

7.1 Source Data Verification

Definition: Source Data Verification 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.

Monitors can perform Source Data Verification on the **Source Data Verification** screen, where they can review and verify data against source records.

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.

Source Data Verification for Severe Headache Study

50 | Show More

Select: All Shown None

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
<input checked="" type="checkbox"/>	001	HEADACHESTUDY	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/>	<input type="checkbox"/> Data
<input type="checkbox"/>	002	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/>	<input type="checkbox"/> Data <input type="checkbox"/> Verify
<input checked="" type="checkbox"/>	002	1234567	1	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/>	<input type="checkbox"/> Data
<input type="checkbox"/>	003	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Data <input type="checkbox"/> Verify
<input type="checkbox"/>	003	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Data <input type="checkbox"/> Verify
<input checked="" type="checkbox"/>	004	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Data
<input type="checkbox"/>	004	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Data <input type="checkbox"/> Verify

Results 1 - 7 of 7.

SDV Requirements

SDV Requirements are defined by your study protocol. Data Managers and Administrators can specify the level of SDV requirement for a Form in Study Designer.

Below is a table that displays basic definitions of each SDV Requirement.

[table id=48 /]

Only Forms with a **Status** of **completed** appear in the **Source Data Verification** table. Forms with an **SDV Requirement** of **Not Applicable** do not appear on the table.

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

SDV Statuses make it easy for Data Managers and Monitors to quickly evaluate which items to focus their review on.

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

If a Form was previously verified, the status will be **Changed since verified**, and it must be verified again.

SDV Statuses are as follows:

[table id=51 /]

You can sort the columns, **Event Date** and **Last Updated Date** by clicking the column headers.

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 that 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.

The **View** button in the **Actions** column opens 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 the Data button to view Form information. You can use the radio buttons in the upper-righthand corner to filter with **Show all items** or **Show only changed since last Verified**. You can also view queries and verify items from this screen.

Verifying Data

Use Case(s):

- The information on the form has been changed to address the query.
- A response clarifies why the existing information is accurate.
- The SDV Plan requires Source Data Verification regardless of whether there is a query.

Source Data Verification is the process of reviewing and verifying data against source records to ensure accuracy.

To Perform Source Data Verification:

1. Click on 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.

Alternately, you can click the **Data** button, review the data, and then click the **Verify** button on that

screen.

Participant ID:	002	Event Name:	Eligibility
Site ID:	1234567	Event Start Date:	20-Aug-2020 12:00
Form Name:	Eligibility	SDV Requirement:	Not Required
Form Status:	data entry complete	SDV Status:	Changed since verified

Clear Filter Show all items Show only changed since last Verified

Brief Description (Item Name)	Value	Last Verified (UTC)	Open Queries	Last Modified (UTC)	Modified By	Actions
Participant suffers from severe headaches (participant_suffers_from)	no ▲	20-Aug-2020 13:50	0	21-Aug-2020 19:05	Kerry Tamm	

[Verify](#)

Or you can check off each item on the **SDV** screen and click the **Verify All Checked**.

Source Data Verification for Severe Headache Study

50 | Show More

Select: All Shown None

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
<input checked="" type="checkbox"/>	001	HEADACHESTUDY	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/>	Data
▲ <input type="checkbox"/>	002	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/>	Data Verify
<input checked="" type="checkbox"/>	002	1234567	1	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/>	Data
<input type="checkbox"/>	003	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/> ⚠	Data Verify
<input type="checkbox"/>	003	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/> ⚠	Data Verify
<input checked="" type="checkbox"/>	004	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required	<input checked="" type="checkbox"/> ⚠	Data
<input type="checkbox"/>	004	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required	<input checked="" type="checkbox"/> ⚠	Data Verify

Results 1 - 7 of 7.

[Verify All Checked](#)

Note: If

you inadvertently marked a record as source data 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.

Approved for publication by Kerry Tamm. Signed on 2021-01-20 2:55PM

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