



6 Using OpenClinica as a Monitor

Before reviewing this section, make sure that you have read [Getting Started](#).

For Information on Using OpenClinica as a Monitor, See the Following Sections:

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6.1 Source Data Verification

Definition: Source Data Verification (SDV) is the process of reviewing and verifying data against source records to ensure accuracy.

The Source Data Verification screen is the Monitor's **Home** screen where they perform Source Data Verification (SDV).

To Access the Source Data Verification screen:

Click **Tasks** in the header bar of Study Runner, and select **Source Data Verification**.

The SDV Table

The **Source Data Verification** table displays the **SDV Status**, **Open Queries**, **SDV Requirements**, **CRF Status**, etc.

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
<input type="checkbox"/>	a123	1	0	Exam (1)	01-Nov-2021	Eligibility	Item Level	<input checked="" type="checkbox"/>	<input type="text"/> <input type="button" value="Data"/> <input type="button" value="Verify"/>
<input type="checkbox"/>	a123	1	0	Exam (1)	01-Nov-2021	Consent	Item Level	<input checked="" type="checkbox"/>	<input type="text"/> <input type="button" value="Data"/> <input type="button" value="Verify"/>
<input checked="" type="checkbox"/>	a1234	1	0	Exam (1)	01-Nov-2021	Eligibility	Item Level	<input checked="" type="checkbox"/> <input type="button" value="⬇️"/>	<input type="text"/> <input type="button" value="Data"/>
<input checked="" type="checkbox"/>	a1234	1	0	Exam (1)	01-Nov-2021	Consent	Item Level	<input checked="" type="checkbox"/> <input type="button" value="⬇️"/>	<input type="text"/> <input type="button" value="Data"/>
<input type="checkbox"/>	a1234	1	0	Treatment (1)	02-Nov-2021	Pre-Treatment Evaluation	Item Level	<input checked="" type="checkbox"/>	<input type="text"/> <input type="button" value="Data"/> <input type="button" value="Verify"/>

Results 1 - 5 of 5.

Note: Only forms the user has access to will appear in the Source Data Verification page.

SDV Requirements

SDV requirements are defined by your study protocol. Data Managers and Administrators can specify the level of SDV requirement for each item on a form in Study Designer. Below is a table that displays basic definitions of each SDV Requirement.

Icon	SDV Requirement	Description
(No Icon)	Not Applicable (Default)	SDV is not applicable for this form.
	Not Required	SDV is not required for the form, but you can still perform SDV if you want. This is often used when 10% of Forms need to be SDVed. Each form record is verified or unverified all together, rather than item-by-item
	Partial Required	Some fields on the form must be verified. Each form record is verified or unverified all together, rather than item-by-item
	100% Required	Every field in the form must be verified. Each form record is verified or unverified all together, rather than item-by-item
	Item-Level	Item-Level SDV allows you to choose which items will be part of SDV by selecting Required, Optional, or Not Applicable for each individual item on a form. Item records will then be marked as Verified or Not Verified independently and will become unverified independently if their data changes on the form.
	Item-Level (To be configured)	This indicates Item-Level SDV was selected, but is not configured validly since all items are set to Not Applicable. Use the Configure SDV link on the Form card in Study Designer to set each item to Required, Optional, or Not Applicable. At least one item needs to be Required or Optional, otherwise change the form's SDV Requirement to Not Applicable.

Not all forms will have all SDV Requirement options available. The SDV options are related to when the form was created and when it was published to Production in relation to the Stack 15 release (December 20th, 2021). The SDV options on forms are as follows:

- Form first published to Production prior to Stack 15 release: *Not Applicable, Not Required, Partial Required, 100% Required*
- Form created prior to Stack 15 release, but not yet published to Production: *Not Applicable, Not Required, Partial Required, 100% Required, Item-Level*
- Form first published to Production after Stack 15 release with one of the following statuses - Not Required, Partial Required, 100% Required: *Not Applicable, Not Required, Partial Required, 100% Required*
- Form first published to Production after Stack 15 release with one of the following statuses - Not Applicable, Item-Level: *Not Applicable, Item-Level*
- Form created after Stack 15 release: *Not Applicable, Item-Level*
 - Individual items have the following SDV Requirement options: *Required, Optional, or Not Applicable*
 - When first selecting Item-Level on a form, the item is set to Optional by default. Additional items that are added will default to Not Applicable.

Item-Level SDV Requirements:

- **Not Applicable:** Items cannot be verified.
- **Optional:** Items can be verified but they do not need to be verified in order to mark the form as Verified. Verifying at the form level does not change the status of unverified **SDV Optional** items.
- **Required:** Items must be verified for the form to be fully verified and get **Verified** status. Verifying at the form level changes the status of unverified **SDV Required** items to **Verified**.

The Source Data Verification table only displays completed forms with an SDV requirement other than **Not Applicable**.

You can click **Show More** to show more rows or filter a column by clicking the gray box below the column header.

Forms can have a status of **Ready to verify**, **Changed since verified**, or **Verified**.

Items can have a status of **Not Verified** or **Verified**.

SDV Form Statuses are as follows:

Icon	Status
	Ready to verify
	Changed since verified
	Verified

You can sort the columns, such as **Event Date** by clicking the column header.

The **Open Queries** column displays the number of queries that are open (**New** or **Updated**) for a specific CRF. This is a good way to keep track of which CRFs are likely to change due to outstanding queries.

If the number of queries is **0**, the number appears as plain text. If the number of queries is greater than **0**, it appears as a link. If you click the link, it takes you to the **Queries** screen, which is filtered to the Participant, Form, and Event that the row in the **SDV** table corresponds to.

The **CRF Status** column displays the status of the form as well as whether it is **Locked**, **Signed**, etc.

Click the **View CRF** (magnifying glass) button in the **Actions** column to open the form in Review-Only mode (unless the form is in a status of **Locked**, in which case, the form opens in Read-Only mode).

Click **Data** to view form information and review the items individually. Use the radio buttons in the

upper-right corner to view only the specific data you want to review on the form:

Form Level:

- **Show all items:** displays all items on the form
- **Show only changed since last Verified:** displays items that have had a value changed since the form was verified

Item-Level:

- **Show all items:** Shows all items on the form regardless of SDV requirement or status
- **Show all SDV items:** Shows all SDV Required or SDV Optional items regardless of status
- **Show items needing verification:** Shows all SDV Required items with unverified status

Verifying Data

Use Case(s):

- The information on the form has been changed to address a query.
- A response clarifies why the existing information is accurate.
- The SDV Plan requires Source Data Verification regardless of whether or not there is a query.

To Perform Source Data Verification:

1. Click the **View** icon in the **Actions** column to view the completed form.
2. Compare the data entered in the form against the source record. If there are any discrepancies between the source record and the data on the form, click the **Query Bubble** for the item in question and create a query for the site to address.
3. Complete the review of the data and close the form.
 1. Click **Verify** to verify all items on that form, or
 2. Check off each form on the **SDV Forms Table** and then click **Verify All Checked** to verify multiple forms at once.

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
Ready to verify + ...									Apply Filter Clear Filter
<input type="checkbox"/>	a123	1	0	Eligibility & Consent	01-Nov-2021	Physical Exam	Item Level		Data Verify
<input type="checkbox"/>	a123	1	0	Eligibility & Consent	01-Nov-2021	Vital Signs	Item Level		Data Verify
<input type="checkbox"/>	a1234	1	0	Exam (1)	01-Nov-2021	Vital Signs	Item Level		Data Verify
<input type="checkbox"/>	a12345	1	0	Exam (2)	30-Nov-2021	Vital Signs	Item Level		Data Verify
<input type="checkbox"/>	a1234	1	0	Adverse Event (1)		AE1	Item Level		Data Verify

Results 1 - 5 of 5.

Verify All Checked

Alternatively, you can click the **Data** button and review the data. Then select items to verify and click **Verify All Checked**.

Participant ID: a12345		Event Name: Exam	
Site ID: 1		Event Start Date: 30-Nov-2021	
Form Name: Vital Signs		SDV Form Requirement: Item Level	
Form Status: data entry complete		SDV Form Status: Ready to verify	

<input type="radio"/> Show all items <input type="radio"/> Show all SDV items <input checked="" type="radio"/> Show items needing verification								
<input type="checkbox"/>	Brief Description (Item Name)	Value	SDV Requirement	Last Verified (UTC)	Open Queries	Last Modified (UTC)	Modified By	Actions
<input checked="" type="checkbox"/>	Visit number (VISIT) (1)	Baseline	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
<input checked="" type="checkbox"/>	Temperature in Celcius (TEMP) (1)	36	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
<input checked="" type="checkbox"/>	Heart Rate (BPM) (HR) (1)	98	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
<input checked="" type="checkbox"/>	Mean Arterial Pressure (mmHg) (MAP) (1)	76	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
<input checked="" type="checkbox"/>	Systolic arterial blood pressure (mmHg) (SABP) (1)	110	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
<input type="checkbox"/>	Diastolic arterial blood pressure (mmHg) (DABP) (1)	60	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
<input type="checkbox"/>	Central Venous Pressure (mmHg) (CVP) (1)		Required	Never	0	06-Dec-2021 14:15	Riley Bianchi	

When the final unverified **SDV Required** item on a form becomes **Verified**, the form will become **Verified**. If there are no **SDV Required** items configured on a form, verifying the final unverified **SDV Optional** item on a form will verify the form. Clicking **Verify** for a form will mark all **SDV Required** items on that form as verified. Clicking **Verify** for a form will **not** mark **SDV Optional** items as verified. **Note:** *If you inadvertently marked a record as Verified, you can reset its status by clicking the double-check icon in the **SDV Status** column. You are prompted to confirm resetting the status. If a form is marked as not verified after it was verified, this does not reset the status for all items on the form. Use the **Data** button to update the SDV status for individual forms as needed.*

Changes Made After Verification

Form-Level:

If a value on a verified form was changed, the status of the form will become **Changed since verified**, and the form must be verified again.

Item-Level:

If the value of a verified item (whether the item is configured as **SDV Required** or **SDV Optional**) was changed:

- If the form was verified, the form becomes **Changed since verified** and the item becomes **Not Verified**
- If the form was not verified, the status of the form does not change, and the item becomes **Not Verified**

If the value of an unverified **SDV Optional** item changed after the form was Verified, the form status will remain **Verified**. If an additional repeating group occurrence containing **SDV Required** items was added to the form:

- If the form was verified, the form becomes **Changed since verified** and the Required item remains **Not Verified**.
- If the form was not verified, the status of the form does not change and the Required item remains **Not Verified**.

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6.2 Queries (Monitor)

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)

□ **Warning:** Only **Data Managers** and **Monitors** can close queries.

□ **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	Available only to Data Managers and Monitors . These roles can close or reopen queries.

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.

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?	0	 

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.

□ **Note:** System-generated queries appear in the Queries table with **System** listed as the user.

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; only Data Managers and Monitors can 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 **x**, and review the entire form in question.

Data Managers and **Monitors** have the additional option to close the query.

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**.

The screenshot displays a medical data management interface. At the top, there are four main sections: **Diagnosis** (Emphysema), **Body System** (Respiratory), **Date of Diagnosis** (2019-11-12), and **Ongoing?** (Yes/No). Below these is a central panel for adding a new query. It features a text input field with the placeholder "Add a new query" and the instruction "Please check date". Below the input field, there is an "Assign to:" dropdown menu set to "Rob Rittberg (rr)", a checked "Email?" checkbox, and a red-bordered "Add Query" button. A history section below shows a value change from "" to "2019-11-12" on 13-Nov-2019, with a checked "Show value changes" checkbox. At the bottom, there are "Back", "Close", and "Complete" buttons.

Best Practices

- If a form has not been started when expected, a **Data Manager** can add a query to the event's start date.
- 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 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**.
- **Data Managers** can also access their assigned queries directly from the **Home** screen by clicking **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.

- **Data Managers** and **Monitors** should review the full list of queries regularly to identify and resolve any unassigned queries.

□ **Tip**

Queries on conditional or repeating fields may remain active even if the field is no longer visible on the form (for example, if a conditional response hides the item or a repeating record row is deleted). OpenClinica displays a message when this occurs. Click **OK** to review the remaining data on the form. The hidden query still exists and must be addressed.

Close a Query

Data Managers and **Monitors** can close queries when the issue has been resolved. These roles are also the only users who can reopen a closed query.

Use Cases

- The issue has been corrected in the form.
- A user has provided a valid explanation for the existing data.

□ **Note:** Some queries may close automatically due to system actions such as form removal, version updates, or field visibility changes. These closures are attributed to the **System** user.

Close a Query In a Form

1. Open the **Form**.
2. Click the **Query Bubble** in the field containing the query.
3. Select the query you want to close.
4. Click the **Close** button.

Close a Query from the Queries Table

1. In the **Queries** table, locate the query you want to close.
2. In the **Actions** column, click **View Query Only** or **View Query Within Record**.
3. Click **Close**.

□ **Tip:** Queries can also be closed in bulk using the Data Review Table. For more information, refer to [Data Review Tables](#).

□ **Note:** Only **Data Managers** and **Monitors** have permission to close queries.

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.

□ **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. At the top of the **Queries** table, click **Print**.

2. When the print window opens, choose 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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