

9.1 Queries (Data Manager)

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 or you can manually create a query.

Another user can respond to it 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 |
| Total | | 14 |

| 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 |
| 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) |   |

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 |  | -- |
| Total | | 9 |

| 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 |
|----------|----------------|---------|-------------------|-------------------|-----------|--------------------|-----------------------|-------------|--|------------|----------------|---------------|---|
| N/A | 002 | 1234567 | Annotation Query | Not Applicable | | | Eligibility & Consent | Eligibility | participant_suffers_from | no | Test | () | Apply Filter Clear Filter |
| N/A | 002 | 1234567 | Reason for Change | Not Applicable | | | Eligibility & Consent | Consent | i_consent_to_participate_in_this_study | option_1 | Test | () | Apply Filter Clear Filter |
| N/A | 002 | 1234567 | Reason for Change | Not Applicable | | | Eligibility & Consent | Consent | i_consent_to_participate_in_this_study | option_1 | Test | () | Apply Filter Clear Filter |

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 |


| <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 |
| | | | Query | | | | | | | | | | Apply Filter Clear Filter <div><div></div><div></div></div> |
| 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) | <div><div></div><div></div></div> |
| 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) | <div><div></div><div></div></div> |
| 3 | 004 | 1234567 | Query | New | 82 | 82 | Eligibility & Consent | Eligibility | participant_is_18_years_of_age_or_older | yes | Check this | Kerry Tamm (ktammninvadmin) | <div><div></div><div></div></div> |

View Query Only:

View Query

▼ Participant ID: 002
Event Name: Headache

Form Title: Other symptoms

How many times a week does the participant take an analgesic? 

11

View All History

Queries

 New

 #4


Automatic query
for: Value not ...

Annotations

 New

Respond to query

Assign to:

Kerry Tamm ()

☐ Email?

Close This Query

Update

R

10-Nov-2020



Automatic query for: Value not allowed

#4 assigned to ktamm. Status: new

KT

10-Nov-2020

Value changed from "" to "11"

KT

10-Nov-2020

Value changed from "1000000" to ""

KT

Value changed from "" to "1000000"

linica

View Query Within Record:

Is the participant taking any preventative measures?

☐ Caffeine

☐ Propranolol

☐ Botox Injections

☐ Magnesium

☐ Herbal Remedies

☐ Chronic use of analgesics

How many times a week does the participant take an analgesic?

11

View All History

Queries + New

#4 Automatic query for: Value not ...

Annotations + New

Respond to query

Assign to: Kerry Tamm () ☐ Email?

Close This Query Update

10-Nov-2020 Automatic query for: Value not allowed
#4 assigned to ktamm. Status: new

10-Nov-2020 Value changed from "" to "11"

10-Nov-2020 Value changed from "1000000" to ""

Value changed from "" to "1000000"

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** 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:

- 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
- Ongoing?:** Yes (selected), No

A modal window is open for adding a new query:

- Text Input:** "Add a new query" with the value "Please check date".
- Assign to:** Rob Rittberg (rr) (dropdown menu)
- Email?:** ☒ (checkbox)
- Add Query:** (button, highlighted with a red box)
- History:** A circular icon with 'S' and the text "Value changed from '' to '2019-11-12'" dated "13-Nov-2019".
- Show value changes:** ☒ (checkbox)

Navigation buttons at the bottom: 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 'Respond to query' form. On the left, there is a sidebar with 'View All History', 'Queries' (with a '+ New' button), and 'Annotations' (with a '+ New' button). The main area contains a text input field with the placeholder 'Respond to query' and the text 'Date Confirmed'. Below this is an 'Assign to:' dropdown menu, an 'Email?' checkbox, and two buttons: 'Close This Query' and 'Update' (which is highlighted with a red border). At the bottom, there is a checkbox labeled 'Show value changes'. The form also displays a list of annotations: a red dot for 'Please check date' with ID #46, a 'KT' icon for '1 minute', and an 'S' icon for '13-Nov-2019' with the text 'Value changed from "" to "2019-11-12"'. A callout bubble shows the text 'Please check date' and '#46 assigned to rritberg. Status: new'.

Closing Queries

Use Case(s):

- The information on the form has been changed to address the query.
- A response clarifies why the existing information is accurate.

Data Managers and Monitors can close queries when the issue has been resolved. Data Managers and Monitors are also the only user roles with the ability to reopen a closed query.

Best Practice:

- A new query should be created rather than reopening a query that has already been closed.
- 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 Close a Query 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 close.
4. Click the **Close** button.

To Close 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. Click the **Close** button.

The screenshot shows a web interface for responding to a query. On the left is a sidebar with 'View All History', '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 with 'Date Confirmed'. Below this is an 'Assign to:' dropdown menu, an 'Email?' checkbox, and two buttons: 'Close This Query' (highlighted with a red box) and 'Update'. At the bottom right is a checkbox labeled 'Show value changes' which is checked. In the center, there are two circular icons: 'KT' with '1 minute' and 'S' with '13-Nov-2019'. A speech bubble next to the 'KT' icon contains the text 'Please check date' and '#46 assigned to rritberg. Status: new'. Below the 'S' icon, it says 'Value changed from "" to "2019-11-12"'.

Queries can also be closed in bulk using the **Data Review Table**.

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 web interface for viewing history. On the left is a sidebar with 'View All History' at the top. Below it are two sections: 'Queries' with a '+ New' button, and 'Annotations' with a '+ New' button. The main area displays a list of annotations. Each entry includes a circular icon with a letter (KT or B), a date, and a description of the change. One entry is highlighted with a callout box containing an 'i' icon and the text 'Corrected the age. So this calculated field changed'. At the bottom right of the list is a checkbox labeled 'Show value changes' which is checked.

| Icon | Date | Description |
|------|-------------|---|
| 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 | |

Functional approval by Riley Bianchi. Signed on 2022-03-21 12:04PM

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

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