4 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 the **Using OpenClinica as an Investigator** section.

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

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4.1 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:

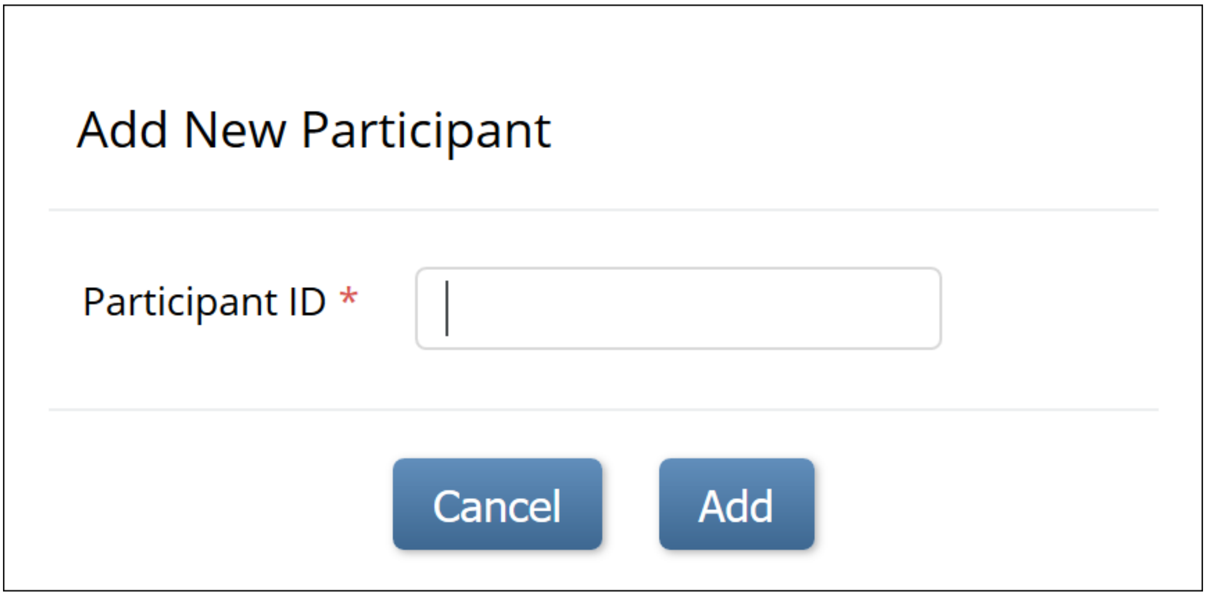
- Manually enter the Participant ID.
- Automatically generate a Participant ID based on a predefined format template.
- Add Participants in batch using **Web Services** (for **Administrators** with **Data Manager** access).

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.*

To Manually Add a Participant ID:

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

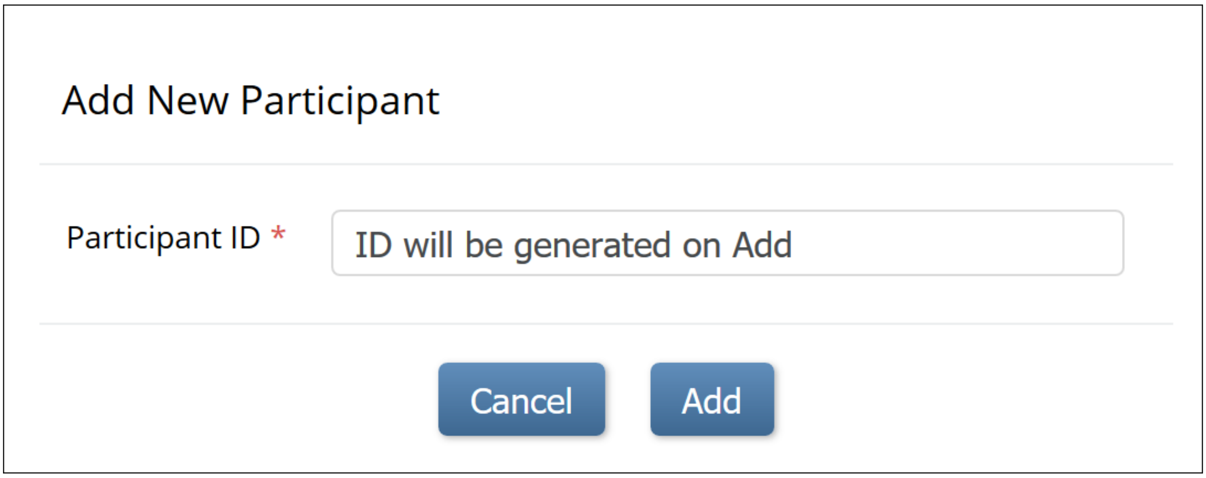
1. From the **Tasks** menu, select **Add Participant,** or on the **Participant Matrix** screen, click **Add New Participant** above the matrix.
2. Enter a Participant ID in the **Add New Participant** screen. (This should be a unique identifier, e.g. **001**).
3. Click the **Add** button.



To Make the System Automatically Generate a Participant ID:

If your Data Manager has chosen the **Automatic** 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. Click the **Add** button in the **Add New Participant** screen to generate a Participant ID.



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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4.2 Entering Data

As a Clinical Research Coordinator (CRC), you will move between the **Participant Matrix** and the **Participant Details** screen to complete your data-entry tasks. This workflow guides you through the full process—from locating a participant to entering, editing, reviewing, and managing form data.

OpenClinica supports efficient data entry through:

- **Auto-Save** — your work is saved as you type
- **Conditional Field Display** — only relevant fields appear
- **Automatic Checks and Calculations** — ensures accuracy
- **Queries** — document questions or discrepancies

Before You Begin

Before entering data, ensure the following steps are complete:

1. Add a Participant

A participant must be created before any scheduling or data entry can begin.
For instructions, refer to **Add Participants**.

2. Schedule an Event

Data entry occurs within scheduled events.
For instructions, refer to **Scheduling and Editing Events**.

Your ability to schedule events depends on your **access permissions**.

Step 1: Locate and Select a Participant

Begin in the **Participant Matrix**, your primary workspace for monitoring participant progress.

Use the Participant Matrix to:

- View participant status at a glance
- Identify forms that need attention

- Navigate to participant records
- Review icons that indicate form statuses and attributes
  - □ **Note**: For more information, refer to **Status Icons**.

To open a participant:

1. In the Participant Matrix, find the Participant ID.
2. Click the **Participant ID** or a form/event icon to open the **Participant Details** screen.
3. Your available actions depend on your **access permissions**.

For more information, refer to **The Participant Matrix**.

Step 2: Navigate to the Participant Details Screen

Once a participant is selected, the **Participant Details** screen becomes your workspace for all form-related actions.

Use this screen to:

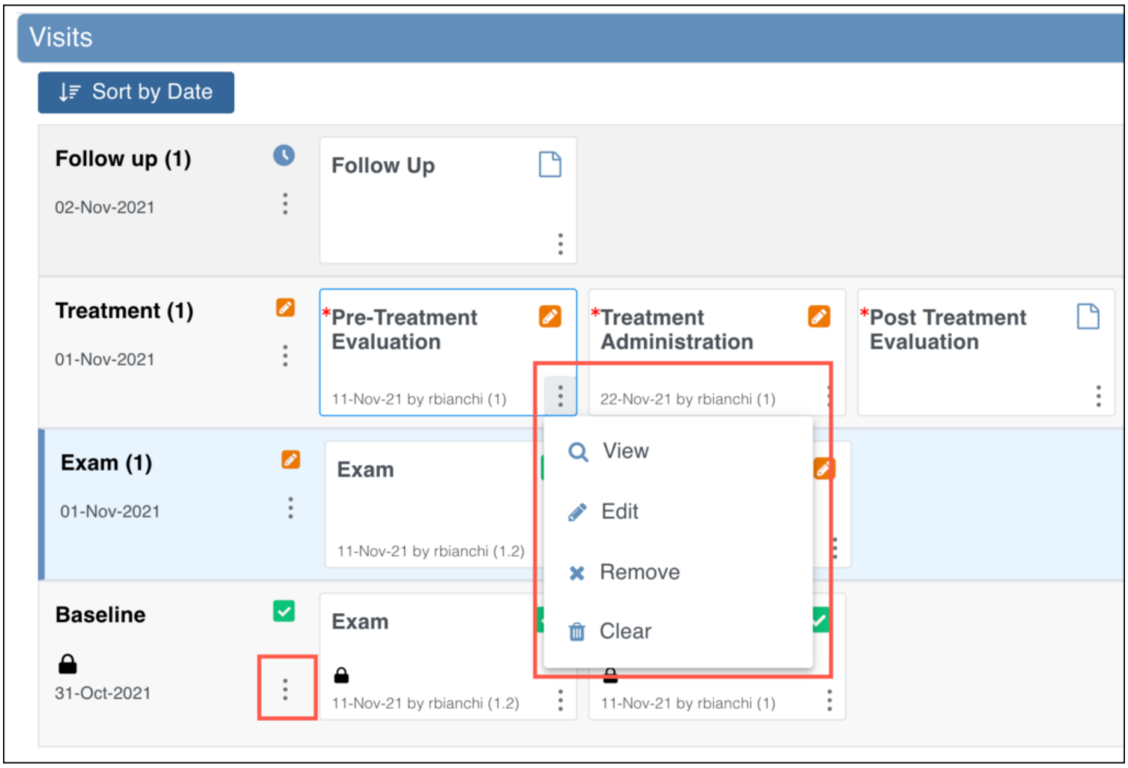
- Access all visit-based and common events
- Open forms for data entry
- Edit or review form data
- View form statuses and attributes
  - □ **Note**: For more information, refer to **Status Icons**.
- Download uploaded files or media

For more information, refer to **The Participant Details Screen**.

Step 3: Open a Form and Enter Data

To begin entering data:

1. Locate the form card on the **Participant Details** screen.
2. Click the **Edit (□)** icon to open the form.



3. Enter data in each required field.
4. If the form contains multiple pages, click **Next** to continue.
5. Your work is automatically saved as you enter data.

When finished:

- Click **Complete** to finalize the form, or
- Click **Close** to save your progress and return later.

Step 4: Handling Item Constraints

If a field violates a constraint (for example, a date falls outside the allowed range), you can choose how to proceed.

Option 1: Correct the Data or Add a Manual Query

1. Click **Cancel** to return to the field.
2. Update the value **or** create a manual query with an explanatory message.

Option 2: Allow the System to Create a Query

- Click **Proceed** to allow OpenClinica to generate a system query using the default message defined in the form.

For more information, refer to [Queries (CRC)](#).

Step 5: Edit Existing Data (If Permitted)

If you need to update a form:

1. Open the **three-dot menu** on the form card.
2. Select **Edit**.
3. Make the necessary updates.
4. Enter a **Reason for Change** when prompted.
5. Save and close the form.

 Note: If you cannot open or edit the form, your user role may restrict access or the status may prevent editing.

Step 6: Manage Supporting Actions

While working with forms, you may need to perform additional actions.

Download Files or Media

- Forms may include uploaded files, images, or signatures.
- Click **Download** within the field to retrieve supporting files.
- Downloads are available in **Edit**, **Review**, and **Read-Only** modes.

Address Queries

Depending on the form and your permissions, you can:

- Review system-generated queries
- Create manual queries
- Respond to outstanding queries

For details, refer to **Queries (CRC)**.

Step 7: Perform Form-Level Actions

From the form card's three-dot menu, you may be able to perform the following (based on access permissions and form status):

View a Form

- Review the form in Read-Only mode by selecting **View**
- 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.

Remove a Form

Removes form data from the participant's record. Use this action when a form was entered in error—for example, if data were entered for the wrong participant, or if a repeating or non-repeating common event form was created that is not needed for this participant.

To remove a form:

1. Select **Remove** from the three-dot menu.

2. Enter a **Reason for Change**.

3. Click **Remove Event CRF** to confirm.

 Note: Removing a signed form invalidates the signature. If restored, the form must be signed again.

Restore a Form

Restores previously removed form data to the participant record.

1. Select **Restore**.
2. Enter a **Reason for Change**.
3. Click **Restore Event CRF**.

 Note: Restoring a signed form requires re-signing.

Clear a Form

Users with **Edit access** can clear form data. Use this action when data was entered in error but the same form instance still needs to be used for the participant (for example, in a non-repeating common event form or a visit form that must be completed correctly). To clear a form:

1. On the **Participant Details** screen, open the **three dots menu** and click **Clear Form**.
2. The system performs the following actions:
    - Clears all data from the form
    - Closes all queries associated with the form
    - Removes a signature, if present
    - Sets the form status to **Not Started**
    - Records this action in the **Participant Audit Log**

Print a Form

1. Click **Print** at the top of the form.
2. Select printing options.

    - (Optional) Check the checkbox next to **Show** to include Query and Edit History on the printed Form.
    - Select a Paper Size.
    - 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.

□ **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.

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4.3 Queries (CRC)

Learn how to create, respond to, and close queries in OpenClinica. Queries help ensure data accuracy and compliance by flagging discrepancies or missing information. A **Query** is an inquiry or alert regarding potentially incorrect or incomplete data. Queries can be:

- **Manually created** by users
- **Automatically generated** by the system when certain conditions occur (for example, when closing a form with unaddressed errors)

□ **Note:** Queries created or closed automatically by OpenClinica (for example, when you leave a form, remove a form or event, publish a form version, or run an import) are attributed to the **System** user in the Queries table. This distinguishes them from queries added manually by users.
Annotations are notes added to a form that do not contain clinical data. They are typically used for workflow tracking or internal communication. **Reasons for Change** are notes entered by a user when modifying data on a form that has already been marked as **Complete**. These notes provide traceability for data edits.

Access Levels for Query Management

Access Level	Description
Read-Only	Allows users to view form data only. Users with Read-Only access cannot create, update, or respond to queries.
Review	Allows users to view form data and create or update queries, but not edit form data.
Edit	Allows users to enter or modify data and create or update queries.
Close Query	Not available for CRC users.

Queries Page

The **Queries** page is the central location 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 other columns.

The Queries page includes two sections:

- **Query Summary Table**
- **Queries Table**

Query Summary Table

The **Query Summary Table** displays a count of all query resolution statuses and their totals as shown in the **Queries Table**.
These totals reflect the number of items currently displayed in the Queries Table, based on any filters applied.

When filters are added to the Queries Table, both the total number of rows and the Summary Table totals update automatically to reflect the filtered view.

Summary count by status (based on table filters)

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

For information about query statuses, refer to **Query and Annotation Status Icons**.

Queries Table

The **Queries Table** lists all **queries**, **annotations**, and **reasons for change** recorded in the study.
You can filter the table to display only specific note types (for example, queries only, annotations only, or reasons for change only), or any combination of the three.
The table can also be **printed** or **downloaded** for offline review.

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
		0	Query										Apply Filter Clear Filter
182	abc123	67890	Query	New	99	99	Event1	Safety Officer	question		Automatic query for: Only Safety Officers can update this field	User1 User1@openclinica.com	
181	67890-001	67890	Query	New	104	104	Contact Testing Event	No Contact - No Manual	no_contact_no_manual_item_2	We can make it home with one headlight	Did Cinderella help you with this?	()	

Results 1 - 2 of 2.

Columns and Filtering Options

- **Query ID** – A unique identifier automatically assigned to each query when it is created.
  - If the view is filtered to show only annotations or reasons for change, this column displays **N/A**.
- **Detailed Notes** – Displays the full content of the query, annotation, or reason for change.
- **Assigned User** – Displays the user assigned to the query.
  - If no user is assigned, the column will appear empty (no name shown in parentheses).

Click **Show More** at the top of the table to display additional columns.
Available columns include:

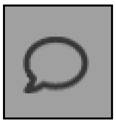
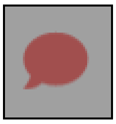
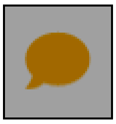
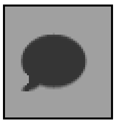
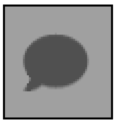
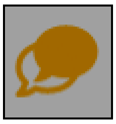
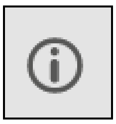
Date Created

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.

 Tip:
You can filter any column that includes a gray filter box.
For example, to filter by **Reason for Change**, click the gray filter box under the **Type** column and select **Reason for Change**.

Query and Annotation Status Icons

The following table describes the icons and statuses that appear in the **Queries** panel.

Icon	Status	Description
	**No Query**	Click this bubble to create a new query.
	**New**	A query has been added by a user with Review access to the form (ex. Monitor or a Data Manager) or was automatically generated by OpenClinica based on built-in edit checks.
	**Updated**	A user with Review access to the form has added information to the query.
	**Closed**	The query is considered resolved by the Data Manager or Monitor.
	**Closed Modified**	A slightly lighter version of the Closed icon indicates that data was changed after the query was closed.
	**Multiple New Queries**	Indicates that multiple new queries exist. You can select each query from the sidebar.
	**Multiple Updated Queries**	Indicates that multiple updated queries exist. You can select each query from the sidebar.
	**One or Multiple Annotations**	Indicates that one or more annotations exist. You can select each annotation from the sidebar.

Review Data Associated with a Query

You can review query-related data using one of two view options, accessible from the **Actions** column in the **Queries** table.

Icon	View option	Description

	View Query Only	Opens a shaded window showing the queried item's value with the query and item history in the foreground. You can add comments, assign the query, or email the assigned user. All users with Review access to the form can update queries; but **CRCs** cannot close queries.
	View Query Within Record	Opens the entire form in **Edit, Review** or **Read Only** mode (depending on user permissions) with all queried fields highlighted. This view displays full form context, allowing users with **Edit** access to review and update related data. Use this option when you need to review or modify data in context. Note: Opening a form in **Edit** mode may trigger field calculations and conditional logic, which can automatically recalculate or update field values and generate corresponding audit log entries. If you do not want to trigger calculations or logic, use **View Query Only**.

After reviewing, you can update the query comment, close the query details by clicking ×, and review the entire form in question.

Queries for Hidden or Deleted Items

In some cases, queries may remain even when the associated item or record is no longer visible on the form:

- **Conditionally displayed items:**
  If a query was added to an item that is only visible based on another response, and the lead-in response changes, the queried item may become hidden. The query still exists and must be resolved.

- **Repeating records:**
  If a query was added to a row that has since been deleted, the query remains active but no longer appears on the form.

When this occurs, OpenClinica displays a message informing you of the hidden item and providing an option to resolve the query.

To proceed:

- Click **OK** to review the remaining data on the form, **or**
- Return to the **Queries** screen and use the **View Query Only** option for that query (as instructed in the message).

Create a Query

You can create a query to inquire about participant data that appears incorrect, incomplete, or inconsistent with source records.

Common Use Cases

- Participant data does not match source records.

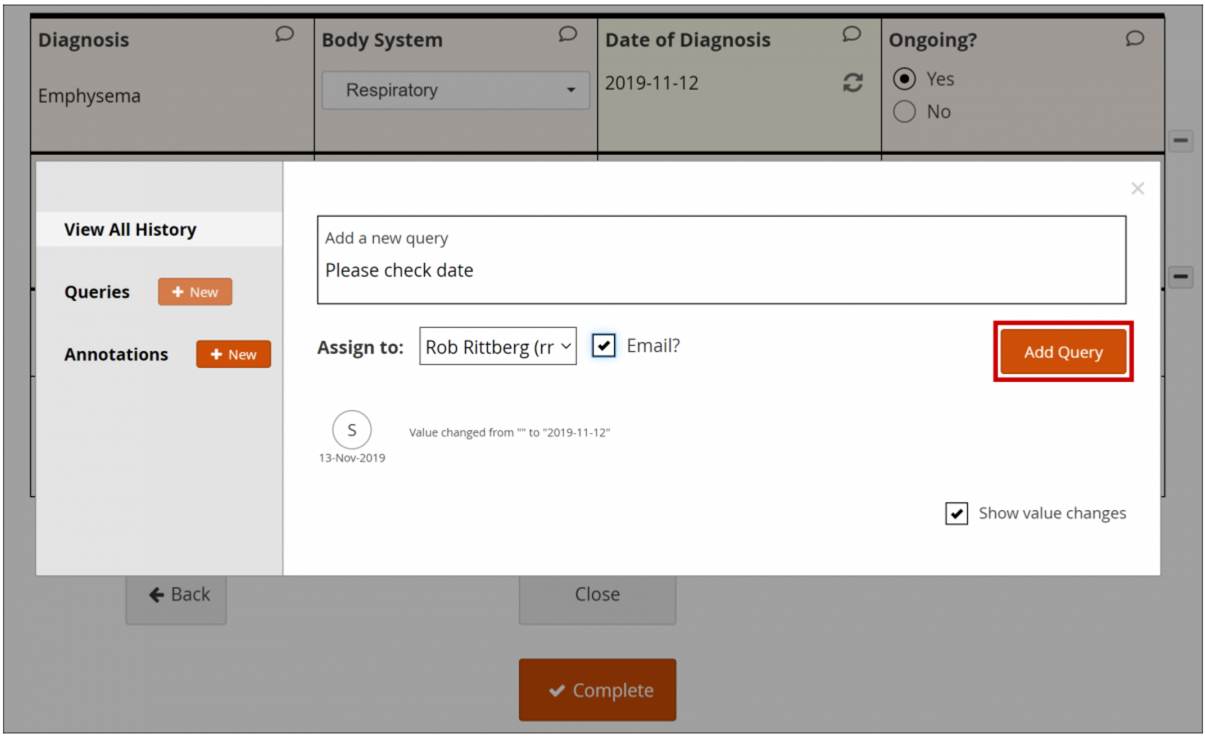
- Data appears clinically inaccurate or contains typographical errors.
- A form must be marked Complete, but an edit check prevents it.
- Required information is missing from a form.
- A form within an event was not started on time.

 Note: You can only add or respond to queries and annotations when you have **Edit** or **Review** access to the form, as defined by your user role. Users with **Read-only** access cannot create or respond to queries.

Each query is automatically assigned a **unique Query ID** within the study environment (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.

Steps to Create a Query

1. Open the **Form**.
2. Click the **Query Bubble** in the field where you want to create a query.
3. Click the **+New** button next to **Queries**.
4. In the **Add a new query** field, enter a clear description of the issue.
5. (Optional) Select a user from the **Assign to** dropdown.
    - 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 **Add Query.**



Best Practices

- When creating a query, assign it to the correct recipient.
- If action is required excluding if the query needs to be closed, the **Email** checkbox should be checked off.
- Create a new query for a single issue instead of combining multiple issues.
- Always create a new query rather than reopening one that has already been closed.

View Query History

To view the history for all queries and annotations on a single item:

1. Click **View All History**, or
2. Select an individual query or annotation from the left panel.

To include value changes in the history, select the **Show Value Changes** checkbox.

Respond to or Update a Query

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 form data changes, you must enter a **Reason for Change**.

 Note: You can only add or respond to queries and annotations when you have **Edit** or **Review** access to the form, as defined by your user role. Users with **Read-only** access cannot create or respond to queries.

To Respond to or Update in a Form:

1. Open the **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 Assign to dropdown.
    - 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 **Update** to save your response and keep 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 Assign to dropdown.
    - 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 **Update** to save your response and keep the query open.

Best Practices for Managing Queries

General Guidelines

- All users can view queries assigned to them by expanding the **Quick Links** header in the left-hand sidebar and selecting **Queries Assigned to Me**.
- When a query is updated or responded to, assign it to the correct recipient.
  - If action is required, select the **Email** checkbox to notify the assigned user.

Annotations

You can add **annotations** to a field to record workflow-related notes or comments. Annotations cannot be assigned, responded to, or closed.

Use Case

Add annotations to track workflow notes or internal comments on a form field.

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

□ **Tip:** Do not include clinical information in annotations.

To Enter an Annotation:

1. Open the **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 **Add Annotation**.

□ **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.
- You can view annotation history via **View All History** or by selecting individual annotations in the left panel.
- Selecting **Show value changes** displays associated value changes.

Download Queries, Annotations, and Reasons for Change

1. At the top of the **Queries** table, click **Download**.
2. In the **Format** field, select **Comma-Separated Values (CSV)** or **Portable Document Format (PDF)**.

3. Click **Download Notes**.

Print Queries, Annotations, and Reasons for Change

1. Click **Print** at the top of the Queries table.
2. When the **Print Window** opens, use one of the following methods:
    - Press **Ctrl + P** (Windows) or **Command + P** (Mac).
    - Click **OK**, then right-click the window and select **Print**.

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