

## 6 Using OpenClinica as a CRC

Before reviewing this section, make sure that you have read [Getting Started](#). Investigators should review this section in addition to the [Using OpenClinica as an Investigator](#) section.

**For Information on Using OpenClinica as a Clinical Research Coordinator (CRC), See the Following Sections:**

Approved for publication by Kerry Tamm. Signed on 2020-11-24 3:23PM

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### 6.1 Queries (CRC)

**Definitions:**

- **Queries** are inquiries or alerts about potential incorrect data.
- **Annotations** are notes on a Form that do not contain clinical data and are usually used for keeping track of workflow.
- **Reasons for Change** are notes added by a user when modifying data on a form that has already been marked as Complete.

The system creates queries automatically if you close a Form that has unaddressed errors. You can also manually create queries as needed.

Another user can respond to a query and/or change the response in the field. Only **Data Managers** and **Monitors** can close queries.

### The Queries Table

A table displays queries, annotations, and reasons for change. Details about each query, annotation, or reason for change are listed in the **Detailed Notes** column.

## Queries

Summary count by status (based on table filters)

New		3
Updated		--
Closed		--
Not Applicable		9
Closed Modified		2
<b>Total</b>		<b>14</b>

<div><div><div></div><div></div><div></div></div><div>50</div><div>Show More</div><div><div></div><div></div></div></div>													
Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
													<div>Apply Filter</div> <div>Clear Filter</div>
4	002	1234567	Query	<div>New</div>	19	19	Headache	Other Symptoms	how_many_times_a_week	11	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	<div><div></div><div></div></div>
5	002	1234567	Query	<div>New</div>	19	19	Headache	Other Symptoms	how_many_times_a_month	12	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	<div><div></div><div></div></div>
3	004	1234567	Query	<div>New</div>	82	82	Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	Check this	Kerry Tamm (ktammadmin)	<div><div></div><div></div></div>













You can click **Show More** at the top of the table to show more columns.

To filter by reason for change, click the gray filter box under the **Type** column, and select **Reason for Change**. You can change the view of the **Queries** screen to filter any column that includes a gray filter box.

## Queries

Summary count by status (based on table filters)

New		--
Updated		--
Closed		--
Not Applicable		9
Closed Modified		--
<b>Total</b>		<b>9</b>

				50	Show More								
Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
													Apply Filter Clear Filter
N/A	002	1234567	Annotation Query Reason for Change	Not Applicable			Eligibility & Consent	Eligibility	participant_suffers_from	no	Test	()	 
N/A	002	1234567	Reason for Change	Not Applicable			Eligibility & Consent	Consent	i_consent_to_participate_in_this_study	option_1	Test	()	 
N/A	002	1234567	Reason for Change	Not Applicable			Eligibility & Consent	Consent	i_consent_to_participate_in_this_study	option_1	Test	()	 

**The Table Below Displays Statuses for Queries and Annotations:**

[table id=17 /]

**To Review Data Associated with a Query, You Have Two Options:**

[table id=18 /] You can access these options from the **Actions** column of the **Queries** table.

Queries

Summary count by status (based on table filters)

New		3
Updated		--
Closed		--
Not Applicable		--
Closed Modified		2
Total		5

50

Show More

Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
			Query										Apply Filter Clear Filter
4	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_week	11	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	
5	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_month	12	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	
3	004	1234567	Query	New	82	82	Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	Check this	Kerry Tamm (ktamminvadmin)	

View Query Only:

View Query

Participant ID: a123

Event Name: Exam

Event Date: 21-Mar-2022

Form Title: Vitals

Temperature:

°C

78

View All History

Queries

+ New

#1

Automatic query for: The expected range for temperature is 34- ...

Annotations

+ New

Respond to query

Assign to:

r b (rbianchi+)

☐ Email?

Update

R

1 day

Automatic query for: The expected range for temperature is 34-41°C, please verify your response.  
#1 assigned to rbianchi+crc. Status: new

RB

1 day

Value changed from "" to "78"

☒ Show value changes

View Query Within Record:

**Vitals (Collected at BL, C1D1, C2D1, C3D1, C4D1)**

<b>Visit collected:</b> none selected	<b>Temperature:</b> °C 78	<b>Heart Rate:</b> [beats/min] This field is required	<b>Mean Arterial Pressure:</b> mmHg This field is required	<b>Systolic arterial blood pressure:</b> mmHg This field is required	<b>Diastolic arterial blood pressure:</b> mmHg This field is required
--	---------------------------------	---	--	--	---

**View All History**  
**Queries** + New

#1 Automatic query for: The expected range for temperature is 34-41°C, please verify your response.

**Annotations** + New

Respond to query
 

Assign to: r b (rbianchi+crc) ☐ Email? Update

R  
1 day

Automatic query for: The expected range for temperature is 34-41°C, please verify your response.  
 #1 assigned to rbianchi+crc. Status: new

RB  
1 day  
 Value changed from "" to "78"

☒ Show value changes

You can then update the query comment, use the **x** to close the query details, and review the entire form in question. **Data Managers** and **Monitors** have the additional option of closing the query. If an item only displays based on the response to another question, there may be instances where an item was conditionally displayed, a query was added to that item, and then the response to the lead-in question was changed, so that item is no longer displayed. That query still exists, however, and needs to be addressed. Similarly, if there is a form that has repeating records and a query was added to a row, but that row has since been deleted, the query still exists, but is no longer displayed on the form. OpenClinica informs you of these hidden items and provides an option for resolving the associated queries. For example, when the item in question is a response that has since been hidden, or is on a repeating record that has since been deleted, the following message displays:

**Hold on a second...**

The item you are trying to access has been removed from this form. Please use the View Query Only icon instead of the View Query Within Record icon to see it.

OK

To review the remaining data on that form, click **OK** and review the data. To review the data for the item in question, return to the **Queries** screen and use the **View Query Only** icon for that query (as instructed in the message).

## Creating Queries

### Use Case(s):

- Participant data does not match the source record.
- Participant data is clinically inaccurate.
- Participant data contains a typographical error.
- A form needs to be marked complete but an edit check prevents it.

- Information is missing from a form.
- A form in an Event was not started on time.

Users can create queries to inquire about participant data.

**Note:** Each query is automatically assigned an ID that is unique to the study environment (i.e. **Test** or **Production**). The ID appears in the **Queries** widget but is not visible until you close and reopen the Form. It also appears on the **Queries** table.

You can add multiple queries regardless of any existing ones.

You can only add/respond to queries and annotations in **Edit Mode**, as determined by your User Role. You cannot do so in **Read-Only Mode** or **Review-Only Mode**.

You can view the history for all queries and annotations on a single item by selecting **View All History**, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the **Show value changes** checkbox, each value change is included in the history.

#### **Best Practice:**

- If a form has not been started when it should have been, a Data Manager can add a query to the events start date.
- When a query is created, it should be assigned to the correct recipient. If action is required excluding if the query needs to be closed, the **Email** checkbox should be checked off.
- A new query should be created for a single issue, instead of combining multiple issues.
- A new query should be created rather than reopening a query that has already been closed.

#### **To Create a Query:**

1. Open a Form.
2. Click the **Query Bubble** in the field you want to create a query for.
3. Click the **+New** button next to **Queries**.
4. In the **Add a new query** field, enter text explaining the possible error or question.
5. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
6. Click the **Add Query** button.

The screenshot shows a medical form with the following fields: **Diagnosis** (Emphysema), **Body System** (Respiratory), **Date of Diagnosis** (2019-11-12), and **Ongoing?** (Yes/No). A modal window is open for adding a new query. The modal contains a text input field with the text "Add a new query" and "Please check date". Below this is an "Assign to:" dropdown menu set to "Rob Rittberg (rr)" and an "Email?" checkbox. An "Add Query" button is highlighted with a red border. A history section shows a change from "" to "2019-11-12" on 13-Nov-2019. At the bottom of the modal is a "Show value changes" checkbox. Navigation buttons at the bottom of the form include "Back", "Close", and "Complete".

## Responding To/Updating Queries

### Use Case(s):

- A response is required for the query to be resolved.
- Participant data must be changed for the query to be resolved.

Users can update queries by responding to a query and/or changing data in the form. If data is changed, they will be prompted to enter a reason for change.

**Note:** You can only add/respond to queries and annotations in **Edit Mode** or **Review-Only Mode**, as determined by your User Role. You cannot do so in **Read-Only Mode**.

You can view the history for all queries and annotations on a single item by selecting **View All History**, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the **Show value changes** checkbox, each value change is included in the history.

### Best Practice:

- All users can view a list of queries that have been assigned to them by expanding the **Quick Links** header in the left-hand sidebar and clicking **Queries Assigned to Me**.
- Data Managers can view a list of queries that have been assigned to them by clicking **Queries Assigned to Me** on the **Home** screen.
- When a query is responded to/updated, it should be assigned to the correct recipient. If action is required, the **Email** checkbox should be checked off.
- Data Managers and Monitors should review the entire queries list regularly to check for unassigned queries.
- If a conditional field (a field that appears based on the response to another field) has a query on it but a user has changed the response to the main field so that the conditional field no longer appears, the query still exists and needs to be addressed, but the field no longer appears on the Form. To review the remaining data on that Form, click **OK**, and review the

data.

- If there is a form that has repeating records, and a query was added to a row, but that row has since been deleted, the query still exists, but no longer appears on the Form. A message appears to inform you of these hidden items and provides an option for resolving the associated queries. To review the remaining data on that Form, click **OK**, and review the data.

## To Respond to or Update In a Form:

1. Open a Form.
2. Click the **Query Bubble** in the field you want to create a query for.
3. Select the query you want to respond to and/or update.
4. (Optional) If you need to change information in a form, close the **Query** widget, and make changes to the Form manually. You must provide a **Reason for Change** before completing the Form.
5. In the **Respond to query** field, enter text explaining the query response.
6. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
7. Click the **Update** button to add the response and leave the query open.

## To Respond to or Update a Query from the Queries Table:

1. Click **View Query Only** or **View Query within record** in the **Actions** column of the **Queries** table.
2. (Optional) If you need to change information in a form, close the **Query** widget, and make changes to the form manually. You must provide a **Reason for Change** before completing the form.
3. In the **Respond to query** field, enter text explaining the query response.
4. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
5. Click the **Update** button to add the response and leave the query open.

The screenshot shows a web interface for responding to a query. On the left, there are two sidebar panels: 'View All History' and 'Queries' (with a '+ New' button), and 'Annotations' (with a '+ New' button). The main area is titled 'Respond to query' and contains a text input field for the response, a 'Date Confirmed' label, and an 'Assign to:' dropdown menu. To the right of the dropdown is an 'Email?' checkbox. A red-bordered 'Update' button is located at the bottom right of the main area. Below the 'Assign to:' dropdown, there is a circular icon with 'RB' and the text 'just now' next to a speech bubble containing the text 'Please check date' and 'Status: new'. At the bottom right, there is a checkbox labeled 'Show value changes' which is currently checked.

## Closing Queries

Only **Data Managers** and **Monitors** can close queries.

# Annotations

## Use Case(s):

A user adds an annotation to keep track of workflow

You can add an annotation to a field to make a note. Annotations cannot be assigned, responded to or closed.

**Best Practice:** Annotations should not contain clinical information.

**Note:** You can view the history for all queries and annotations on a single item by selecting **View All History**, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the Show value changes checkbox, each value change is included in the history.

## To Enter an Annotation:

1. Open a Form.
2. Click the **Query Bubble** in the field for which you want to create an annotation.
3. Click the **+New button** next to **Annotations**.
4. In the **Add a new annotation** field, enter text for the annotation.
5. Click the **Add Annotation** button.

The screenshot shows a 'View All History' panel on the left with 'Queries' and 'Annotations' sections, each with a '+ New' button. The main area displays a list of annotations. The first annotation is highlighted with a callout box. The list includes annotations with icons (KT, B) and dates (20-Apr-2020, 25-Sep-2019, 24-Sep-2019). A checkbox labeled 'Show value changes' is at the bottom right.

Icon	Date	Annotation Text
KT	20-Apr-2020	Value changed from "113.6" to ""
B	25-Sep-2019	Value changed from "" to "113.6"
B	25-Sep-2019	Value changed from "113.6" to ""
B	24-Sep-2019	Corrected the age. So this calculated field changed
B	24-Sep-2019	Value changed from "114.4" to "113.6"
B	24-Sep-2019	Value changed from "" to "114.4"

**Note:**

Annotations are indicated with an **i** icon. They appear as **N/A** in the **Query ID** column and **Not Applicable** in the **Resolution Status** column.

## Downloading Queries, Annotations, and Reasons for Change

### To Download Queries, Annotations, and Reasons for Change:


1. Click the **Download** button at the top of the table. A Download window appears.
2. Select **comma-separated values** or **portable document format** in the **format** field.
3. Click the **Download notes** button.



## Queries

Summary count by status (based on table filters)

New		3
Updated		--
Closed		--
Not Applicable		9
Closed Modified		2
Total		14

    50  Show More  

Query ID	Participant ID	Site ID	Type	Resolution Status

Please choose a format for downloading queries

format:

[Download notes](#) [Close Window](#)


## Printing Queries, Annotations, and Reasons for Change




### To Print Queries, Annotations, and Reasons for Change:

1. Click the Print button at the top of the table. A Print window appears.
2. Click **ctrl + p** (Windows) or **command + p** (Mac) or click **Ok**, right click the window, and select **Print**.

## Queries

Summary count by status (based on table filters)

New		3
Updated		--
Closed		--
Not Applicable		9
Closed Modified		2
Total		14

    50  Show More  

Query ID	Participant ID	Site ID	Type	Resolution Status

Queries

Query ID	Participant ID	Site ID	T	cust1.staging.openclinica.io says								CRF	CRF Status	Item Name
				Press <control + p> or right click on the page to print.										
4	002	1234567	Q			2020	2020					Other Symptoms	initial data entry	how_many_time
5	002	1234567	Query	New	10-Nov-2020	10-Nov-2020	19	19	Headache			Other Symptoms	initial data entry	how_many_time
3	004	1234567	Query	New	09-Sep-2020	09-Sep-2020	82	82	Eligibility & Consent	20-Aug-2020	Eligibility	data entry complete	participant_is_1	
1	002	1234567	Query	Closed Modified	20-Aug-2020	04-Sep-2020			Eligibility & Consent	20-Aug-2020	Eligibility	data entry complete	participant_is_1	

cust1.staging.openclinica.io says

Press <control + p> or right click on the page to print.

OK

Functional approval by Riley Bianchi. Signed on 2022-03-23 10:45AM

Approved for publication by Paul Bowen. Signed on 2022-04-13 12:18AM

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## 6.2 Add Participants

**Definition:** A Participant is a person who participates in your study and provides data. This could be a patient receiving treatment or a test subject in a clinical trial.

**Example:** A Participant might have a specific demographic or medical condition that is required to participate in the study.

You must add Participants to a Study before you can enter data for those Participants. There are different ways to add Participants:

Your study must have a **Status** of **Available** to add Participants. **Best Practice:** OpenClinica recommends adding Participants at the site-level instead of the study-level. A site should be created for Participants even if they do not belong to a physical site. Before adding Participants, click the **Change** button in the header bar of Study Runner to select a site. Study-level Participants can't be created in bulk via API, added to Participate, or have data entered for them because CRCs and Investigators can't see them. In addition relevance logic that requires that the user knows the site can't be triggered at the study level.

### Depending on the Study Settings, Studies can be Configured to Allow You to Do One of the Following:

- Manually enter the Participant ID.
- Automatically generate a Participant ID based on a predefined format template.
- Add Participants in batch using **Web Services** (for **Administrators** with **Data Manager** access).

**Note:** If you do not see the **Add New Participant** link above the **Participant Matrix**, either your

**User Role** does not have access to add Participants, or the **Data Manager** has set a limit for the number of Participants allowed in the study, and your study has reached the maximum number of Participants. In addition, you cannot add Participants if a study has a status of **In Design**, **Frozen**, or **Locked**. If you are a **Data Manager** and want to change the maximum number of Participants allowed for a study, see the **Study Settings** information in [Create a Study](#).

## You Can Add Participants:

- Manually
- Automatically
- In a batch

## You Can Build Your ID Template Using One or More of the Following Components:

1. **\${siteId}**: The unique identifier for the site the Participant is being added to.
2. **\${siteParticipantCount}**: The current number of Participants at the site. This is generally used like **\${(siteParticipantCount+1)}** to have the ID increment the Participant count for each new Participant added.
3. **\${helper.random(n)}**: Generates a random number with up to n digits each time a Participant ID is generated.
4. **?string[000]**: Added to the resulting values to pad them with leading zeros to equal the number of digits specified, for example, **\${(siteParticipantCount+1)?string[000]}** or **\${(helper.random(5))?string[00000]}**.
5. Prefixes, suffixes, separators - Include other text (such as - or a Study-specific prefix) to include standard content in each ID.

**Note:** Each ID Template must include #2 or #3.

**Examples:** The Participant Count Method template, **\${siteId}-\${(siteParticipantCount+1)?string[000]}**, for site University Hospital (**Site ID = UH**) would produce the IDs, **UH-001**, **UH-002**, **UH-003**, etc.

The Random Number Method template, **P-\${(helper.random(5))?string[00000]}**, would produce IDs with a fixed prefix of P- followed by a 5-digit random number (including leading zeros), for example **P-00362**, **P-82394**, **P-35070**.

## To Manually Add a Participant:

If your Data Manager has chosen the **Manual** Method of Creation:

1. From the **Tasks** menu, select **Add Participant**, or on the **Participant Matrix** screen, click **Add New Participant** above the matrix.
2. Enter a Participant ID in the **Add New Participant** screen. (This should be a unique identifier, e.g. **001**).
3. Click the **Add** button.

## Add New Participant

Participant ID \*

Cancel

Add

### To Make the System Automatically Generate a Participant:

1. Set the **Method of Creation** field to **System-generated** (see above).
2. From the **Tasks** menu, select **Add Participant**, or on the **Participant Matrix** screen, click **Add New Participant** above the matrix.
3. Click the **Add** button in the **Add New Participant** screen to generate a Participant ID.

## Add New Participant

Participant ID \*

ID will be generated on Add

Cancel

Add

### To Add Participants in a Batch:

1. From the **User** menu, select **Administration**.
2. Click the **Web Services Information** button.
3. Execute the API to create a batch of Participant IDs.

Once you have added a Participant to your study, you can enter data.

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## 6.3 Entering Data

The features of OC4 data entry include the following:

- **Participant Matrix:** Easily see the data entry status of participants.
- **Auto-save:** Automatically save during data entry.
- **Conditional field display:** Only see relevant fields during data entry.
- **Automatic calculations and data checks:** Automatically use calculations and checks.
- **Queries:** Easily create or view queries.

### Before You Enter Data

To enter data into OpenClinica, you must do the following:

- Add a Participant
- Schedule an Event

See [Adding Participants](#) for more information on adding Participants.

### Scheduling an Event

Once a Participant has been added, you can schedule events and start to enter data.

You can schedule events from the **Participant Matrix**, **Participant Details** screen, or the **Tasks** menu.

#### To Schedule a Visit-Based Event from the Participant Matrix:

1. Click the **Schedule** button for the Participant and the Event that you want to schedule.
2. Select **Schedule**.
3. Select a **Study Event Definition** from the drop-down list.
4. (Optional) Select a **Start Date/Time**. The current date is the start date by default, but you can change it.
5. (Optional) Select an **End Date/Time**.
6. (Optional) To schedule additional Events, click **Schedule Another Event**, and enter information for that Event. Repeat as needed.
7. To go to the **Participant Details** screen to enter data, click the **Proceed to Enter Data** button.

#### To Schedule a Visit-Based Event from the Participant Details screen:

1. Click the Participant ID or **View** button next to a Participant on the Participant Matrix.
2. Under the **Visits** header on the **Participant Details** screen, click **Add New**.
3. Select a **Visit Name** from the drop-down list.
4. The current date is the start date by default, but you can change it.
5. (Optional) Click **Show advanced options** to change the **Start Time** or **End Date/Time**.
6. (Optional) To schedule additional Visits, click **+ Add another visit**, and enter the new visit information. Repeat as needed.
7. When you are ready, click **Add visits**.

**Note:** Once a non-repeating event has been scheduled, it will no longer be available in the

**Add Visits** window for that participant.

### **To Schedule a Visit-Based Event from the Tasks Menu:**

1. Click the **Tasks** button in the header bar of Study Runner.
2. Select **Schedule Event**.
3. Enter a Participant ID in the **Participant ID** field.
4. Select a **Study Event Definition** from the drop-down list.
5. (Optional) Select a **Start Date/Time**. The current date is the start date by default, but you can change it.
6. (Optional) Select an **End Date/Time**.
7. (Optional) To schedule additional Events, click **Schedule Another Event**, and enter information for that Event. Repeat as needed.
8. To go to the **Participant Details** screen to enter data, click the Proceed to **Enter Data** button.

### **To Add a Common Event from the Participant Details screen:**

1. Click the Participant ID or **View** button next to a Participant.
2. Under a header for a common event on the **Participant Details** screen, click **Add New**.

**Note:** For Common Events, such as Adverse Events and Concomitant Medications, a visit date is not required, and the **Add New** button opens the form directly.

## **Entering Data**

### **To Enter Data Directly into Forms:**

1. Click the **Add New** button to add a form associated with the Event. This will open the form directly for you to document.
2. Click the **Edit** button in the **three dots** menu to open the form.
3. Enter information into each field.

### **To Continue to the Next Page of the Form:**

Click the **Next** button.

### **To Mark Data Entry Complete:**

Click the **Complete** button.

### **To Close the Form and Continue Data Entry Later:**

Click the **Close** button.

**Note:** If you cannot access a Form, the access to that Form might be restricted in your Study.

### **To Download Data for Files, Audio Recordings, Videos, Images, Annotations, Drawings, or Signatures**

Click the **Download** button that appears in the field. This button is available in **Edit**, **Review-Only**, and **Read-Only** modes.

# Event/Form Independent Attributes

**Event/Form Independent Attributes** are separate from the **Event/Form Statuses**. Each Event or Form has a single status, but can have multiple attributes. For example, an Event might be **Completed**, **Signed**, and **Locked**.

## The Participant Matrix

Once you have entered data for Participants, use the **Participant Matrix** to view and navigate Participant records.

The Participant Matrix lists visit-based events across the top and participant IDs down the side. Each icon represents the status of the participant/event combination.

A legend of the icons is listed on the left side of the screen.

Hover over the icons in the **Participant Matrix** to see more details about the participant event. Click an icon for options to view and/or edit data, depending on your access.

You can filter Events by status, including the independent statuses of **Locked** and **Signed**. You can also filter Events with **Not Locked** and **Not Signed**.

**Participant Matrix for PAB 35**

50 | Show More | Select An Event | Add New Participant

Participant ID	Event 1	Event 3	Event4	CDASH	SD	Actions
001						
002						
003						
004						
005						
006						
007						

**Note:** If you filter Events with a status of **Not Started**, the Participant Matrix only includes Events that were previously started and then deleted, i.e. Events that have never been started are excluded.

If you have a repeating Event for a Participant, the **Participant Matrix** shows the least complete status. For example, if the first event is **data entry started** and the second event is **completed**, only the status of **data entry started** will display.

For information on removing, reassigning, and restoring Participants, see [Reviewing and Managing Data](#).

# The Participant Details Page

To access the **Participant Details Page**, click on the Participant ID or the **View** button that corresponds to that Participant.

The **Participant Details Page** is divided into sections. Below the **General Information** section, there are sections for **Visits** and repeating or non-repeating **Common Repeating**.

The **General Information** section displays information about the Participant, the study, the site, and the Participant status.

**Common Events** collect data that is not necessarily related to a specific visit, but may occur between visits (e.g., adverse events, concomitant medications, or early termination). When you view the **Participant Details** screen, all **Visit-Based Events** are listed first, followed by the **Common Events**.

The **Participant Details Page** includes **Visit-based Events** and related forms followed by any common events and related forms.

The page initially opens with the **Visit-Based Events** displayed and all **Common Events** collapsed.

## To Expand the Common Events Section:

Click the **Expand All** link to expand all sections including **Common Events** or click an individual common event section to expand only that section.



Participant 005

Custom View On

005 Audit Log | Showing Active Records

Expand All | Collapse All

General Information

Edit

Participant ID	005	Status	Available	First Name		Mobile	
Study Name	Kate_New_Study	Site Name	Best Hospital	Participate Status		Email	

Invite

Visits

Sort by Date

Search form or visit name

Add New

Follow-Up

09-Jul-2024

Follow-Up

Vital Signs

Labs

Treatment (1)

09-Jul-2024

Pre-Treatment Evaluation

Treatment Notification

Post-Treatment Evaluation

Vital Signs

Pathology

Labs

Daily (1)

09-Jul-2024

Daily Data

Baseline

09-Jul-2024

Medical History

Randomization Result

Vital Signs

Screening

09-Jul-2024

Screening Form

Inclusion and Exclusion

Adverse Events

Adverse Events

Add New

Search here

Actions	Form Status	Last Updated	Updated By
	Completed	09-Jul-2024	klambert+crc@openclinica.com
	Completed	09-Jul-2024	klambert+crc@openclinica.com

Result 1-2 of 2

Show 10 per page

< 1 >

Casebook

# The Update Event Screen

To update an Event status from the **Participant Details** screen, click the three-dot menu on the event and select **Edit**.



Available statuses are **Data Entry Started**, **Completed**, **Stopped**, and **Skipped**.



If you are a Data Manager or Administrator, you can click the **Lock Event** button at the bottom of the screen to lock the Event.

## Update Study Event

Participant ID: 123

Event: Exam


Start Date/Time:   \*  :  (DD-MMM-YYYY HH:MM) 

End Date/Time:    :  (DD-MMM-YYYY HH:MM) 

Status:

---

**Other Actions**



Lock Event: 



If you are an Investigator or Data Specialist, you can click the **Sign Event** button to sign. You cannot remove an Event from this screen.

## Update Study Event

Participant ID: a123

Event: Exam


Start Date/Time:   \*  :  (DD-MMM-YYYY HH:MM) 

End Date/Time:    :  (DD-MMM-YYYY HH:MM) 

Status:

---

**Other Actions**

Sign Event: 

## Event and Form Statuses/Actions

Events appear on the **Participant Matrix**, **Participant Details** screen, and many other screens throughout Study Runner. If you click on the Event on the **Participant Matrix**, you can choose from some of the actions.

**Note:** If you filter Events with a status of **Not Started**, the **Participant Matrix** only includes Events that were previously started and then deleted, i.e. Events that have never been started are excluded.

# Participant Matrix for Severe Headache Study

50

Show More

Select An Event

Add New Participant

Participant ID	Eligibility & Consent	Exam	Check In	Actions
				Apply Filter Clear Filter
001				
002				
003				
004			x3	
005				
006				

Results 1 - 6 of 6.

**Form Statuses** and **Attributes** do not appear on the **Participant Matrix**, but do appear on the **Participant Details** screen, and many other screens throughout Study Runner.

Visits

Sort by Date

Search form or visit name

Add New

Follow up (1)	Follow Up	
02-Nov-2021		
Treatment (1)	*Pre-Treatment Evaluation	*Treatment Administration
01-Nov-2021	11-Nov-21 by rbianchi (1)	22-Nov-21 by rbianchi (1)
Exam (1)	Exam	Vitals
01-Nov-2021	11-Nov-21 by rbianchi (1.2)	11-Nov-21 by rbianchi (1)
Baseline	Exam	Vitals
31-Oct-2021	11-Nov-21 by rbianchi (1.2)	11-Nov-21 by rbianchi (1)

Use the three-dot **Actions** menu to view all available actions for the Events and Forms.

**Visits**

Sort by Date

**Follow up (1)**  
02-Nov-2021

**Follow Up**

**Treatment (1)**  
01-Nov-2021

**\*Pre-Treatment Evaluation**  
11-Nov-21 by rbianchi (1)

**\*Treatment Administration**  
22-Nov-21 by rbianchi (1)

**\*Post Treatment Evaluation**

**Exam (1)**  
01-Nov-2021

**Exam**  
11-Nov-21 by rbianchi (1.2)

**Baseline**  
31-Oct-2021

**Exam**  
11-Nov-21 by rbianchi (1.2)

11-Nov-21 by rbianchi (1)

View  
Edit  
Remove  
Clear

Alternatively, hover over the form card to view the default action for the form and click the form card to take the default action. The default action is based off of your role and the status of the form.

**Follow-Up**  
03-Nov-2021

**Follow-Up**

**Vitals**

Edit Follow-Up

For **Common Events** on the **Participant Details** screen, the Independent Attributes appear in the **Form Status** column. **Actions** are available within the menu in the first column in the table.

**Adverse Event**

Add New

Search here

Actions	AE - Y/N	Start Date	Ongoing?	End Date	Form Status	Last Updated	Updated By
...	Yes	11-Nov-2022	Yes		completed	18-Nov-2022	rbianchi@openclinica.com
...		Nov-2022	No	10-Nov-2022	completed	18-Nov-2022	rbianchi@openclinica.com

Res **total** Show 10 per page < 1 >

Edit  
View  
Remove  
Lock

The form that was opened most recently is indicated by the yellow background.

Below are tables that display the statuses and actions you can take on Events and Forms. Below the tables are instructions on how to perform each action.

## Event Statuses

[table id=20 /]

## Event Attributes

[table id=21 /]

## Event Actions

[table id=22 /]

## Form Statuses

[table id=52 /]

## Form Attributes

[table id=53 /]

A red asterisk (\*) on a form card indicates that the form is required.

## Form Actions

[table id=54 /]

## Events

### To View an Event:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

### Edit an Event:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

### To Lock an Event:

If you are a Data Manager you can lock an Event so that no Form data can be entered or edited and Forms cannot be removed, restored, or cleared.

Click the **Lock** button in the **three dots** menu on the **Participant Details** screen.

or

Click the **Edit** button in the **three dots** menu on the **Participant Details** screen. On the **Update Study Event** screen, click the **Lock** button under **Other Actions**.

## To Sign an Event:

If you are an Investigator or Data Specialist, you can sign an Event to indicate that all Forms have been reviewed and approved.

Events must have a status of **completed**, **stopped**, or **skipped** before they can be signed. The Event cannot have been archived or removed. To sign a participant event, first review the data captured in the event, then change the status to **signed**.

Click the **Sign** button in the **three dots** menu on the **Participant Details** screen.

or

Click the **Edit** button in the **three dots** menu on the **Participant Details** screen. On the **Update Study Event** screen, click the **Sign** button under **Other Actions**.

**Note:** *If an Event is signed, changes to an item in a Form in that Event removes the signature. This also occurs if an Event status is changed from completed, stopped, skipped or **Not Scheduled** after being signed. In addition, this changes the Participant Status from **signed** to **available** and the Event Status to **completed**.*

Archiving/unarchiving or removing a form will unsign the Event. The exception is that when archiving/unarchiving, a form with a status of **Not Started** will not be unsigned.

Multiple users can sign an Event, so even if an Event has already been signed, the **Sign** action will still be available. If there are multiple signatures, the most recent one appears on the Form, and the others appear in the Audit Log.

## To Remove an Event:

Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Remove Event from Study**.

**Note:** If an Event is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.

Alerts & Messages >

Quick Access >

My Queries

Recent

OC-015

Instructions >

Confirm REMOVAL of this event. Data in forms in this removed event will be retained and viewable on the forms, but not included in any extracted data sets. This removed event can be restored at any time. All queries associated with this event and its forms will be automatically closed.

If this event or participant is currently signed, the signature will be invalidated by this action.

Info >

Remove Event from Study

Event Definition Name: Event 4

Visit#: 1

Date Started: 30-May-2022

Date Ended:

Status: data entry started

Event CRFs

CRF Name	Version	Status
MH	1	data entry complete
Vital-1	1	data entry complete

Reason for Change: \*

Remove Event from Study

Cancel

## To Restore an Event:

If you have removed an Event you want to restore, click the **Restore** button in the three dot **Event Actions** menu on the **Participant Details** screen. Enter a Reason for Change and click Restore Event to Study.

Restore Event from Study

Event Definition Name: Event 4

Visit#: 1

Date Started: 30-May-2022

Date Ended:

Status: data entry started

Event CRFs

CRF Name	Version	Status
MH	1	data entry complete
Vital-1	1	data entry complete

Reason for Change: \*

Restore Event to Study

Cancel

**Note:** If an Event is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again. When data was entered on the Form prior to the Event being removed, **The event this form is in has been removed** appears at the top of the Form.

## Forms


### To View a Form:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

## To Enter/Edit Form Data:

Click **Edit** in the **three dots** menu on the **Participant Details** screen. If you have permission to access the Form, you can start entering or editing data.


If you edit a form that has already been completed, you must enter a reason for change.

**Ethnicity** 

☐ Hispanic/Latino

☒ Not Hispanic/Latino

Please enter a reason for change at bottom of page.

**Race** 


☒ White

☐ Black/African American

☐ Asian

☐ Native Hawaiian/Other Pacific Islander

☐ Other

**Comorbidities** 

☒ Hypertension

☐ High Cholesterol


☐ Coronary Heart Disease

☐ Stroke

☐ Retinopathy

☐ Neuropathy

☐ Other

**Smoking Status** 

☐ Current Smoker

☒ Former Smoker

☐ Non-Smoker

Please enter a reason for change at bottom of page.

Looks like you've made some updates. Please tell us why:

☐ Apply to all

**Ethnicity** \*

**Smoking Status** \*

If your changes do not meet form requirements, such as constraints, you will see a message alerting you that specific values have errors and must be changed.



## To Remove a Form:

Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Remove Event CRF**.

**Note:** If a Form is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.

Alerts & Messages ▶

Quick Access ▼  
My Queries

Recent  
123  
Eligibi > Eligible  
Scree > Demographi  
Dai (1) > Daily Data

Instructions -  
Confirm REMOVAL of this form from this event. Data in this removed form will be retained and viewable on the form, but not included in any extracted data sets. This removed form can be restored at any time. All queries associated with this form will be automatically closed.  
  
If this event or participant is currently signed, the signature will be invalidated by this action.

Info ▶

### Remove Form from Event

Event Definition Name:	Eligibility and Consent
Visit#:	1
Date Started:	
Date Ended:	
Status:	data entry started

#### Event CRF

CRF Name	Version	Status
Eligible	1	initial data entry

#### Item Data

Id	Value
154	no

Reason for Change: \*

error

Remove Event CRF

Cancel

## To Restore a Form:

Click the **Restore** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Restore Event CRF**.

**Note:** If a Form is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again.

Alerts & Messages ▶

Quick Access ▼

My Queries

Recent

123

Eligibi > Eligible

Scree > Demographi

Dai (1) > Daily Data

Instructions

Confirm restoration of this form to this event. Data associated with this form will be restored to this participant's record.

If this event or participant is currently signed, the signature will be invalidated by this action.

Info ▶

Restore Form to Event

Confirm restoration of this form to this event. Data associated with this form will be restored to this participant's record.

If this event or participant is currently signed, the signature will be invalidated by this action.

Event Definition Name:	Eligibility and Consent
Visit#:	1
Date Started:	
Date Ended:	
Status:	data entry started

Event CRF

CRF Name	Version	Status
Eligible	1	initial data entry

Item Data

Id	Value
154	no

Reason for Change: \*

Restore Event CRF

Cancel

## To Clear a Form:

To clear form data, click the **Clear Form** button in the **three dots** menu on the **Participant Details** screen. The system does the following:

- Clears all data from the Form
- Closes all queries associated with the Form
- Removes a signature, if present
- Sets the **Status** of the Form to **Not Started**
- Records this action in the Participants Audit Log.

## To Print a Form:

1. Click the **Print** button that appears at the top of the screen for each Form.
2. Enter information on the Options screen
  - a. (Optional) Check the checkbox next to **Show** to include Query and Edit History on the printed Form.
  - b. Select a Paper Size.
  - c. Select a Paper Orientation.

**Note:** The **Paper Size** and **Paper Orientation** fields appear only for Forms with the **Style** of **theme-grid** and printing options must be set correctly in your browser for these settings to take

effect.

3. Click the **Prepare** button to show a preview.
4. Click the **Print** button.

×

## Options

To prepare an optimized print, please select the options below

**Show History**

☒ show

**Paper Size**

☒ A4    ☐ Letter

**Paper Orientation**

☒ Portrait    ☐ Landscape

Remember to set these same print settings in the browser's print menu afterwards!

CLOSE

PREPARE

**Note:** If your form includes a **visual analog scale** item, the **Background graphics** browser setting must be selected in the print screen so that the scale will display properly on the printed form.

7/10/24, 10:29 AM

OpenClinica

100: Vital Signs - Optimized

The form is currently displaying **English** text

This is EventS Repeat 2: /

This note is only shown for event not ordinal 2 in SE\_EVENTS

Please enter vital signs information below. BMI will be calculated automatically if weight and height are entered.

This patient has been randomly assigned to **Group E**

Was Temperature Measured?

These are radio buttons

☐ Yes
☒ No

Temperature

Triggered to 98.6 on selecting Temperature Measured = Yes

98.6

Temperature Units

☐ °C
☒ °F

The temperature you entered is

An answer has changed to another question that requires this question to be hidden, but we cannot hide it while it has data. Please clear out the data or modify the dependent answers.

Were weight & height measured?

Check the box if Yes

☐ Yes

Respiratory Rate:

Pulse:

This is required when Respiratory Rate is entered. It will be cleared whenever Respiratory Rate is changed.

Date of Birth

yyyy-mm-dd

Age at Event Start Date:

(in years)

Visit Date

Defaults to Event Start Date

2024-06-18

The subject's DOB is . The visit's date is 2024-06-18.

The current user's username is . The current user's role is Data Manager.

For more information about roles, please visit:

<https://openclinica.com>

Total Span of the Multifocal

Gross Masses:

static default value

This is a default value

heading text 1

heading text 2

heading text 3

https://cst1.eu.openclinica.io/OpenClinica/ParticipantDetailsPage?participantId=SS\_100&enetoOpen=true

1/1

Print

1 page

Destination

Save as PDF

Pages

All

Layout

Portrait

More settings

^

Paper size

Letter

Pages per sheet

1

Margins

Default

Scale

Default

Options

☒ Headers and footers
☒ Background graphics

Print using system dialog... (⌘P)

Cancel

Save

## Queries

### Review the Data and/or Add a Manual Query:

1. Click the **Cancel** button.
2. Review the value to make sure you entered it correctly.
3. If the value is correct, create the query that includes an appropriate message for that value. Otherwise, change the value.

### Allow the System to Automatically Create a Query for the Value in Question:

1. Click the **Proceed** button.
2. The system auto-generates a query based on the default message text defined in the Form.

## Alert



Some field values have errors. These must be addressed before the form is closed.

Click Cancel to return to the form to manually update the value or add a query for each field marked in red.

Click Proceed to continue closing the form now. A query will be automatically added for each field marked in red.

CANCEL

PROCEED

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