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:

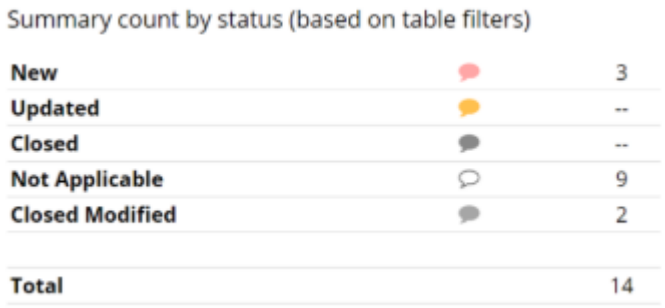
- **Query Summary Table**
- **Queries Table**

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

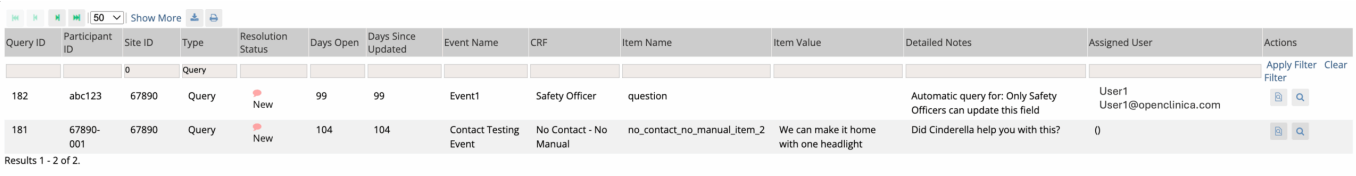
totals update automatically to reflect the filtered view.



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.



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

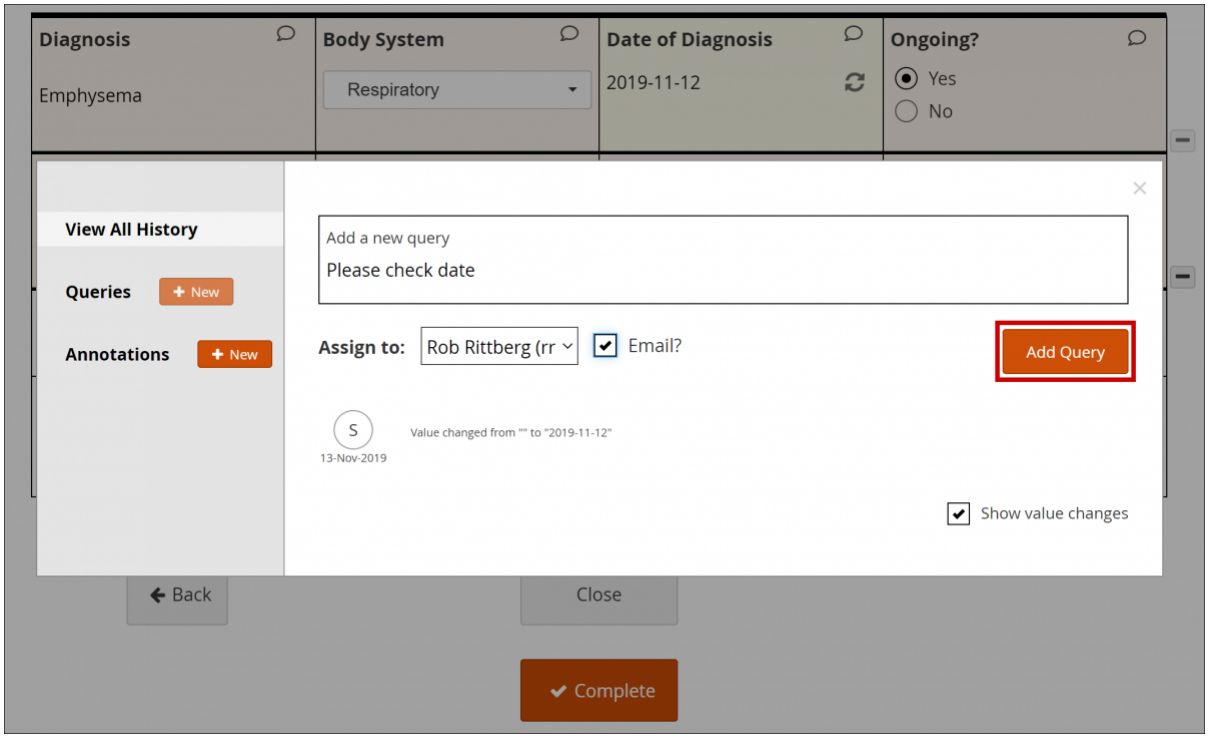
- Participant data does not match source records.
- Data appears clinically inaccurate or contains typographical errors.
- A form must be marked Complete, but an edit check prevents it.
- Required information is missing from a form.
- A form within an event was not started on time.

 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**.

Approved for publication by Kate Lambert. Signed on 2025-11-13 4:08PM

Not valid unless obtained from the OpenClinica document management system on the day of use.