8 Using OpenClinica as a Data Manager

Before reviewing this section, make sure that you have read **Getting Started**.

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

Approved for publication by Kate Lambert. Signed on 2025-07-15 1:00PM

8.1 Managing Sites

The *Manage All Sites* screen allows Data Managers to configure form behavior and event settings at the site level. This is essential in multi-center studies where site-specific variations—such as form versions, source data verification (SDV) rules, or form visibility—may be required. Using this screen, you can tailor settings per site without affecting the global study design.

For more information about how to add or edit sites, refer to **Adding Sites.**

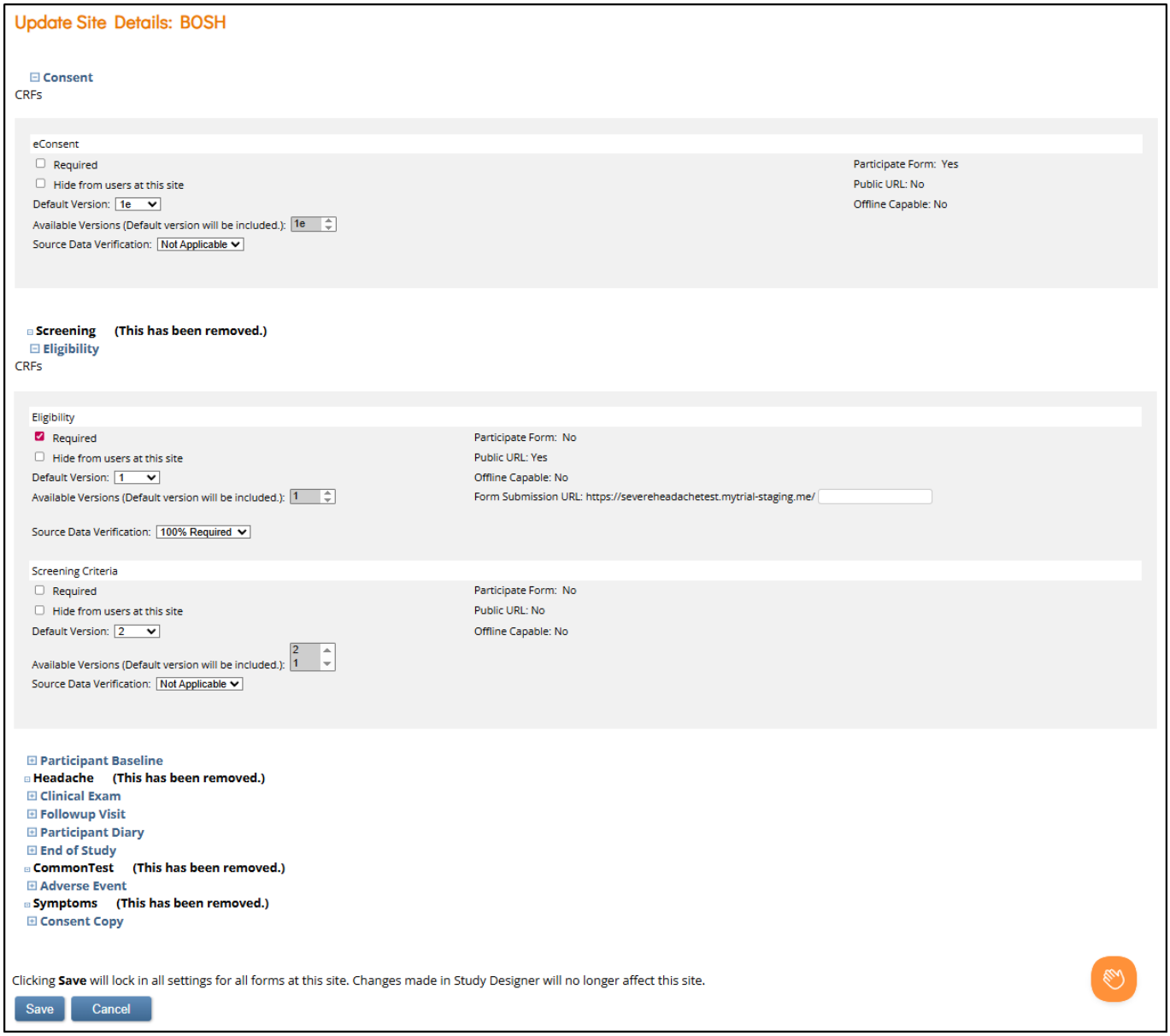
Access the Manage All Sites Screen

1. Ensure the site has been created and status set to Available, and that the study is published and set to Available.
2. Go to **Tasks > Sites**.
3. The **Manage All Sites in Study** screen opens.

Click the **Edit** icon ( ) for the site you want to configure. This opens the **Update Site Details** page.

Update Site Details Page

The **Update Site Details** page shows all study events. You can expand an event to view its associated CRFs. In each CRF row, you can configure site-specific settings such as default form version, which form versions are available for the site, and visibility. Some settings are editable at the site level, while others are non-editable and must be configured in **Study Designer**.



Each CRF row allows configuration of the following site-level settings:

- **Required**: Marks the form as required for completion at this site.
- **Hide from users at this site**: Hides the form from site users while keeping it visible for study-level users.
- **Default Version**: Selects the default form version shown when an event is scheduled.
- **Available Versions**: Specifies which version(s) are available for data entry. For example, during a protocol amendment rollout, some sites may have IRB approval for a new version while others do not.
- **Source Data Verification (SDV)**: SDV settings define how forms are monitored for source data verification. Available options depend on the type of SDV used on the form. For more information on SDV, refer to **SDV for Data Manager.**
    - **Item-Level SDV:** Applies the item-level SDV settings defined in Study Designer to the site, or opts the site out from item-SDV on the given form. The following options will appear only if the form has Item-Level SDV defined:
        - **Item-Level SDV:** SDV is applied based on item-level settings. Items can be marked as Required, Optional, or Not Applicable
        - **Not Applicable:** SDV is not used for this form.

When all Required items are verified, the form is automatically marked as

verified.

 Use item-level SDV settings at the site level to align with your monitoring plan. *For example, configure a form as Not Applicable (N/A) at sites that do not require additional quality checks.*

- **Form-Level SDV:** Only applicable to forms created prior to the release of Stack 15 on 20-Dec-2021. Applies verification to the entire form. The form is either marked as verified or not.
  - **100% Required:** All items must be verified.
  - **Partial Required**: Intended for selected items but functions the same as 100% Required.
  - **Not Required:** No items need verification, but the form can still be marked as verified.
  - **Not Applicable:** SDV is not used for this form; it is excluded from SDV reports and views.

 Use form-level SDV settings at the site level to reflect your monitoring plan. While the options (100% Required, Partial Required, Not Required) behave the same within OpenClinica, you can still configure them to document site-specific monitoring intentions (e.g., stricter oversight for sites with data quality concerns, or reduced requirements for high-performing sites).

- **Public URL**: If a form is configured for **Public URL** access (used in the Participate module), a **Form Submission URL** field appears. Each site must be assigned a unique URL suffix. The prefix is standardized across the study and is based on the URL configured in the Participate module settings. Public URL forms allow participants to self-enroll or submit contact/pre-screening information without site staff intervention.
- Additionally, there are three settings that are visible but not configurable within the Managing Sites interface:
  - **Participate Form**: Indicates whether it is an electronic Patient Reported Outcomes (ePRO) Form for Participant data entry. For more information, refer to **OpenClinica Participate**.
  - **Public URL**: Indicates whether it is a form designed to allow Participants to self-register for the study.
  - **Offline Capable**: Indicates whether the form has been configured for Offline Mode capability.

For more information and setup instructions for Offline Capable or Public URL, refer to **Configure Forms for Offline Mode and Public URL.**

Archived Events and Forms

If an event or form is labeled **(This has been removed.)**, it was archived in Study Designer. These events:

- Remain visible for reference
- Cannot be configured further
- Are excluded from new data entry
- Retain existing data for reporting and review

Save Locks in Site Settings

Clicking **Save** on the **Update Site Details** page saves all settings for all forms for the site, regardless of whether any changes were actually made. After saving:

- The site stops inheriting updates from **Study Designer**.
- Future changes (e.g., SDV adjustments, new form versions) will not apply automatically.
- To apply study-level changes, you must reconfigure the site manually.
- If a new form is created after site settings are saved, the form will automatically inherit its configuration and any subsequent settings changes from **Study Designer**.

8.2 Queries (Data Manager)

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.

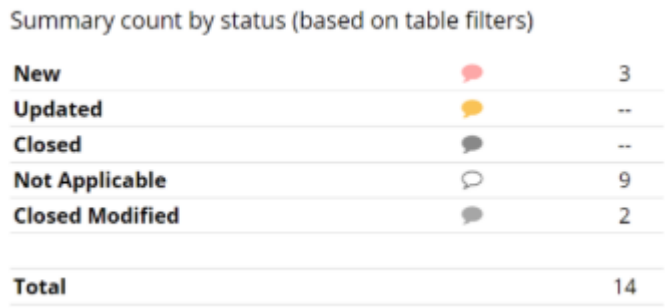
The Queries page includes two sections:

- **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.

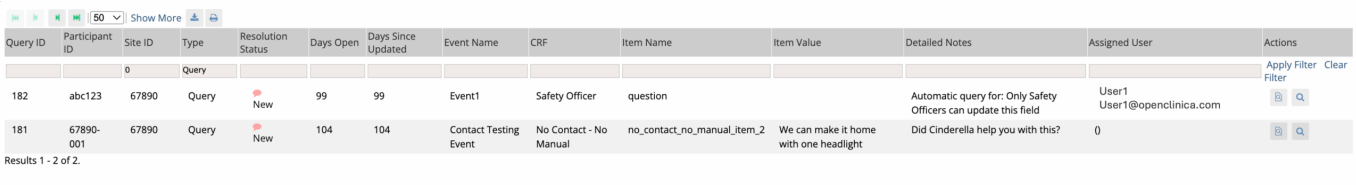
When filters are added to the Queries Table, both the total number of rows and the Summary Table totals update automatically to reflect the filtered view.



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.

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 ×, 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.

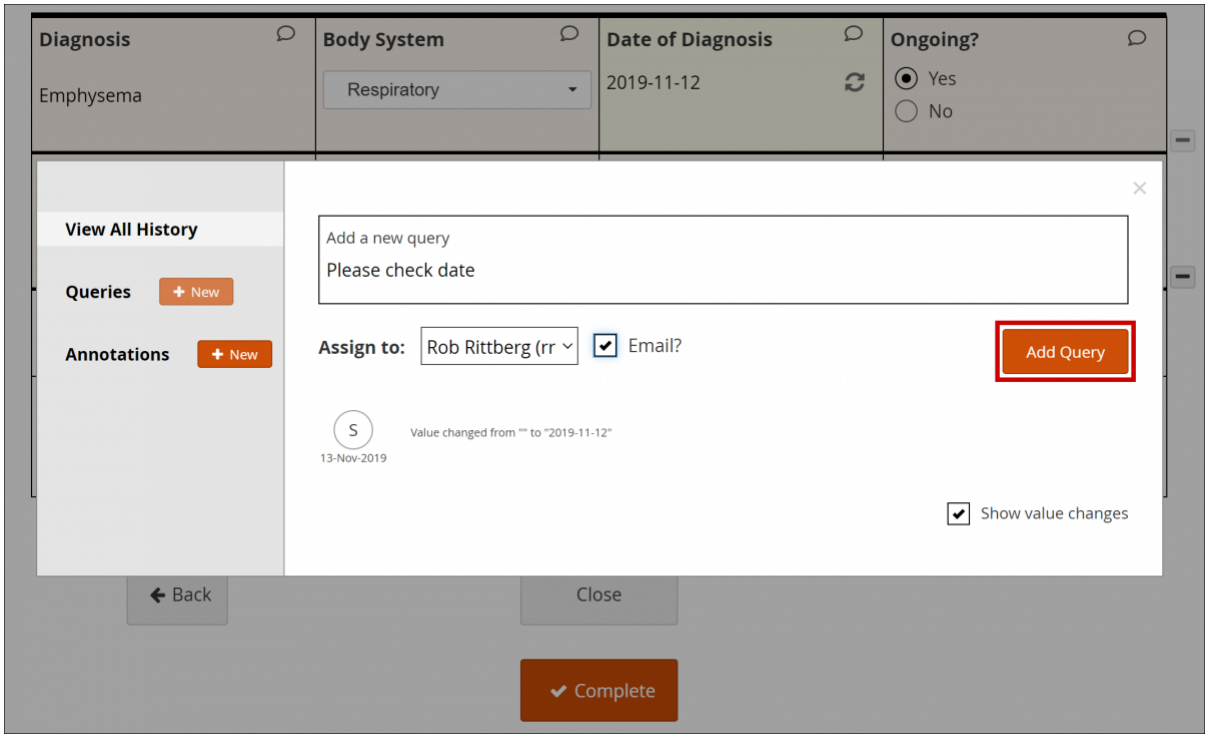
Each query is automatically assigned a **unique Query ID** within the study environment (Test or Production).The ID appears in the **Queries** widget but is not visible until you close and reopen the Form. It also appears on the **Queries table**. You can add multiple queries regardless of any existing 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.**



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**.

8.3 Source Data Verification

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

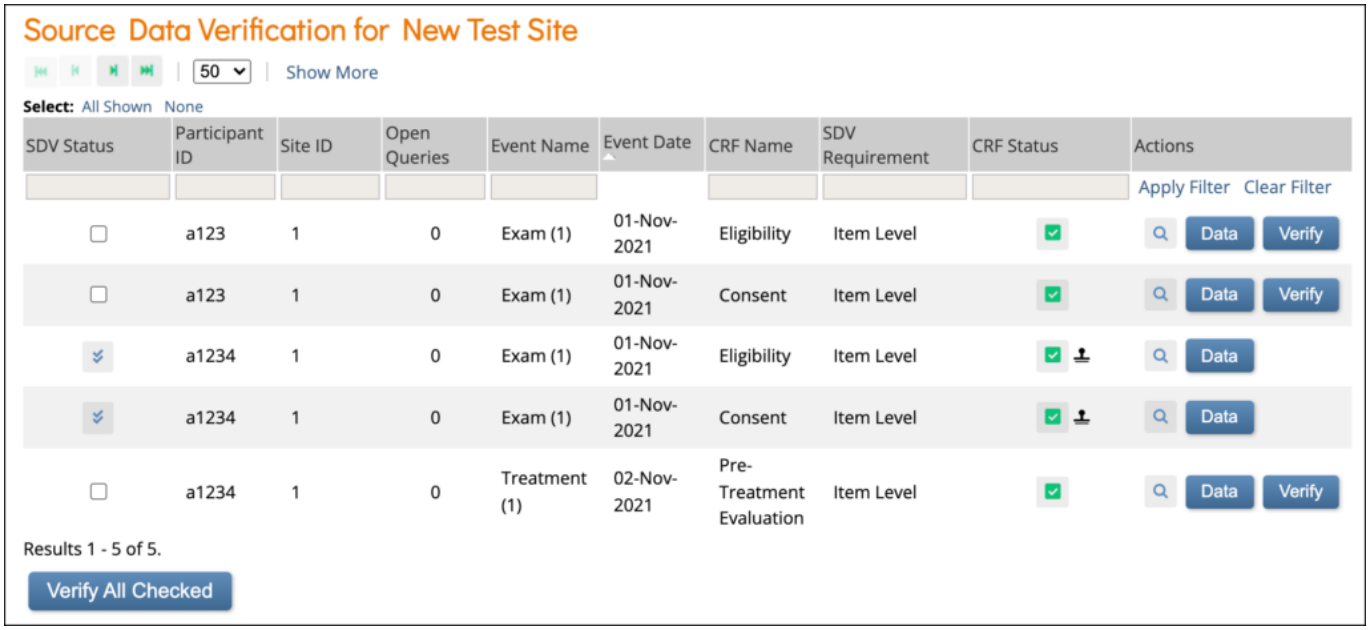
The Source Data Verification screen is the Monitor's **Home** screen where they perform Source Data Verification (SDV).

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.



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.

Icon	SDV Requirement	Description
	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

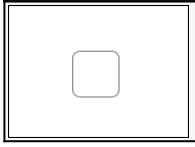
The Source Data Verification table only displays completed forms with an SDV requirement other than **Not Applicable**.

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**.

SDV Form Statuses are as follows:

Icon	Status
	Ready to verify

Icon	Status
	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.

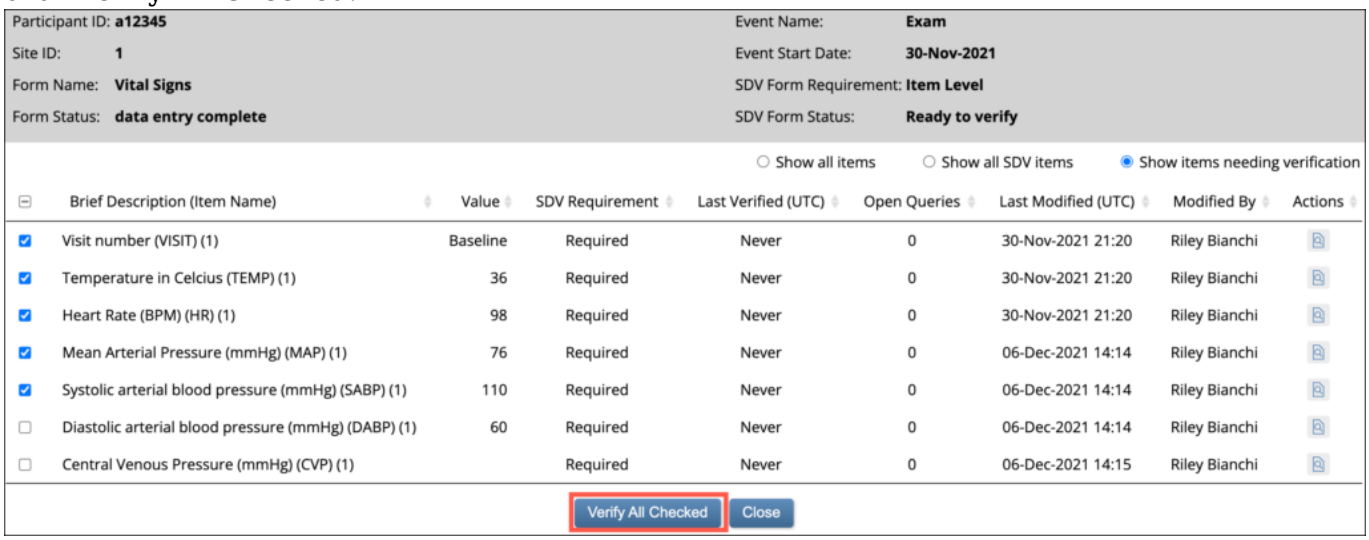
To Perform Source Data Verification:

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.

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



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. 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 (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 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 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.**

Approved for publication by Kate Lambert. Signed on 2025-11-24 9:26AM

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

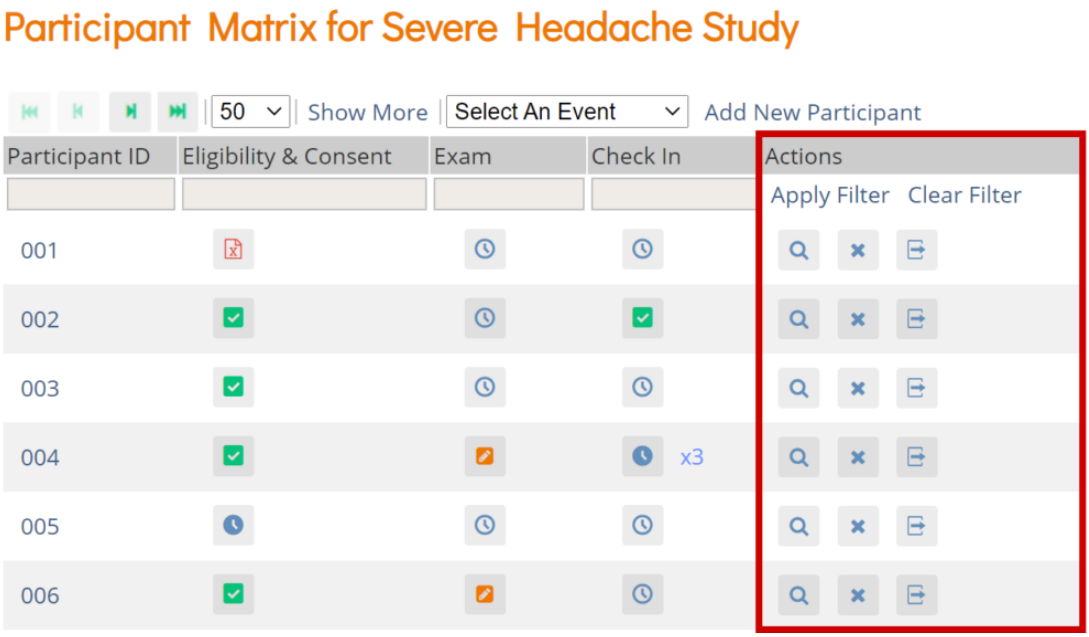
8.4 Reviewing and Managing Data

Data can be reviewed using the **Participant Matrix**, **Queries**, or **Source Data Verification** screen.

Review and Manage Data from the Participant Matrix

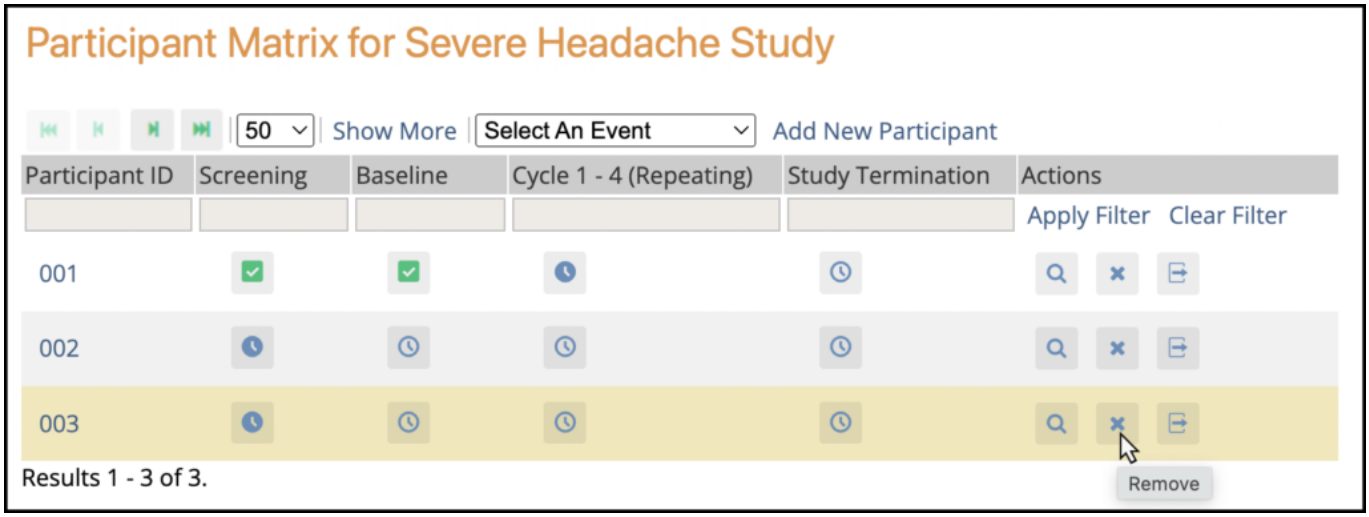
The Participant Matrix

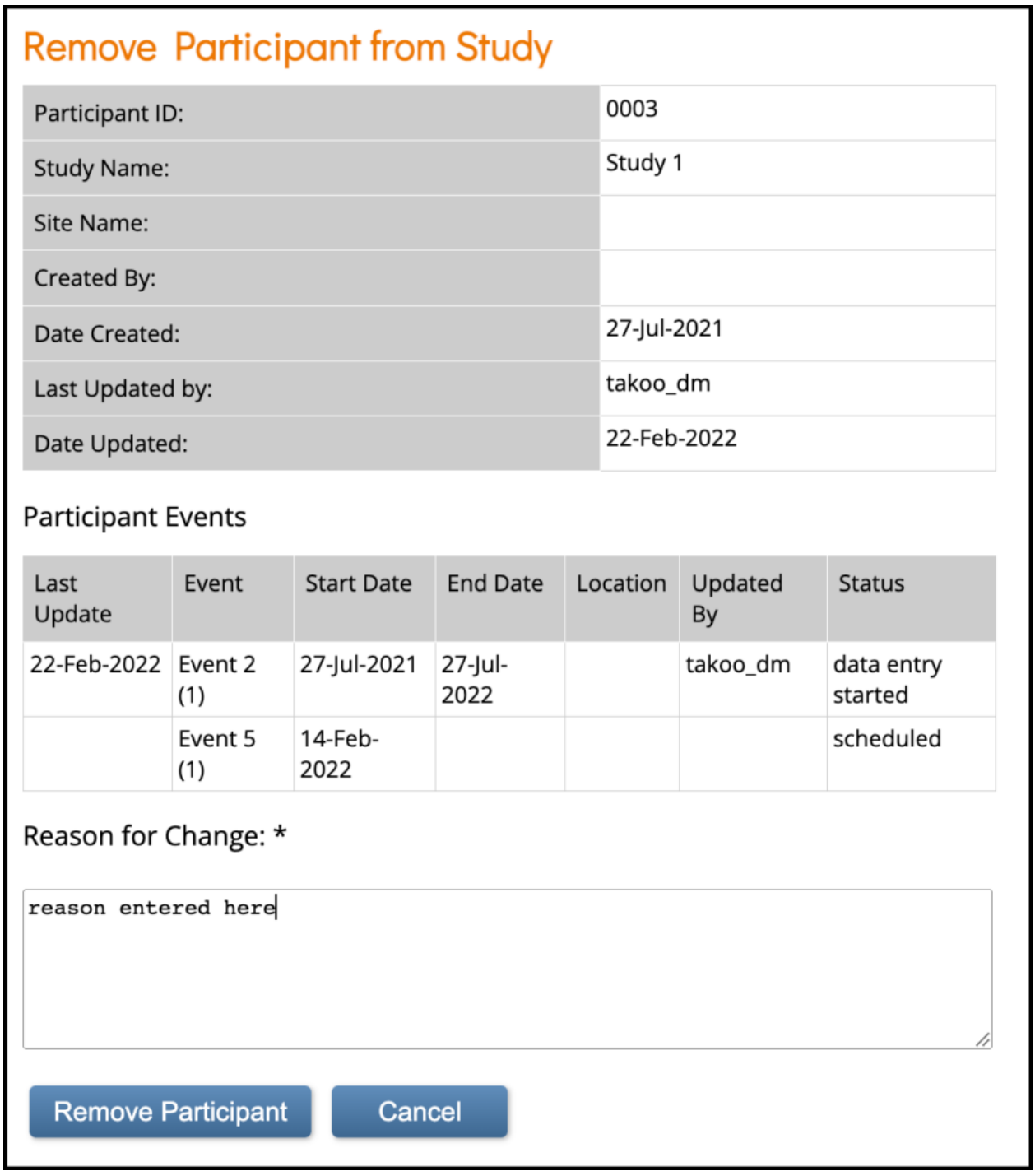
Typically, **Data Managers** and **Monitors** are responsible for reviewing data, but anyone with access to the Participant Matrix can view/review data as needed. Data Managers can also remove a participant and/or reassign a participant to a different site. The actions column presents the appropriate actions available, based on your user role. The following displays the actions available to a Data Manager:



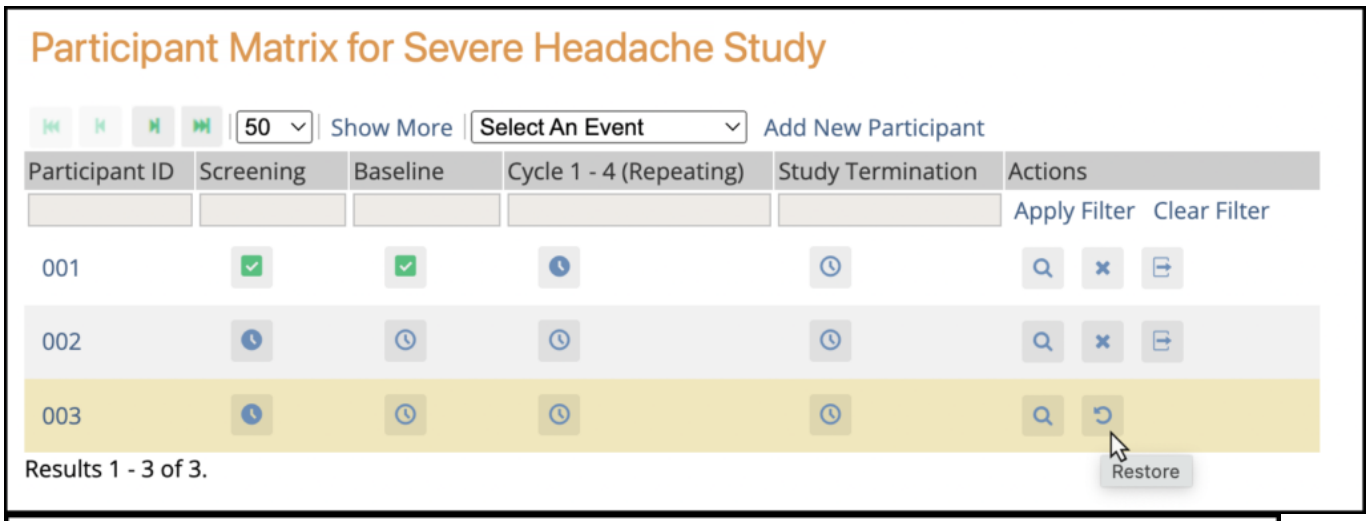
Remove a Participant

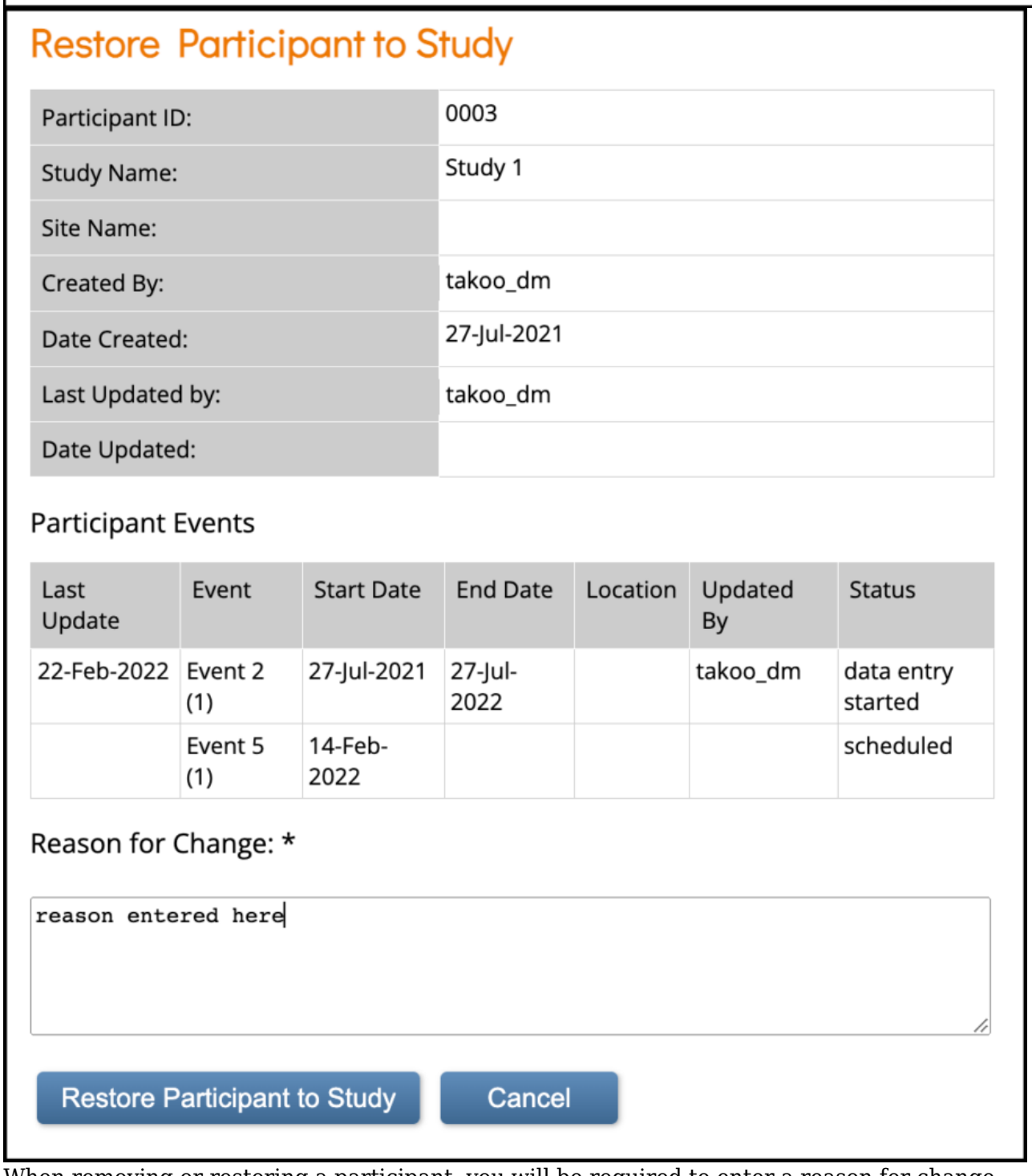
Data Managers have access to remove Participants. Removing a Participant does not delete the Participant, but instead removes access to that Participant's data. The data for that subject can still be viewed, but cannot be edited and will not be included in data extracts.





Once a Participant is removed from the study, the **Remove** icon changes to a **Restore** icon. To restore access to that Participant's data, simply click the **restore** icon and the data is available again for editing and extracts.

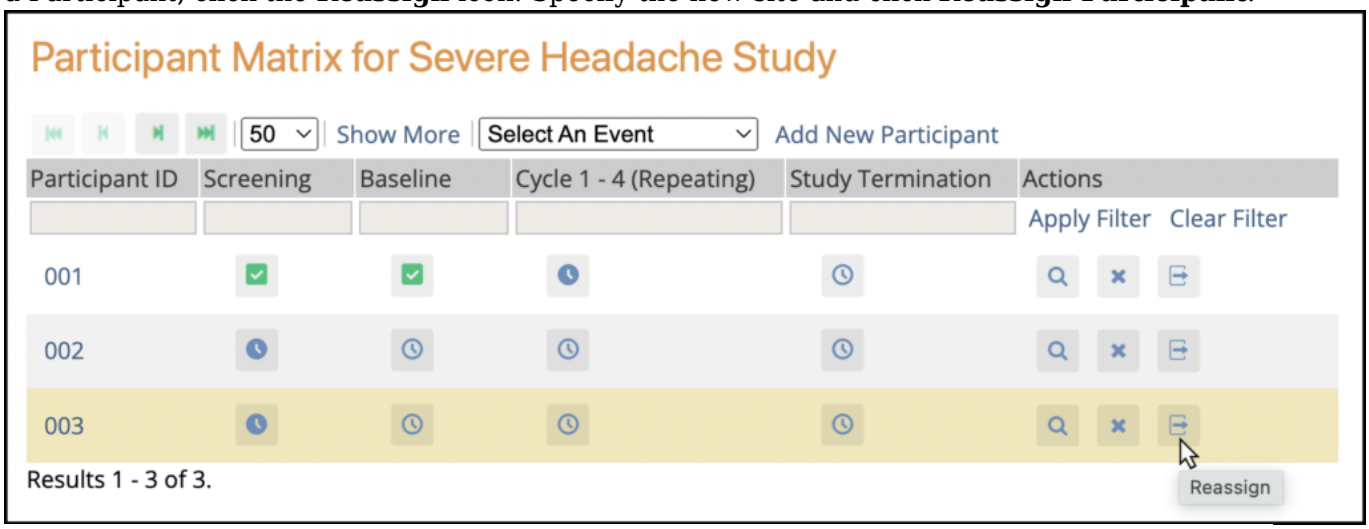


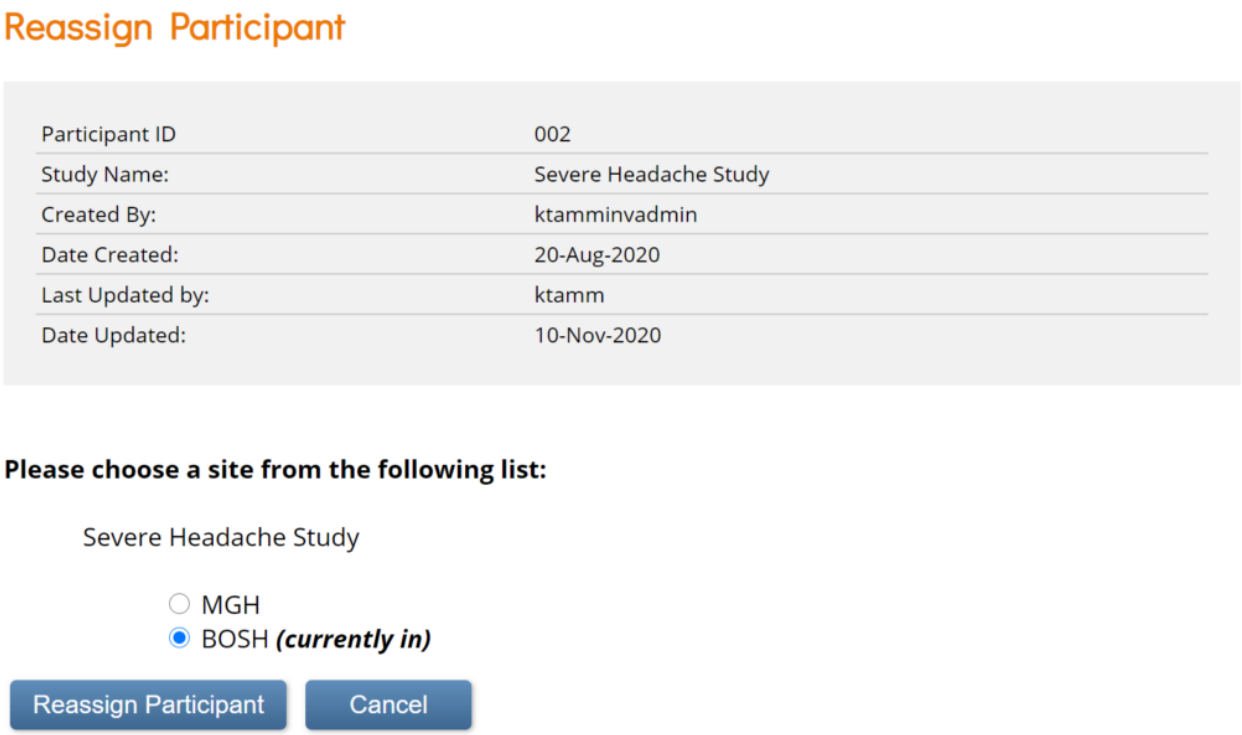


When removing or restoring a participant, you will be required to enter a reason for change.

Reassign a Participant

Data Managers also have access to reassign a Participant to another site. This may be needed if a Participant moves to a different location but still wants to continue on the study. Prior to reassigning, be sure that the original site has an extract of that Participant's data. Then, to reassign a Participant, click the **Reassign** icon. Specify the new site and click **Reassign Participant**.





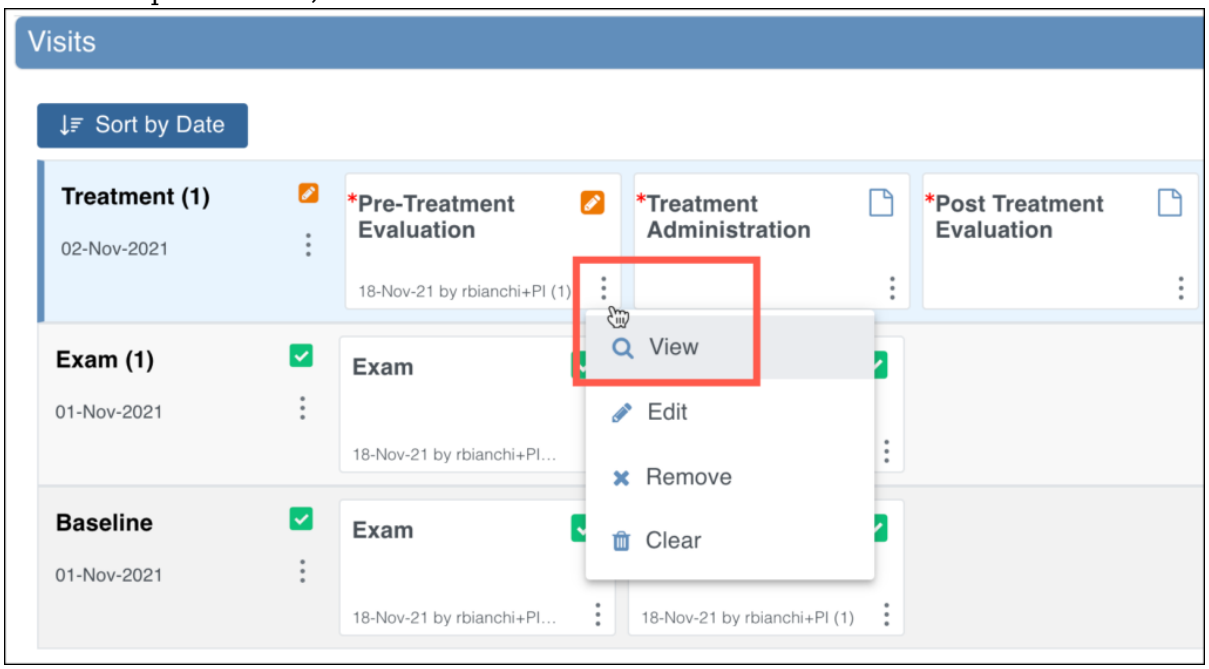
The new site has immediate access to that Participant's forms and all data previously collected for the Participant. The original site no longer has access to that Participant's ongoing data.

View, Edit, Lock, Remove and Restore Events

Click an **Event** icon on the Participant Matrix to display a pop-up. Then, click the action you want to take. When removing or restoring an event, you will be required to enter a reason for the change. ***Note:*** *When reviewing a form which had data entered prior to the event being removed, you will see the message "**The event this form is in has been removed**" at the top of the form.*

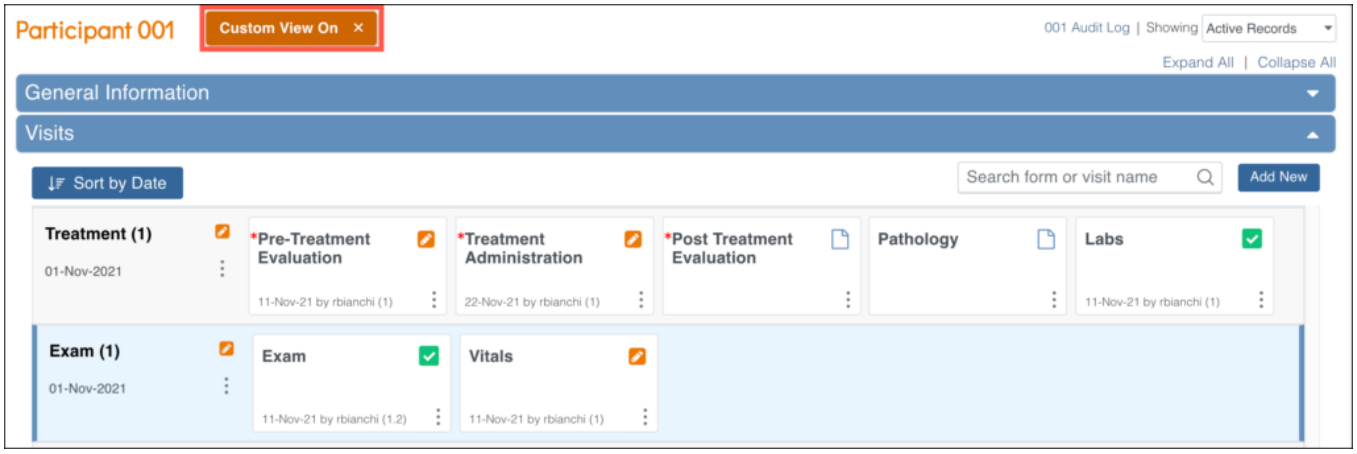
Review Participant Data

To review data, click the **View** icon for the participant whose data you'd like to review. To review data on a specific form, click the **View** icon for that form.



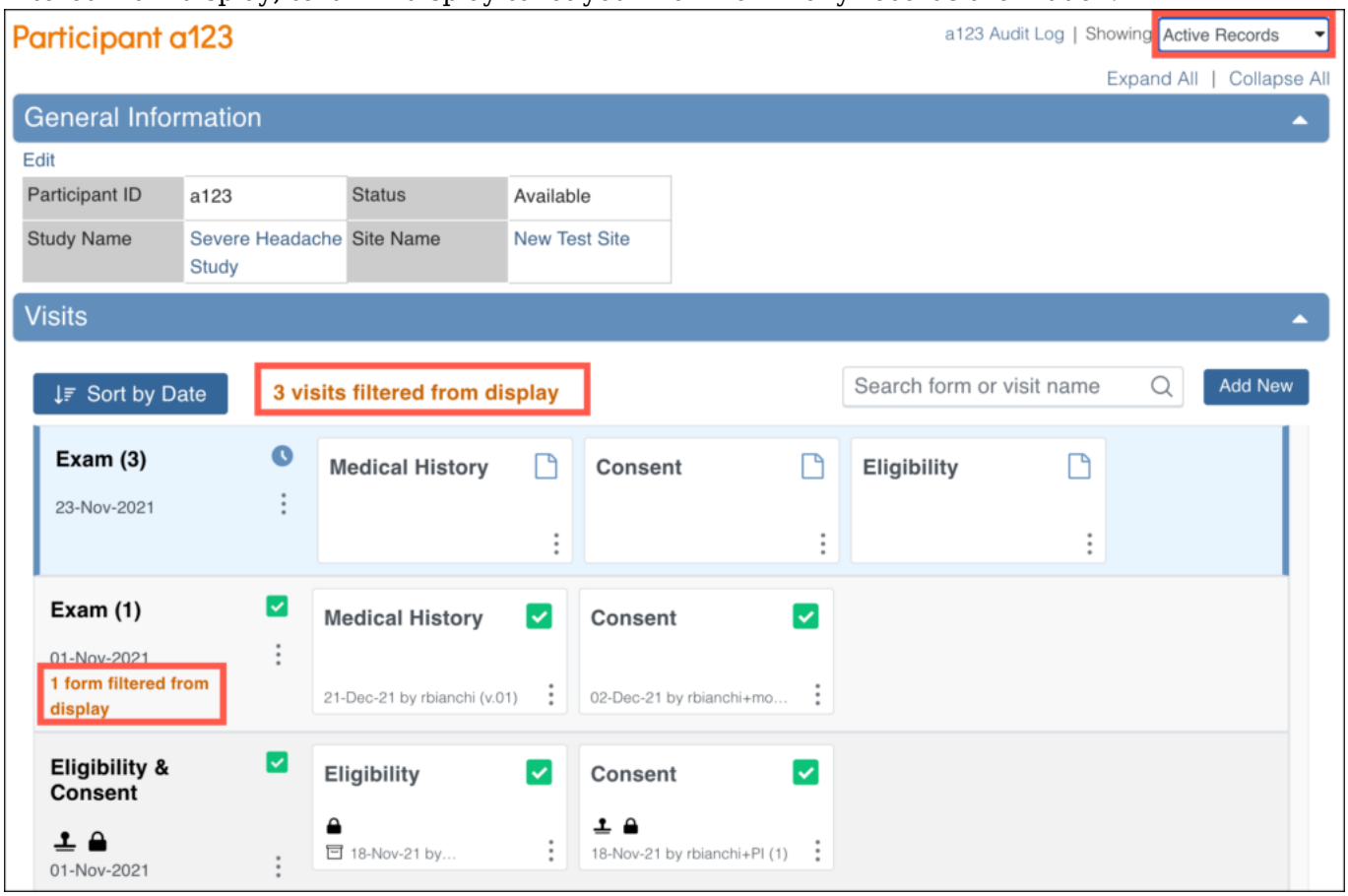
Filter Participant Details

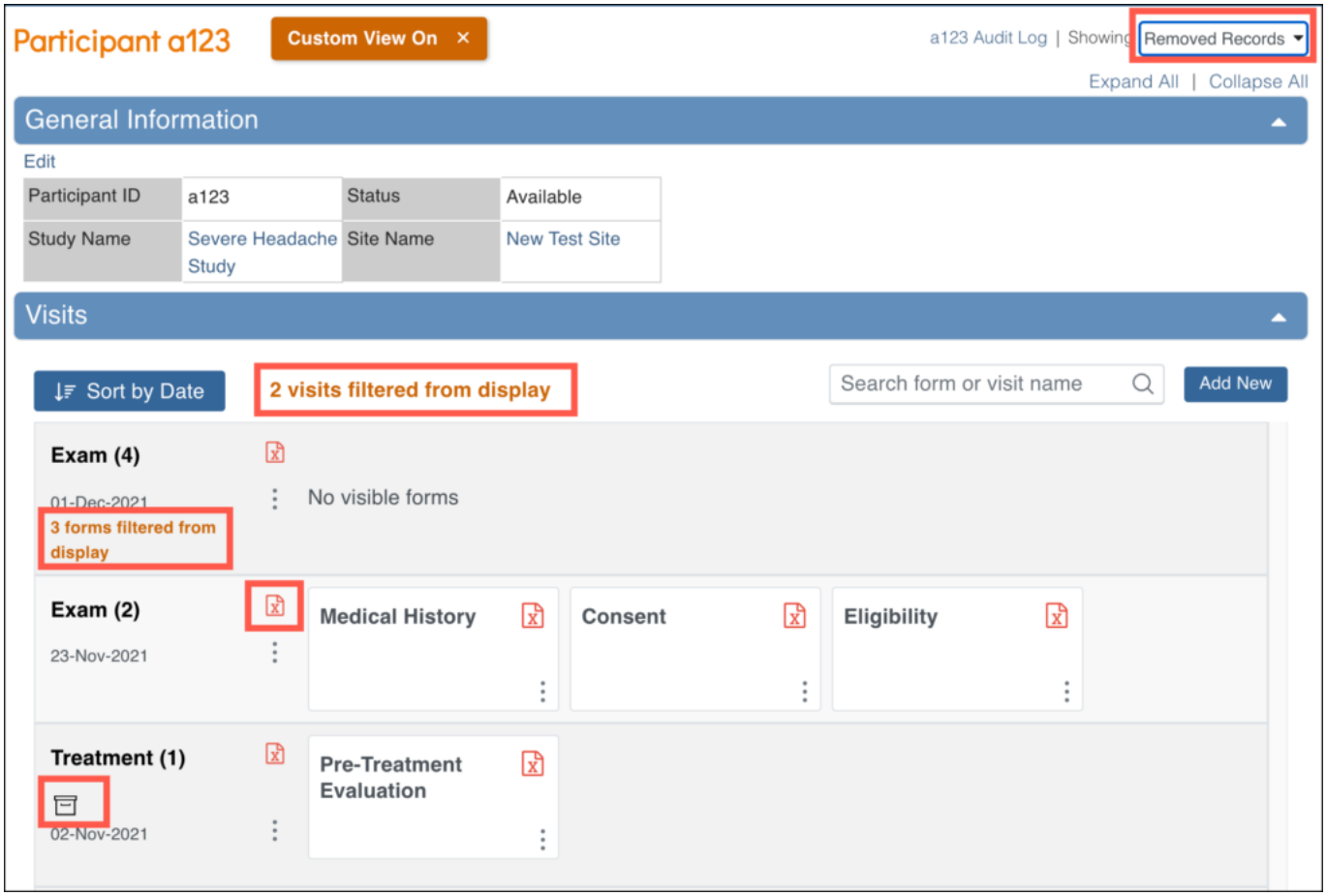
As you review data, you can enter search criteria for the Common Events - for example, to show only AEs that are ongoing. You can also change the number of rows listed for any of the Common Events, and you can sort Common Events by clicking any of the column headings. When you customize anything related to what is displayed for Common Events, the **Custom View On** button displays at the top of the **Participant Details** screen. **Custom View On** also displays when collapsing or expanding sections (changing from their default), sorting and searching in the Visits section, and changing the default **Showing record filter** in the upper right corner (Active Records, All Records, Removed Records).



The **Custom View** is active for that participant throughout the time you are logged into OpenClinica. If you view a different Participant's details, the view might not be customized, or it may be a different customization. In the example above, throughout the current session, any time you view participant 001, that same custom view is in effect, even if you leave the page and come back to the same participant. To clear a custom view, click the **X** on the **Custom View On** button and all view customizations are removed for that participant, bringing you back to the default view. The Custom View could be as simple as collapsing the General Information section or searching for a

specific form name, but it will persist on that participant until you either clear the custom view by clicking the **X**, manually change the custom view back to the default, or begin a new session. Filtering records using the Showing option in the upper right corner of the Participant Details screen filters Visits as well as Common Events. The three options for filtering records are **Active Records**, **Removed Records** (includes Archived as well), and **All Records**. When visits or forms are filtered from display, text will display to let you know how many records are hidden.





Form Migration

Definition: *Form migration is the ability to transfer data from one Form version to another.*

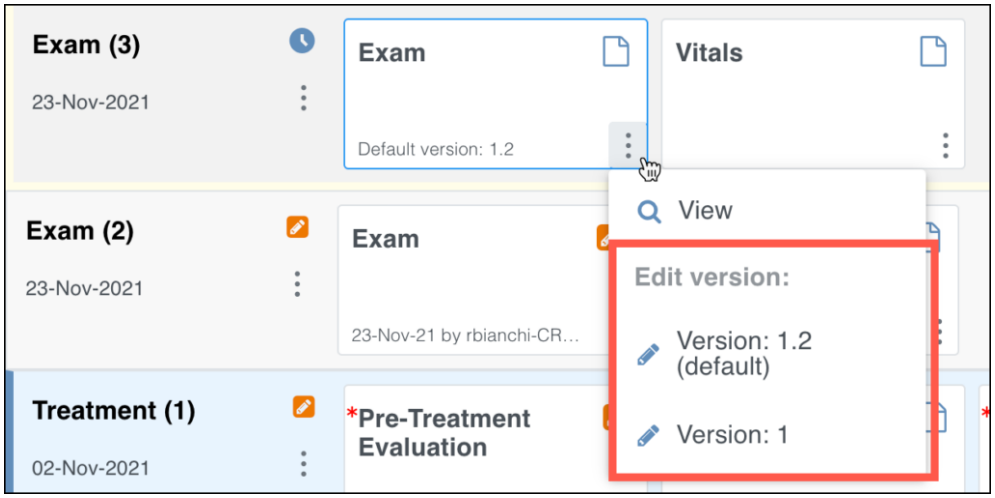
Example: *A Data Manager might choose to migrate Form data in order to update the Form to a new version.*

Data Managers can migrate Form data on a Participant-by-Participant basis or in a batch.

If multiple versions of a form are available before data has been entered, any user can choose which version to use. The forms with multiple versions will display the default on the form card.

When clicking on the form card, the form will open in the default version.

To edit the form in a version other than the default, click the actions menu and select which version to use.



However, if data has already been entered and a new Form version becomes available afterward, you must have a **User Role** of **Data Manager** to migrate Form data. You can migrate data either on a Participant-by-Participant basis or in a batch.

Form Migration Causes the Following:

- **Audit Log:** Form migration appears in the Audit Log for the Participant(s) the data was migrated for.
- **Extracts:** If data existed in the original Form version that does not exist in the new Form version, that data does not appear on extracts.
- **Response Options:** You can remove responses, but the values in the **Name** field for those that remain cannot be changed. For example, if the options were **Mild**, **Moderate**, and **Severe** (**1**, **2**, and **3**) you can remove **Severe**, but you cannot change **Mild** from **1** to any other value.

Note: *Data will not be deleted from the database due to Form version migration, even if it no longer exists in the new Form version. (See Potential Migration Outcome Examples below for more information.)*

Requirements:

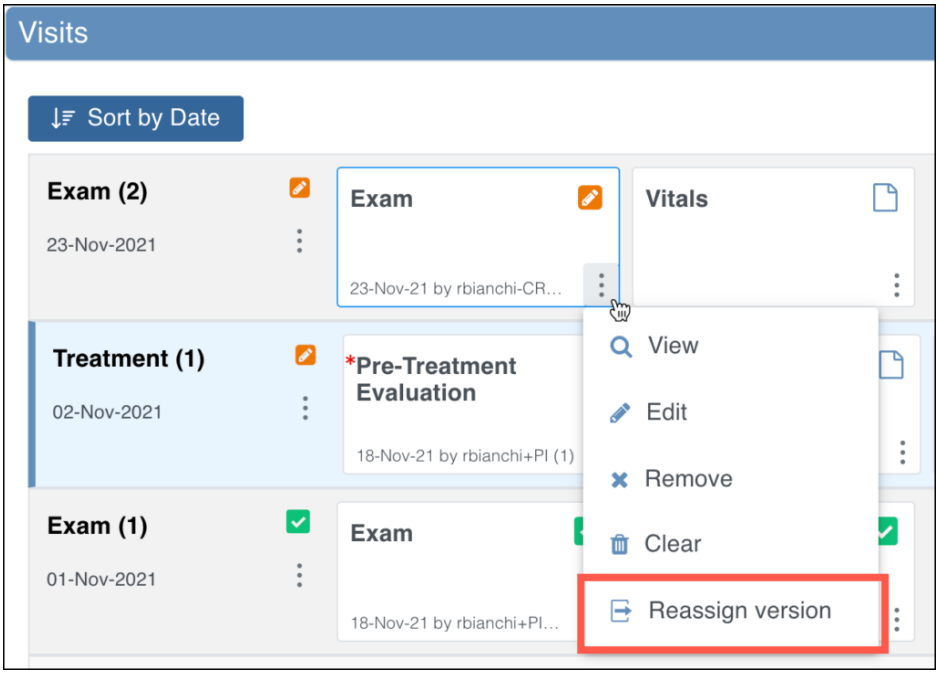
- **Data Entry Status:** Data Entry Started
- **Study Status:** Available
- **User Role:** Data Manager
- **Participant Status:** Active
- **Event Status:** Active (not removed, locked, or skipped)
- **Form Status:** Active (not removed)
- **New Form Version:** Active (not removed)
- **Previous Form Version:** Active (used for initial data entry)

Prerequisites:

- The study must contain at least 2 versions of a Form.
- The study must be published.

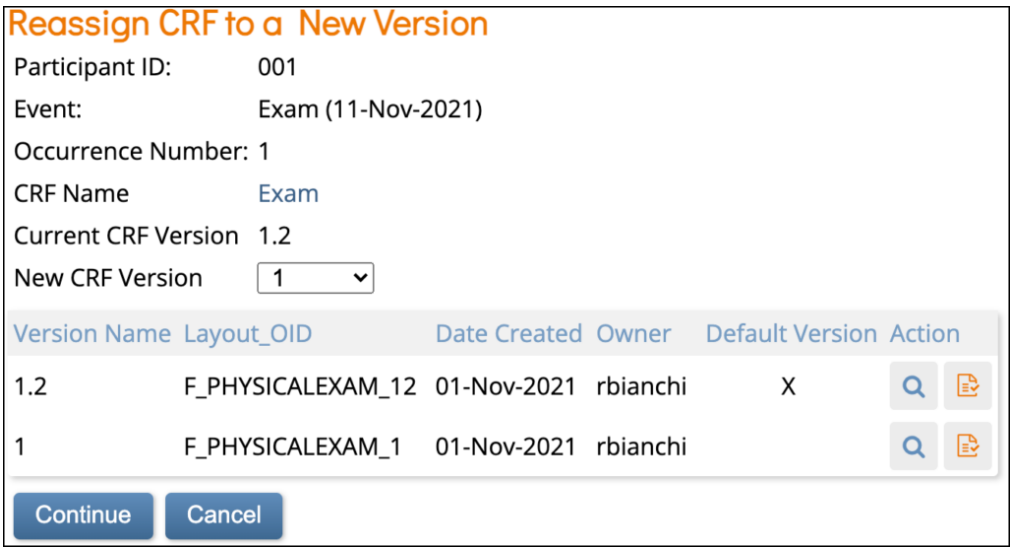
Participant-by-Participant Migration:

1. Click the **View** button for the Participant on the Participant Matrix.
2. Click the **three dot menu** on the form card and select **Reassign version.**



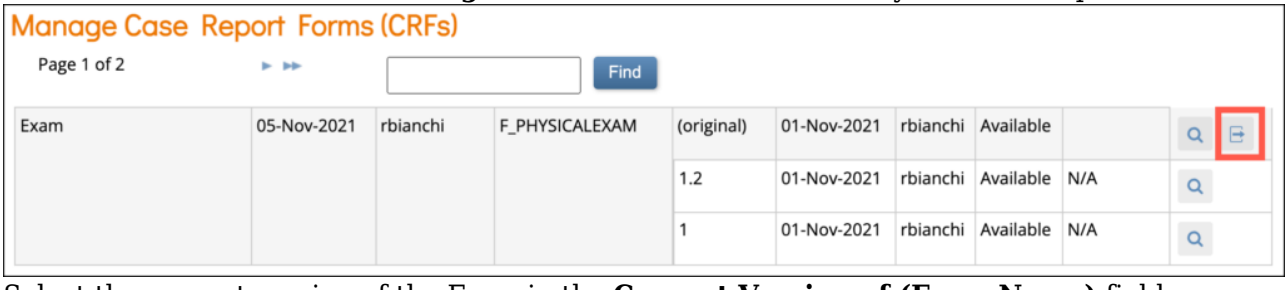
3. Select the new Form version in the **New CRF Version** field.

4. Click the **Continue** button.



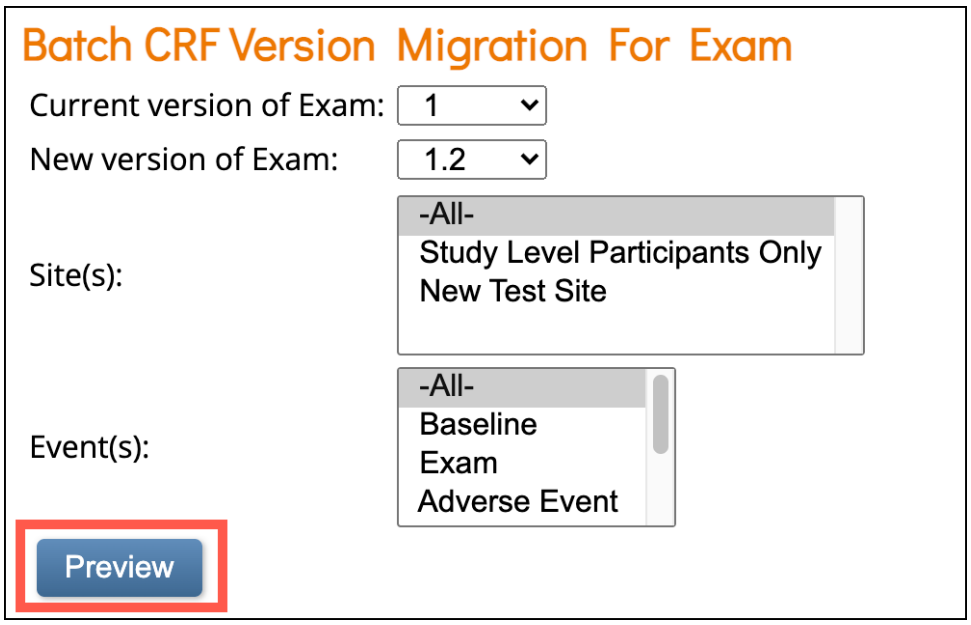
Batch Migration:

1. In the header bar of Study Runner, click **Tasks**.
2. Select **CRFs** under **Monitor and Manage Data**.
3. (Optional) Confirm that you are planning to migrate to and from the correct version. You can either View the Form or Download Annotated CRF.
4. Click the **Batch CRF Version Migration** button next to the CRF you want to update.



5. Select the current version of the Form in the **Current Version of (Form Name)** field.

6. Select the new version of the Form in the **New Version of (Form Name)** field.
7. (Optional) Select a site to update the version at. (The default is all sites.)
8. (Optional) If the Form is in multiple events, select an Event to update the version in. (The default is all Events.)
9. Click the **Preview** button.



8. Verify the Migration Summary information that appears below the **Preview** button.
9. Click the **Migrate** button.

When you return to the CRF screen, the following message appears under **Alerts** in the sidebar: **Batch CRF version migration is running. You will receive an email once the process is complete**

The email you receive has a link to a report of the migration, which provides a list of all Participants and Forms that the data was migrated for.

Potential Migration Outcome Examples:

Example A: More Items in Original Form Version than New Form Version:

Before Migrating from Version A to B:

- Version A has an item named **meditem2**.
- Version B does not have an item named **meditem2**.
- Both versions have an item named **item1**.

After Migrating from Version A to B:

- Data for **meditem2** is migrated but not visible on the Form.
- Data for **item1** is migrated and is visible on the Form.
- Data from both versions appears on extracts, so there are more items.

Example B: More Response Options Available in Original Form Version than

New Form Version:

Before Migrating from Version A to B:

- Both CRF versions have an item named item1.
- Version A has the response options **X**, **Y**, and **Z**.
- Version B only has the response options **X** and **Y**.
- The user selected the response option **Z** in the original Form version.

After Migrating from Version A to B:

- Data for **item1** is migrated, but it will appear as though no response was selected since response option **Z** no longer exists in the new Form version.
- **For single-select types:** New data will overwrite existing data.
- **For multi-select types:** New response options will be added. (If the user selected the response option **Z** in the original Form version, and that option no longer exists in the new version of the Form, if they then select the response option **Y**, both the values of **Z** and **Y** will be stored in the database.)

Example C: The maximum number of repeats in the original Form version exceeds that in the new Form version:

Before Migrating from Version A to B:

- Both Form versions have a repeating group named **group1**.
- The repeat count in Form A is **5**.
- The repeat count in Form B is **3**.
- The user entered data for **5** repeats.

After Migrating from Version A to B:

- Only **3** rows of data appear on the Form even though version A had **5** repeats.
- No additional data can be entered.

8.5 Participant Audit Log

The **Participant Audit Log** tracks all changes made to a participant's data. Each row in the log records an audited event, detailing what changed and which user made the change.

You can access the **Participant Audit Log** in two ways:

1. **From the Study Audit Log**:
    - Click **Study Audit Log** from the navigation menu or the Tasks menu.

- Click the icon in the Actions column for the desired participant.

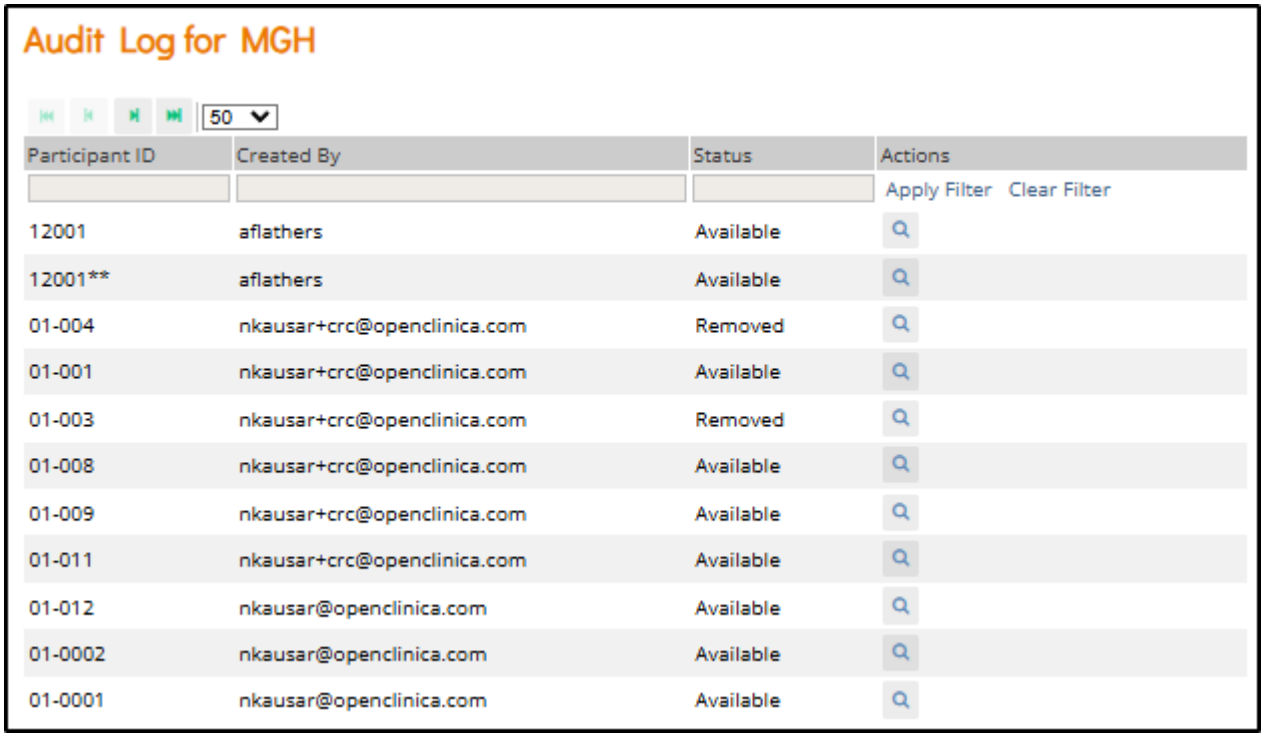
2. **From the Participant Details Page (PDP)**:

   - Navigate to the PDP for the participant you wish to review.

Study Audit Log

The **Study Audit Log** page provides high-level information about each participant, offering a central point of access for all participants' audit logs. The table includes the following elements:

- **Participant Data**
  - **Participant ID:** Unique identifier for each participant. Each row represents a participant in the study.
  - **Created By:** Username of the user who added the participant.
  - **Status:** Current status of the participant (e.g. Available, Removed and Signed).
  - **Actions:** Click the **View** icon to access the detailed audit history for the selected participant.
- **Table Controls**
  - **Pagination Controls:** Located at the top of the table, these allow you to navigate through the list of participants. Use the buttons for first/previous/next/last page, and the page-size selector to adjust the number of rows shown per page.
  - **Filters:** Text boxes or filter links appear in the header row, allowing you to enter criteria and click **Apply Filter** to narrow the list by Participant ID or other values. The **Clear Filter** link resets the filtering.



Participant Audit Log

The **Participant Audit Log** details what data was added, modified, or removed at the participant,

event, and form levels, when it was changed, and who made each change. The combination of timestamp, event type, and old/new values provides a complete history of the participant record, including changes made to participant-level data, event data, and form data.

Participant-Level Data

Participant-level data includes updates to status and contact information. The first two tables within the **Participant Audit Log** show this information.

01-001 Audit Logs

Participant ID	Created By	Status
01-001	nkausar+crc@openclinica.com	Available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Participant status changed	20-May-2025 12:52:01	nkausar@openclinica.com	Status	Removed	Available
Participant status changed	20-May-2025 09:36:42	nkausar@openclinica.com	Status	Available	Removed
Participant first name changed	20-May-2025 09:34:23	nkausar+crc@openclinica.com	Participant First Name	<Masked>	<Masked>
Participant access code reset	20-May-2025 09:34:23	nkausar+crc@openclinica.com	Participant access code		
Participant value changed	20-May-2025 07:17:07	S_HEADACHE.TEST.SS_01001	Secondary Subject ID		
Participant first name changed	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant First Name	<Masked>	<Masked>
Participant email address changed	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant Email Address	<Masked>	<Masked>
Participant access code reset	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant access code		
Participant Created	20-May-2025 06:07:03	nkausar+crc@openclinica.com			

- **Participant ID**: Unique identifier for each participant in the study.
- **Created By**: Username of the person who created the participant record.
- **Status**: Current status of the participant (e.g., Available, Removed).
- **Audit Event**: Type of action recorded (e.g., Participant Created, Participant [contact data type] changed).
- **Date/Time of Server**: Server timestamp when the audit event occurred.
- **User**: Username of the person who performed the logged action.
- **Value Type**: Field that was modified (e.g., Participant First Name, Status).
- **Old**: The value before the change was made (blank if newly created).
- **New**: The updated value after the change (blank if the value was removed).

Note: Protected data, such as a participant's name, email, or other contact information, is masked in the audit logs for all roles except CRC and Investigator, even if the user has access to view the form containing that data. For more information about contact data, refer to Understanding Contact Data.

Event-Level Data

Event-level data includes updates to a participant's events. This section contains a **Table of Contents** with links to the various events and the associated event-specific audit log.

- **Event Table of Contents**
  - **Study Events:** The defined visits or common events for a study participant (e.g., Consent, Follow-up).
  - **Start Date:** The start date of a specific study event.
  - **Occurrence Number:** Displays the sequence number for a repeating study event (e.g., "1" indicates the first occurrence). The highest number indicates how many times the event has occurred.

Study Events	Location	Start Date	Occurrence Number
Consent		20-May-2025	1
Eligibility		20-May-2025	1
Participant Baseline		20-May-2025	1
Clinical Exam		20-May-2025	1
Followup Visit		20-May-2025	1
End of Study		20-May-2025	1

- **Event Audit Log**
  - **Audit Event:** The type of action recorded (e.g., Study Event workflow status changed, Study Event start date changed, etc.)
  - **Date/Time of Server:** The server timestamp when the audit event occurred.
  - **User:** The username of the person who performed the logged action, or **System** for actions triggered automatically, such as Calendaring or Randomization.
  - **Value Type:** The field that was modified (e.g., Status, Start Date).
  - **Old:** The value before the change was made. Blank if newly created.
  - **New:** The updated value after the change. Blank if the value was removed.
  - **Details:** Populated with the signature attestation when an Investigator or Data Specialist signs the participant’s event.

Audit Event	Date/Time of Server	User	Value Type	Old	New	Details
Study Event signed status changed	19-Sep-2025 07:47:28	nkausar+investigator@openclinica.com	Signed		Yes	This event was signed by Neha Kausar (nkausar+investigator@openclinica.com) on Fri Sep 19 07:47:28 UTC 2025 under the following attestation: "I confirm that the data for this participant are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature." This signature applies to the following forms in this event: Eligibility, Screening Criteria.
Study Event workflow status changed	19-Sep-2025 07:45:24	nkausar@openclinica.com	Status	Data Entry Started	Completed	
Study Event workflow status changed	19-Sep-2025 07:45:03	nkausar@openclinica.com	Status	Scheduled	Data Entry Started	
Study Event start date changed	19-Sep-2025 07:38:15	system	Start Date		19-Sep-2025	
Study Event workflow status changed	19-Sep-2025 07:38:15	system	Status		Scheduled	

Form-Level Data

Form-level data includes information about form status as well as all data entry / updates made to form data.

- **High Level Form Information**
  - **Name:** The name of the form.
  - **Version:** The current version of the form.
  - **Owner:** These are the options for the owner:
    - Form entered or modified by the study user in Study Runner: The owner is shown as the user's email address.

Name	Version	Date Interviewed	Interviewer Name	Owner
Screening Criteria	1			nkausar@openclinica.com

    - Form entered or completed by the Participant in Participate: The owner is shown as the participant's unique ID.

Name	Version	Date Interviewed	Interviewer Name	Owner
eConsent	1e			S_HEADACHE.TEST.SS_01001

    - **PublicURL:** Displays “PublicURL” when the form is submitted through the PublicURL feature (no authenticated participant is associated with the submission).

- **Form Data Changes**
  - **Audit Event:** The type of action recorded (e.g., Event CRF workflow status changed,

Item data value updated, etc.)

- For data pulled via Unite from an Electronic Health Record (EHR), this column also includes:
  1. **Source:** The system type where the data originated (e.g., Electronic Health Record).
  2. **Data Originator:** The site or healthcare organization from which the data was retrieved (e.g., hospital or clinic).
  3. **Data Element Identifier:** The unique identifier of the specific data element imported from that site's EHR system.

- **Date/Time of Server:** The server timestamp when the audit event occurred.
- **User:** The username of the person who performed the logged action.
- **Value Type:** The field that was modified (e.g., Status, [form item OID], etc.).
- **Old:** The value before the change was made. Blank if newly created.
- **New:** The updated value after the change. Blank if the value was removed.
- **Details:** Populated with the signature attestation when an eConsent form is signed.

 Note: Form data for which the user lacks access permissions is masked in the Participant Audit Log. For more information about form data access, refer to **Managing Form Access and Permissions**.

Audit Event	Date/Time of Server	User	Value Type	Old	New	Details
Event CRF workflow status changed	20-May-2025 09:26:38	S_HEADACHE.TEST.SS_01009	Status	Initial Data Entry	Completed	
Consent status changed	20-May-2025 09:26:38	S_HEADACHE.TEST.SS_01009	Consent		Consent Signed	This form was signed by <Masked> (01-009) (SS_01009) on Tue May 20 09:26:38 UTC 2025 under the following attestation: "I freely and voluntarily consent to participate in this study. I intend for this electronic signature to be the legally binding equivalent of my written signature."
Item data value updated	20-May-2025 09:26:27	S_HEADACHE.TEST.SS_01009	CONSENT_YN (1)		Yes	
Item data value updated	20-May-2025 09:26:26	S_HEADACHE.TEST.SS_01009	AGREE (1)		I am willing to participate in this study. (1)	
Item data value updated	20-May-2025 09:26:20	S_HEADACHE.TEST.SS_01009	CODE (1)		CAR-T	
Event CRF workflow status changed	20-May-2025 09:26:20	S_HEADACHE.TEST.SS_01009	Status		Initial Data Entry	

Approved for publication by Kate Lambert. Signed on 2025-12-12 2:22PM

8.6 Suggested SOPs

Suggested Data Management Standard Operating Procedures (SOPs) for Electronic Data Capture

This section provides a recommended minimum set of Standard Operating Procedures (SOPs) for organizations using Electronic Data Capture (EDC) systems. It is not intended to be an exhaustive list. You should refer to current regulations and guidelines applicable to your organization and study(ies) to identify all required SOPs. OpenClinica Professional Services can support you in developing new SOPs or reviewing your existing documentation.

 Note: If your organization uses electronic systems for clinical trials, you should audit your software vendor(s) to ensure that appropriate development SOPs were established and consistently followed throughout the software development lifecycle.

List of Suggested SOPs

SOP	Description
1. Development and Maintenance of SOPs	Define the SOP template and the processes for SOP development, review, and approval. Include: • Roles and responsibilities • SOP release and distribution requirements • SOP version control and maintenance procedures
2. SOP Deviations	Describe how you report and document deviations from SOPs, including: • Planned deviations • Unplanned deviations
3. Data Privacy and Protection	Describe the processes you follow to ensure data privacy and protection, including safeguards within: • Your organization • Your software solution or service (if applicable)
4. Document, File, and Study Binder Management	Describe how you manage all documents related to study conduct. Include: • Differences between in-house and CRO-conducted studies • Study Binder version control processes
5. Data Management Roles and Responsibilities	Clearly define the roles and responsibilities for all users participating in study data management.

6. Data Management Plan (DMP)	Describe the Data Management Plan template and include: • SOPs to be followed • Clinical data management system to be used • Descriptions of data sources • Data handling processes • Data transfer formats and process, • Quality control measures Define how you develop, approve, update, and version-control the DMP.
7. Data Monitoring Plan	Describe the Data Monitoring Plan template and specify how it ensures: • Protection of participant rights and well-being • Accuracy, completeness, and verifiability of reported data • The trial is conducted in compliance with currently approved protocol and other applicable regulatory requirements If you use partial data monitoring, clearly define what this means for the study (for example, 100% monitoring of critical data values or 100% verification of 20% of participants). Define the process for developing, approving, and maintaining the Data Monitoring Plan. Include details on version control.
8. Statistical Analysis Plan	Describe the Statistical Analysis Plan template and define processes for its development, approval, maintenance, and version control.
9. eCRF Design and Development	Define how you design, develop, and standardize electronic Case Report Forms (eCRFs). Include: • Design and approval processes • Development procedures • Version control requirements
10. Study-Specific Database Design	Describe how you configure study-specific attributes that fall outside standard eCRFs, such as: • Annotated CRFs • Design documentation
11. Edit Check and Data Validation Programming	Document processes for: • Creating edit check specifications • Edit check development • Review and approval • Testing, documentation, and version control
12. Study User Acceptance Testing (UAT)	Define testing requirements and documentation needed to demonstrate successful system validation. Specify who provides final approval for system use. **Warning:** Testing should not be performed by the individual who built the study database.

13. Data Entry	Define processes for entering and editing data, including: • General data entry guidelines • Use of UI features • Handling of scientific symbols (if applicable) • Documentation of study-specific instructions
14. Data Receipt and Handling	Describe all methods by which data may be received, including: • EDC • ePRO • Imports • Web services • Paper, etc
15. Discrepancy Management	Define how you review and resolve data discrepancies, and specify roles and responsibilities associated with discrepancy management.
16. Coding	Define processes for coding adverse events and medications, including: • Review procedures • Change control processes • Re-coding requirements
17. Serious Adverse Event Reconciliation	Describe how you handle serious adverse events and reconcile them between data management and safety surveillance systems. Include: • Review timeframes • Sign-off procedures prior to database lock
18. Lab Data Management	Define how you handle laboratory data. If necessary, include: • Local vs. central lab differentiation • Data import processes • Discrepancy resolution procedures
19. Data Extraction and Validation	Describe how you extract data and verify that the extracted data accurately matches what was entered into the system.
20. Data Transfer and Validation	Define how you transfer data to external systems and verify that transferred data matches the original system data.
21. Database Security	Describe the requirements, methods, and tests that ensure your database is secure, including: • Username and password requirements • Password expiration and means for resetting passwords • How system or study access is granted or revoked • Roles and role-based access, etc

22. Database Lock, Unlock, and Closure	Define processes for locking, unlocking, and closing a database. Include: • Lower-level (e.g., Event-level locking) (if applicable) • Investigator signature requirements prior to lock
23. Data Retention and Archival	Define the data retention, archival, and retrieval procedures. For databases managed by external sources (CRO, hosting service provider), define the process for accessing the database throughout your defined retention period, including: • Clinical data • eCRFs • Discrepancies or resolutions
24. CRO and Vendor Management	Describe how you select and manage CROs and vendors, including: • Sign-off procedures • Meeting frequency • Metrics • Audit processes and schedules
25. Training	Define how you train data management and site staff on relevant topics, including: • SOPs • HIPAA • GDPR • 21 CFR Part 11 • System(s) • Study-specific issues or practices • Internal (e.g. sponsor) • External (e.g. site) Describe how you document training, manage re-training requirements, and maintain training records.

References and Additional Resources

- 21 CFR Part 11, US Department of Health and Human Services, Food and Drug Administration, March 1997
- Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application, US Department of Health and Human Services, Food and Drug Administration, August 2003
- Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, US Department of Health and Human Services, Food and Drug Administration, April 1996
- Guidance for Industry – Computerized Systems Used in Clinical Trials, US Department of Health and Human Services, Food and Drug Administration, May 2007
- PIC/S Guidance – Good Practices for Computerized systems in Regulated GXP Environments, PIC/S, September 2007
- Susanne Prokscha, Practical Guide to Clinical Data Management, Third Edition, CRC Press, October 26, 2011

Approved for publication by Kate Lambert. Signed on 2025-12-11 3:42PM