDASH)