

9.2 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.

Source Data Verification for New Test Site

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 type="checkbox"/> | a123 | 1 | 0 | Exam (1) | 01-Nov-2021 | Eligibility | Item Level | <input checked="" type="checkbox"/> | <input type="text" value=""/> <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" value=""/> <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" value=""/> <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" value=""/> <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" value=""/> <input type="button" value="Data"/> <input type="button" value="Verify"/> |

Results 1 - 5 of 5.

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. |

| Icon | SDV Requirement | Description |
|--|-------------------------------|---|
|  | 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
- **Required:** items must be verified for the form to be fully verified and get Verified status

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**, and **Verified**.

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 (Required or 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 an additional repeating group occurrence containing a Required item 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**.

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 | ✓ 🔒 | <input type="checkbox"/> Data Verify |
| <input type="checkbox"/> | a123 | 1 | 0 | Eligibility & Consent | 01-Nov-2021 | Vital Signs | Item Level | ✓ 🔒 | <input type="checkbox"/> Data Verify |
| <input type="checkbox"/> | a1234 | 1 | 0 | Exam (1) | 01-Nov-2021 | Vital Signs | Item Level | ✓ | <input type="checkbox"/> Data Verify |
| <input type="checkbox"/> | a12345 | 1 | 0 | Exam (2) | 30-Nov-2021 | Vital Signs | Item Level | ✓ | <input type="checkbox"/> Data Verify |
| <input type="checkbox"/> | a1234 | 1 | 0 | Adverse Event (1) | | AE1 | Item Level | ✓ 🔒 | <input type="checkbox"/> 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 |

Show all items Show all SDV items 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 **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 **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. **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.*

Functional approval by Riley Bianchi. Signed on 2022-06-28 2:07PM

Approved for publication by Paul Bowen. Signed on 2022-06-28 3:16PM

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