9 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 Kerry Tamm. Signed on 2020-11-24 3:17PM

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

9.1 Queries (Data Manager)

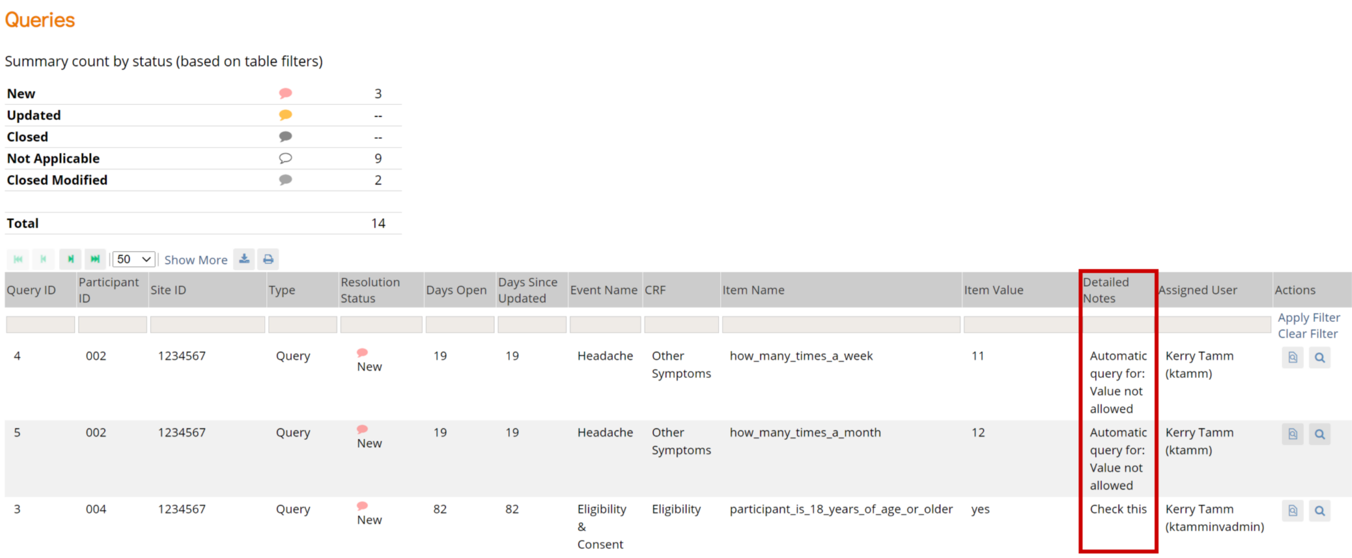
Definitions:
• **Queries** are inquiries or alerts about potential incorrect data.
• **Annotations** are notes on a Form that do not contain clinical data and are usually used for keeping track of workflow.
• **Reasons for Change** are notes added by a user when modifying data on a form that has already been marked as Complete.

The system creates queries automatically if you close a Form that has unaddressed errors or you can manually create a query.

Another user can respond to it and/or change the response in the field. Only **Data Managers** and **Monitors** can close queries.

The Queries Table

A table displays queries, annotations, and reasons for change. Details about each query, annotation, or reason for change are listed in the **Detailed Notes** column.


Queries

Summary count by status (based on table filters)

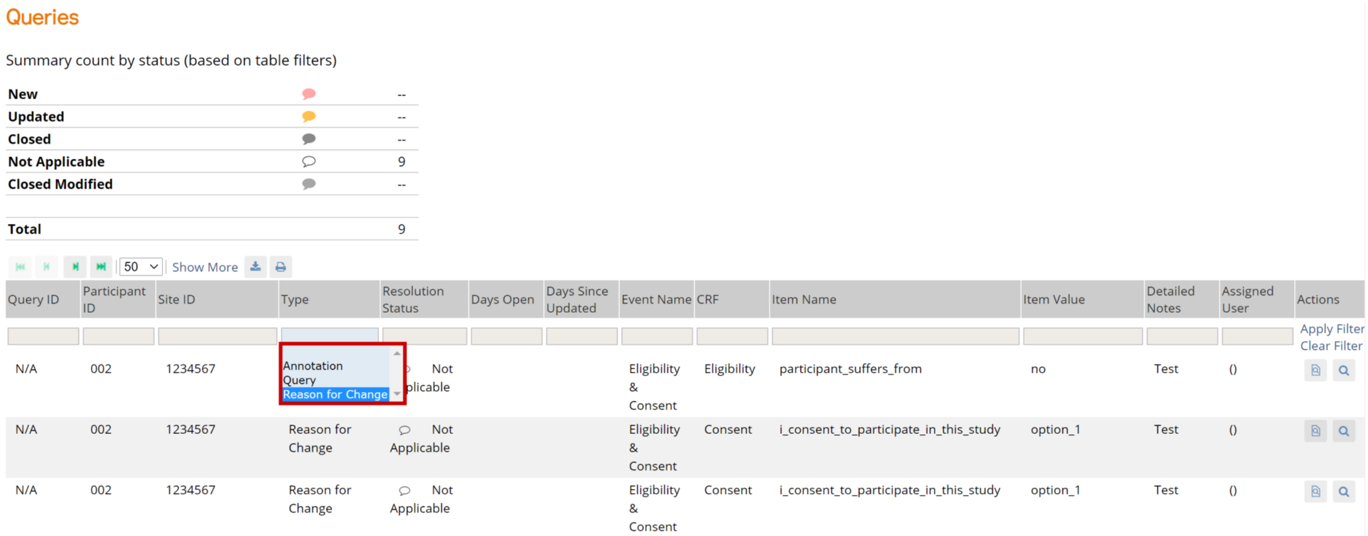
New	3
Updated	--
Closed	--
Not Applicable	9
Closed Modified	2
Total	14

50 Show More

Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
													Apply Filter Clear Filter
4	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_week	11	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	
5	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_month	12	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	
3	004	1234567	Query	New	82	82	Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	Check this	Kerry Tamm (ktamminvadmin)	

You can click **Show More** at the top of the table to show more columns.

To filter by reason for change, click the gray filter box under the **Type** column, and select **Reason for Change**. You can change the view of the **Queries** screen to filter any column that includes a gray filter box.

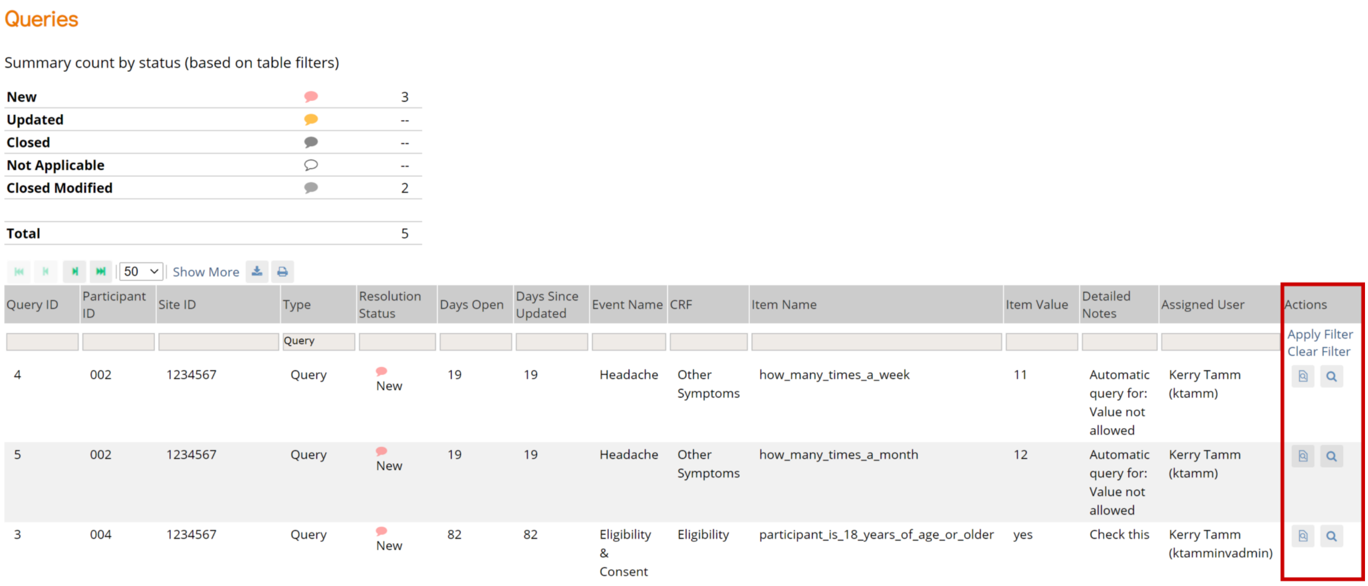


The Table Below Displays Statuses for Queries and Annotations:

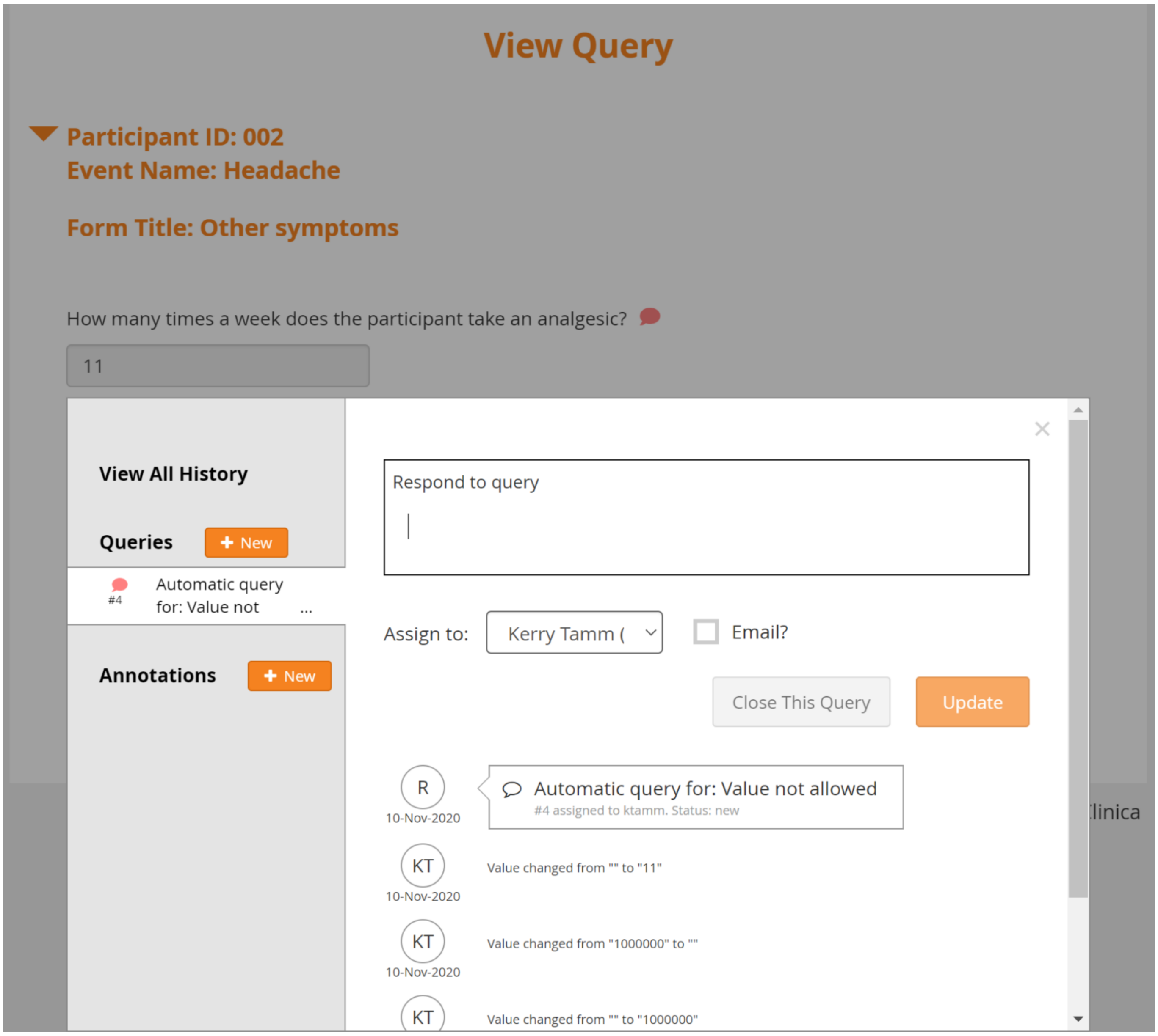
[table id=17 /]

To Review Data Associated with a Query, You Have Two Options:

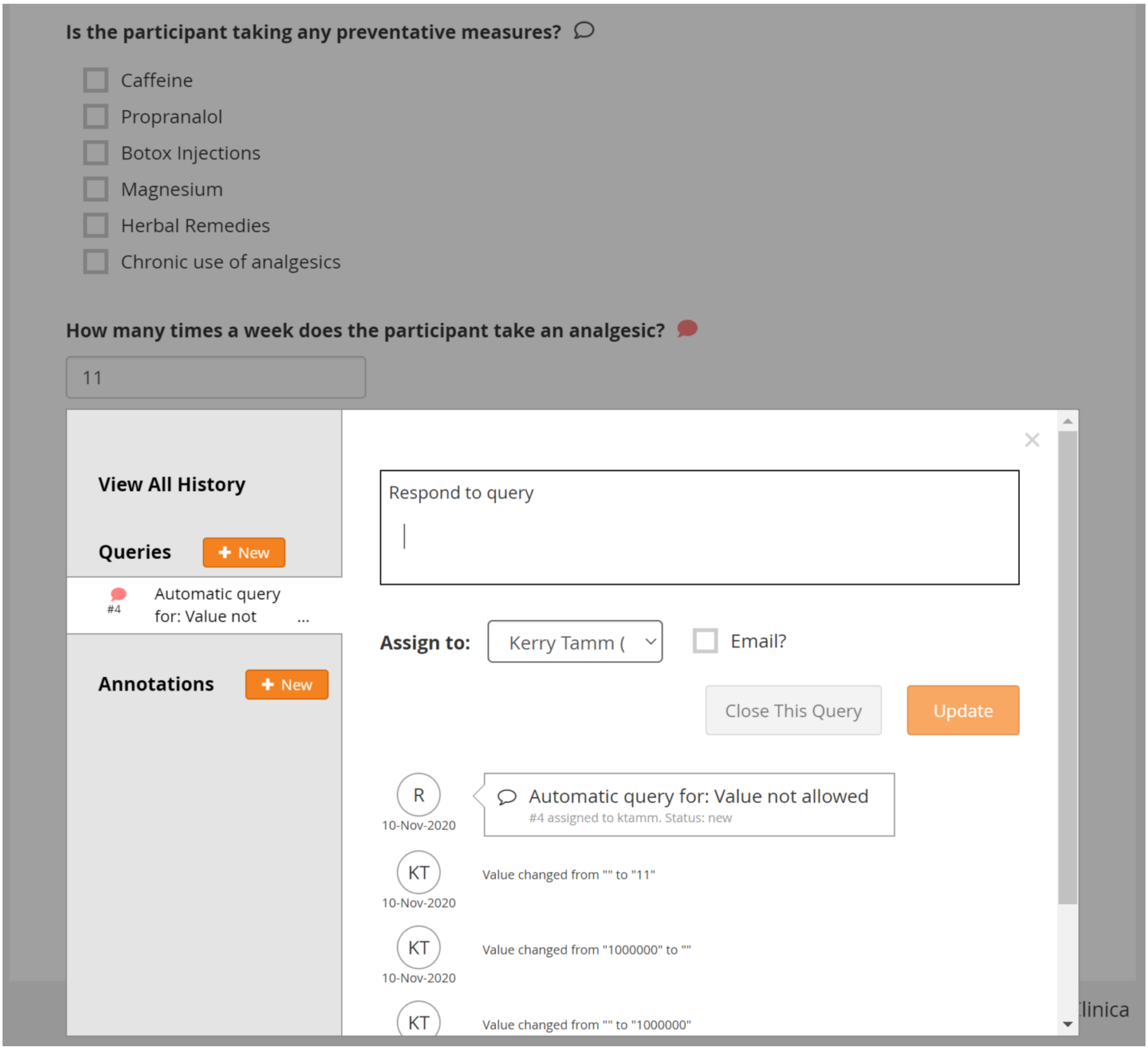
[table id=18 /] You can access these options from the **Actions** column of the **Queries** table.



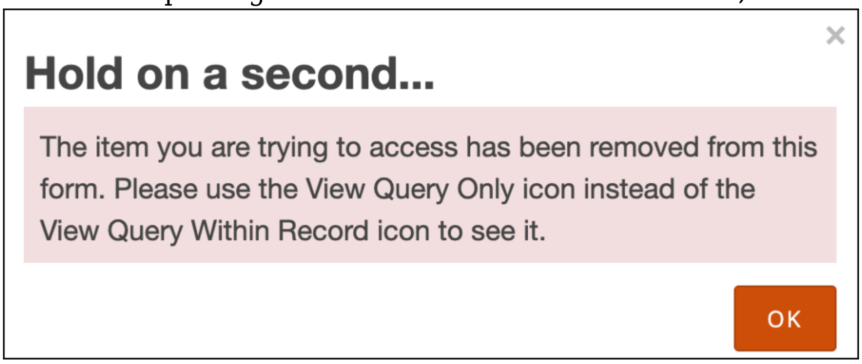
View Query Only:



View Query Within Record:



You can then update the query comment, use the **x** to close the query details, and review the entire form in question. **Data Managers** and **Monitors** have the additional option of closing the query. If an item only displays based on the response to another question, there may be instances where an item was conditionally displayed, a query was added to that item, and then the response to the lead-in question was changed, so that item is no longer displayed. That query still exists, however, and needs to be addressed. Similarly, if there is a form that has repeating records and a query was added to a row, but that row has since been deleted, the query still exists, but is no longer displayed on the form. OpenClinica informs you of these hidden items and provides an option for resolving the associated queries. For example, when the item in question is a response that has since been hidden, or is on a repeating record that has since been deleted, the following message displays:



To review the remaining data on

that form, click **OK** and review the data. To review the data for the item in question, return to the **Queries** screen and use the **View Query Only** icon for that query (as instructed in the message).

Creating Queries

Use Case(s):

- Participant data does not match the source record.
- Participant data is clinically inaccurate.
- Participant data contains a typographical error.
- A form needs to be marked complete but an edit check prevents it.
- Information is missing from a form.
- A form in an Event was not started on time.

Users can create queries to inquire about participant data.

Note: *Each query is automatically assigned an ID that is unique to the study environment (i.e.* ***Test*** *or* ***Production****). The ID appears in the* ***Queries*** *widget but is not visible until you close and reopen the Form. It also appears on the* ***Queries*** *table.*

You can add multiple queries regardless of any existing ones.

You can only add/respond to queries and annotations in **Edit Mode** or **Review-Only Mode**, as determined by your User Role. You cannot do so in **Read-Only Mode**.

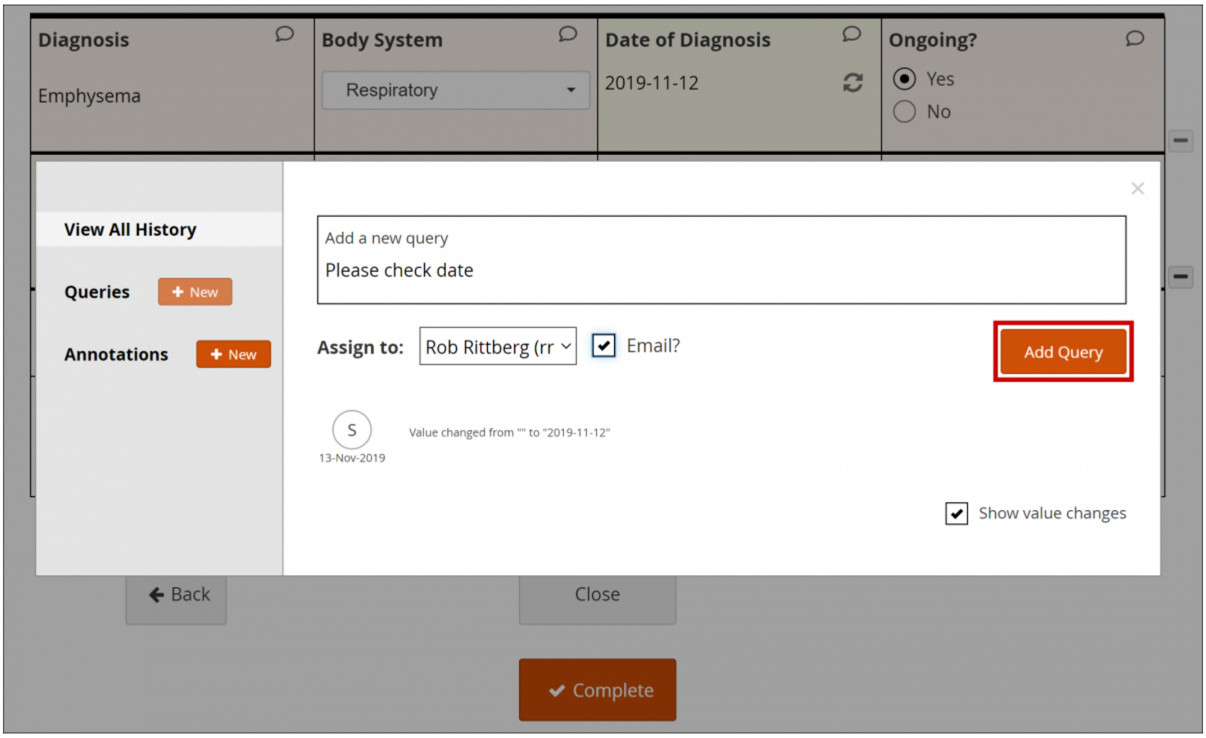
You can view the history for all queries and annotations on a single item by selecting **View All History**, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the **Show value changes** checkbox, each value change is included in the history.

Best Practice:

- *If a form has not been started when it should have been, a Data Manager can add a query to the events start date.*
- *When a query is created, it should be assigned to the correct recipient. If action is required excluding if the query needs to be closed, the* ***Email*** *checkbox should be checked off.*
- *A new query should be created for a single issue, instead of combining multiple issues.*
- *A new query should be created rather than reopening a query that has already been closed.*

To Create a Query:

1. Open a Form.
2. Click the **Query Bubble** in the field you want to create a query for.
3. Click the **+New** button next to **Queries**.
4. In the **Add a new query** field, enter text explaining the possible error or question.
5. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
6. Click the **Add Query** button.



Responding To/Updating Queries

Use Case(s):

- A response is required for the query to be resolved.
- Participant data must be changed for the query to be resolved.

Users can update queries by responding to a query and/or changing data in the form. If data is changed, they will be prompted to enter a reason for change.

Note: *You can only add/respond to queries and annotations in* ***Edit Mode*** *or* ***Review-Only Mode****, as determined by your User Role. You cannot do so in* ***Read-Only Mode****.*

You can view the history for all queries and annotations on a single item by selecting ***View All History****, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the* ***Show value changes*** *checkbox, each value change is included in the history.*

Best Practice:

- *All users can view a list of queries that have been assigned to them by expanding the* ***Quick Links*** *header in the left-hand sidebar and clicking* ***Queries Assigned to Me****.*
- *Data Managers can view a list of queries that have been assigned to them by clicking* ***Queries Assigned to Me*** *on the* ***Home*** *screen.*
- *When a query is responded to/updated, it should be assigned to the correct recipient. If action is required, the* ***Email*** *checkbox should be checked off.*
- *Data Managers and Monitors should review the entire queries list regularly to check for unassigned queries.*
- *If a conditional field (a field that appears based on the response to another field) has a query on it but a user has changed the response to the main field so that the conditional field no longer appears, the query still exists and needs to be addressed, but the field no longer appears on the Form. To review the remaining data on that Form, click* ***OK****, and review the*

data.

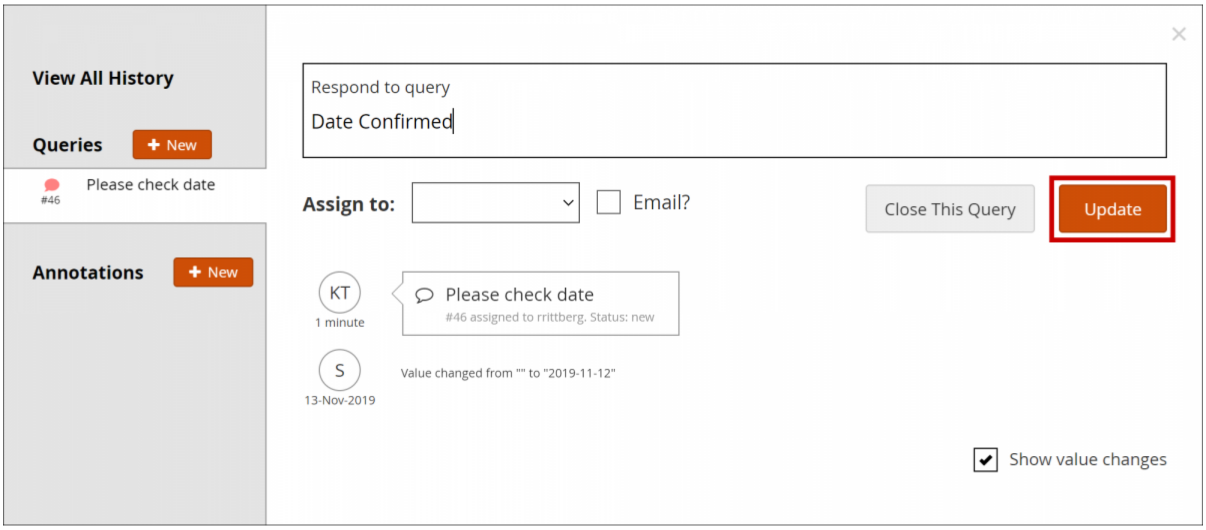
- *If there is a form that has repeating records, and a query was added to a row, but that row has since been deleted, the query still exists, but no longer appears on the Form. A message appears to inform you of these hidden items and provides an option for resolving the associated queries. To review the remaining data on that Form, click **OK**, and review the data.*

To Respond to or Update In a Form:

1. Open a Form.
2. Click the **Query Bubble** in the field you want to create a query for.
3. Select the query you want to respond to and/or update.
4. (Optional) If you need to change information in a form, close the **Query** widget, and make changes to the Form manually. You must provide a **Reason for Change** before completing the Form.
5. In the **Respond to query** field, enter text explaining the query response.
6. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
7. Click the **Update** button to add the response and leave the query open.

To Respond to or Update a Query from the Queries Table:

1. Click **View Query Only** or **View Query within record** in the **Actions** column of the **Queries** table.
2. (Optional) If you need to change information in a form, close the **Query** widget, and make changes to the form manually. You must provide a **Reason for Change** before completing the form.
3. In the **Respond to** query field, enter text explaining the query response.
4. (Optional) Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access.
5. Click the Update button to add the response and leave the query open.



Closing Queries

Use Case(s):

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

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

Best Practice:

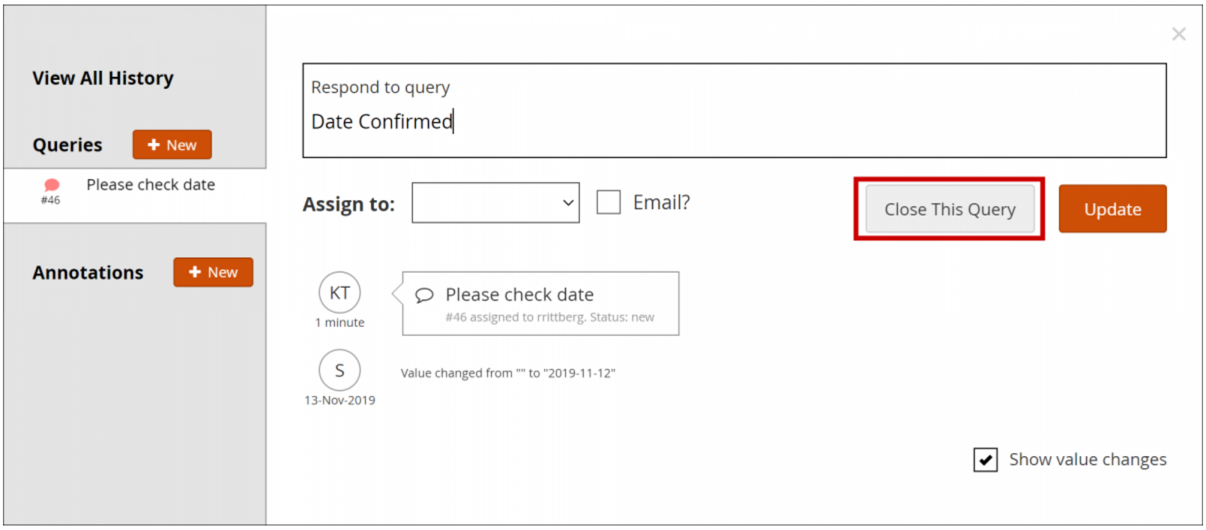
- *A new query should be created rather than reopening a query that has already been closed.*
- *If a conditional field (a field that appears based on the response to another field) has a query on it but a user has changed the response to the main field so that the conditional field no longer appears, the query still exists and needs to be addressed, but the field no longer appears on the Form. To review the remaining data on that Form, click **OK**, and review the data.*
- *If there is a form that has repeating records, and a query was added to a row, but that row has since been deleted, the query still exists, but no longer appears on the Form. A message appears to inform you of these hidden items and provides an option for resolving the associated queries. To review the remaining data on that Form, click **OK**, and review the data.*

To Close a Query In a Form:

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

To Close a Query from the Queries Table:

1. Click **View Query Only** or **View Query within record** in the **Actions** column of the **Queries** table.
2. Click the **Close** button.



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

Annotations

Use Case(s):

A user adds an annotation to keep track of workflow

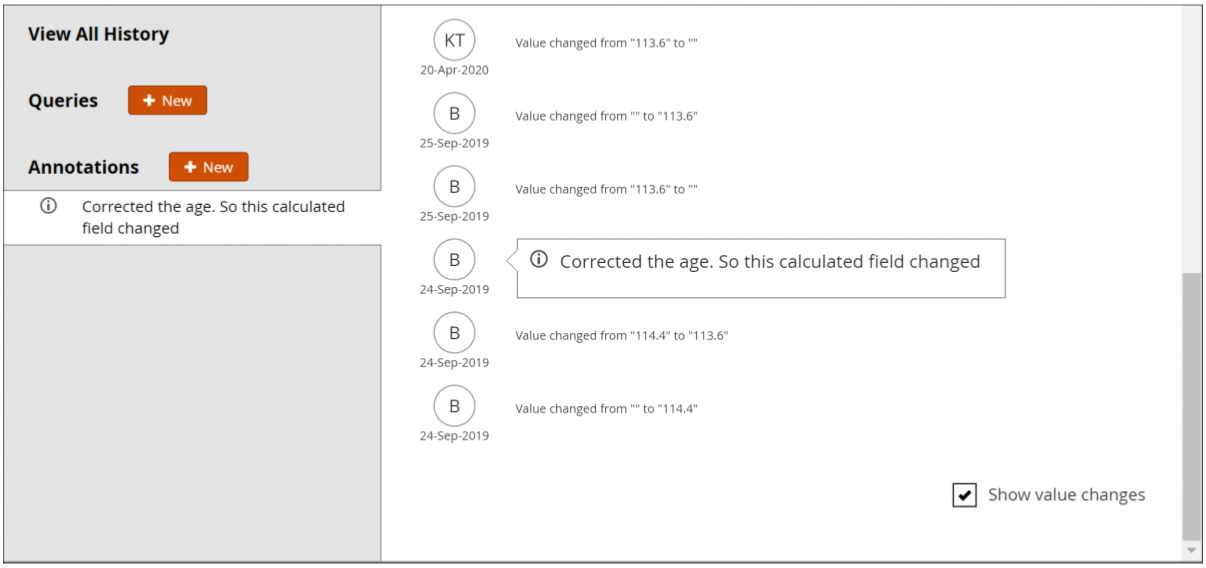
You can add an annotation to a field to make a note. Annotations cannot be assigned, responded to or closed.

Best Practice: *Annotations should not contain clinical information.*

Note: *You can view the history for all queries and annotations on a single item by selecting **View All History**, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the Show value changes checkbox, each value change is included in the history.*

To Enter an Annotation:

1. Open a Form.
2. Click the **Query Bubble** in the field for which you want to create an annotation.
3. Click the **+New button** next to **Annotations**.
4. In the **Add a new annotation** field, enter text for the annotation.
5. Click the **Add Annotation** button.



Note: *Annotations are indicated with an **i** icon. They appear as **N/A** in the **Query ID** column and **Not Applicable** in the **Resolution Status** column.*

Downloading Queries, Annotations, and Reasons for Change

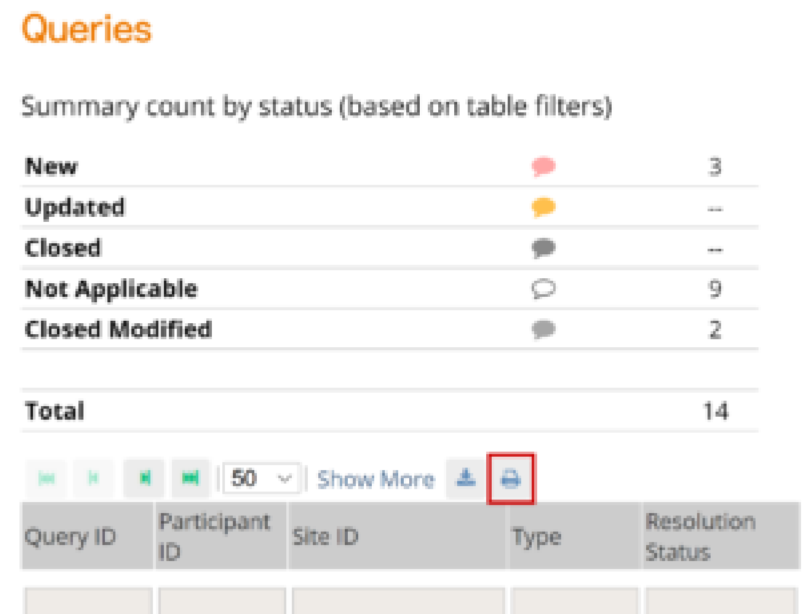
To Download Queries, Annotations, and Reasons for Change:

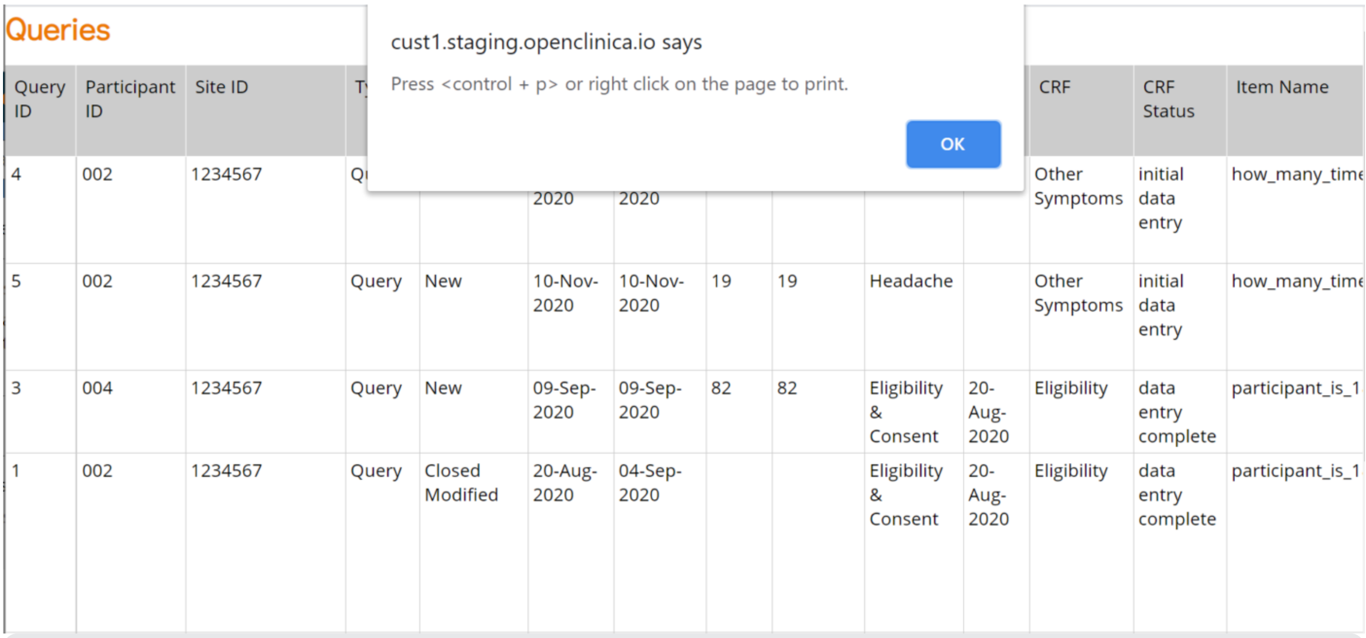
1. Click the **Download** button at the top of the table. A Download window appears.
2. Select **comma-separated values** or **portable document format** in the **format field.**
3. Click the **Download notes** button.

Printing Queries, Annotations, and Reasons for Change

To Print Queries, Annotations, and Reasons for Change:

1. Click the Print button at the top of the table. A Print window appears.
2. Click **ctrl + p** (Windows) or **command + p** (Mac) or click **Ok**, right click the window, and select **Print**.




Queries

cust1.staging.openclinica.io says

Press <control + p> or right click on the page to print.

OK

Query ID	Participant ID	Site ID	T								CRF	CRF Status	Item Name
4	002	1234567	Q		2020	2020					Other Symptoms	initial data entry	how_many_time
5	002	1234567	Query	New	10-Nov-2020	10-Nov-2020	19	19	Headache		Other Symptoms	initial data entry	how_many_time
3	004	1234567	Query	New	09-Sep-2020	09-Sep-2020	82	82	Eligibility & Consent	20-Aug-2020	Eligibility	data entry complete	participant_is_1
1	002	1234567	Query	Closed Modified	20-Aug-2020	04-Sep-2020			Eligibility & Consent	20-Aug-2020	Eligibility	data entry complete	participant_is_1

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

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

9.2 Source Data Verification

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

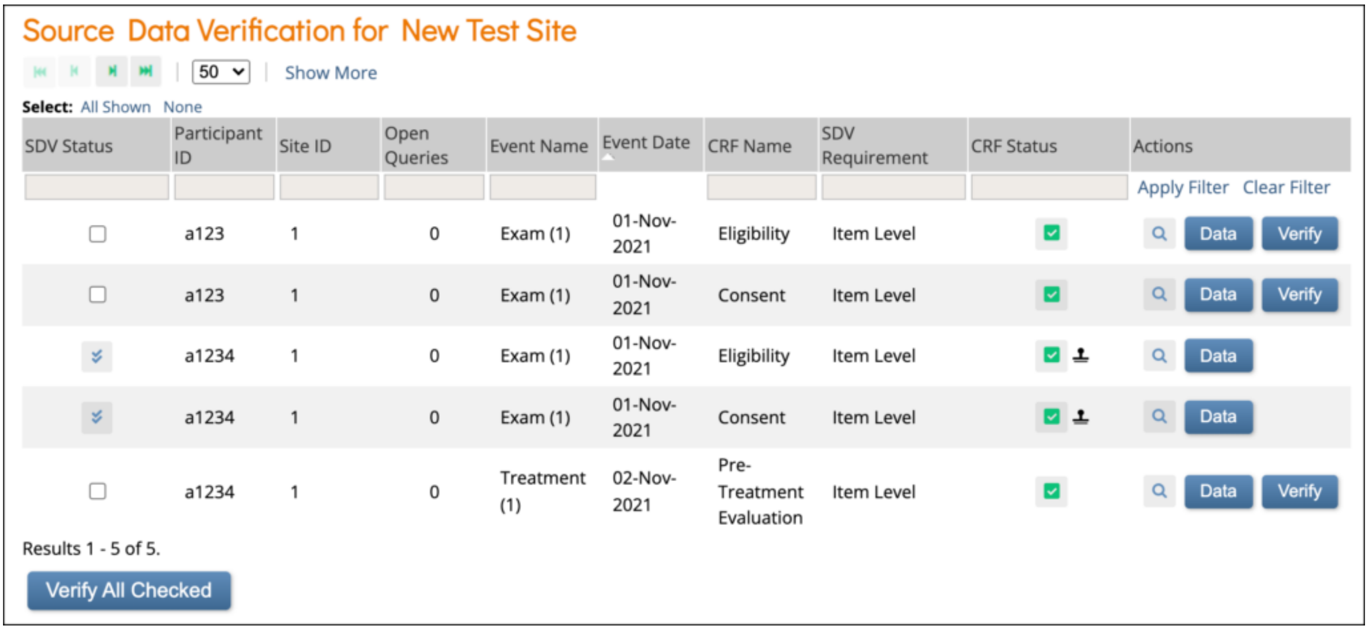
The Source Data Verification screen is the Monitor's **Home** screen where they perform Source Data Verification (SDV).

To Access the Source Data Verification screen:

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

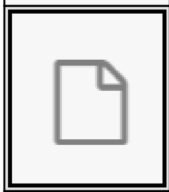
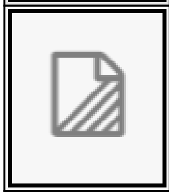
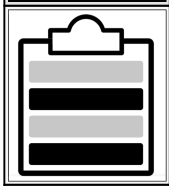
The SDV Table

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



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
- **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.

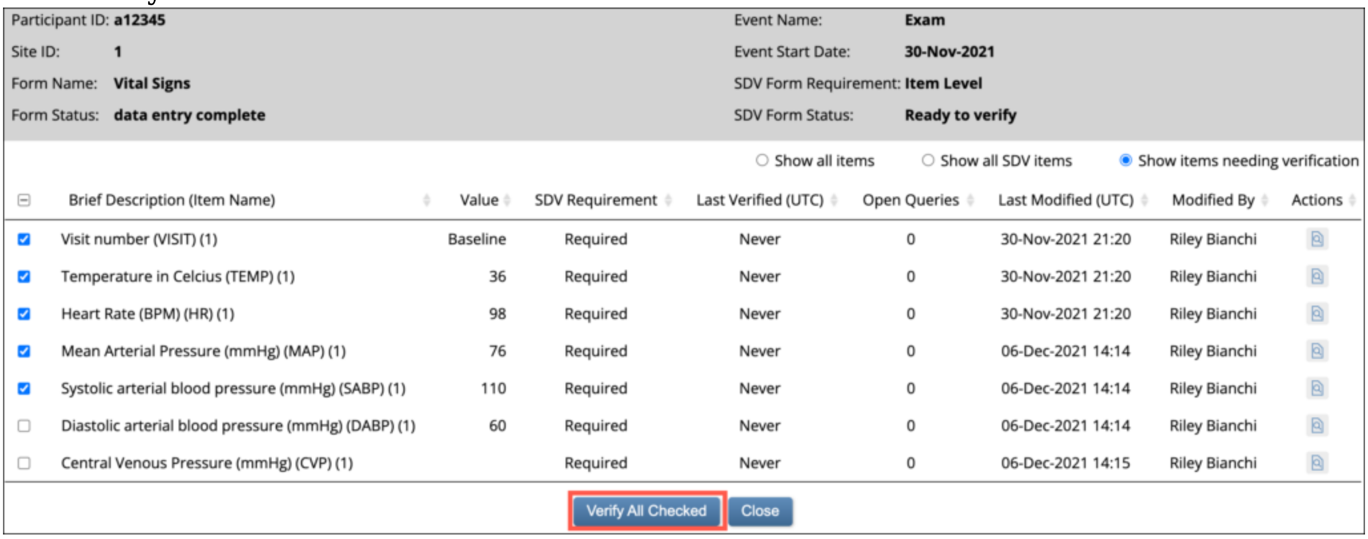
Select: All Shown None

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
	a123	1	0	Eligibility & Consent	01-Nov-2021	Physical Exam	Item Level		Data Verify
	a123	1	0	Eligibility & Consent	01-Nov-2021	Vital Signs	Item Level		Data Verify
	a1234	1	0	Exam (1)	01-Nov-2021	Vital Signs	Item Level		Data Verify
	a12345	1	0	Exam (2)	30-Nov-2021	Vital Signs	Item Level		Data Verify
	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**
Site ID: **1**
Form Name: **Vital Signs**
Form Status: **data entry complete**
Event Name: **Exam**
Event Start Date: **30-Nov-2021**
SDV Form Requirement: **Item Level**
SDV Form Status: **Ready to verify**

Show all items   Show all SDV items   Show items needing verification

	Brief Description (Item Name)	Value	SDV Requirement	Last Verified (UTC)	Open Queries	Last Modified (UTC)	Modified By	Actions
☑	Visit number (VISIT) (1)	Baseline	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
☑	Temperature in Celcius (TEMP) (1)	36	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
☑	Heart Rate (BPM) (HR) (1)	98	Required	Never	0	30-Nov-2021 21:20	Riley Bianchi	
☑	Mean Arterial Pressure (mmHg) (MAP) (1)	76	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
☑	Systolic arterial blood pressure (mmHg) (SABP) (1)	110	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
☐	Diastolic arterial blood pressure (mmHg) (DABP) (1)	60	Required	Never	0	06-Dec-2021 14:14	Riley Bianchi	
☐	Central Venous Pressure (mmHg) (CVP) (1)		Required	Never	0	06-Dec-2021 14:15	Riley Bianchi	

Verify All Checked   Close

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

9.3 Reviewing and Managing Data

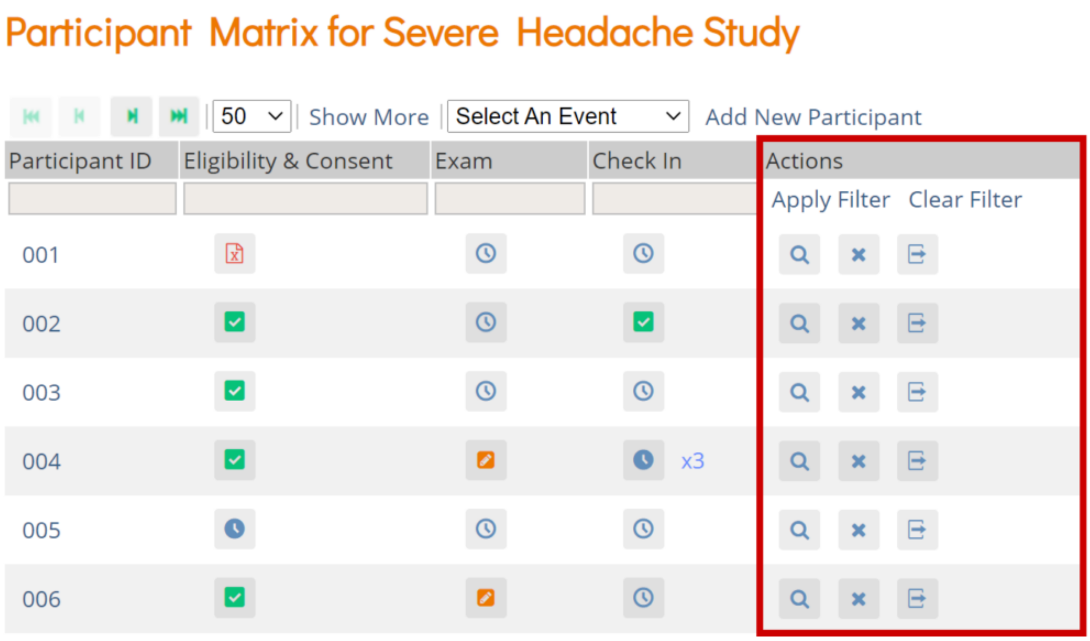
Data can be reviewed using the **Participant Matrix**, **Queries**, or **Source Data Verification** screen.

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.

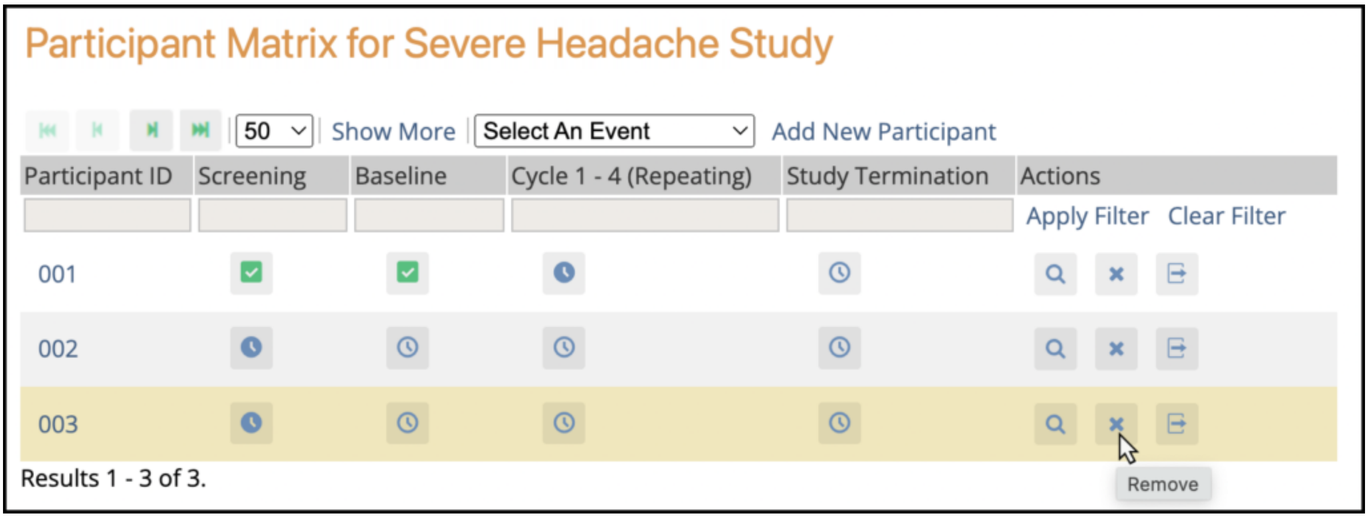
The following displays the actions available to a Data Manager:

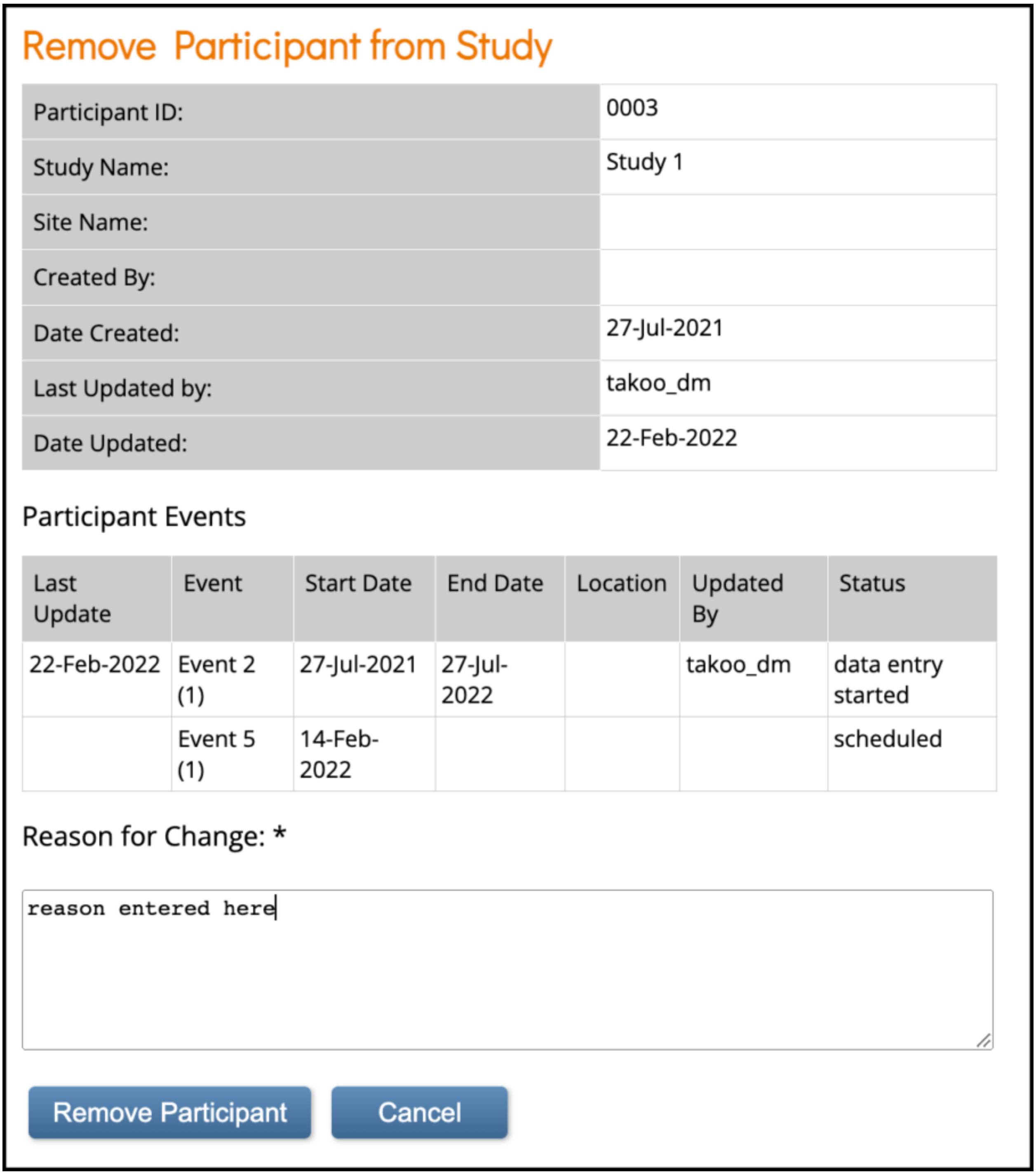


Remove a Participant

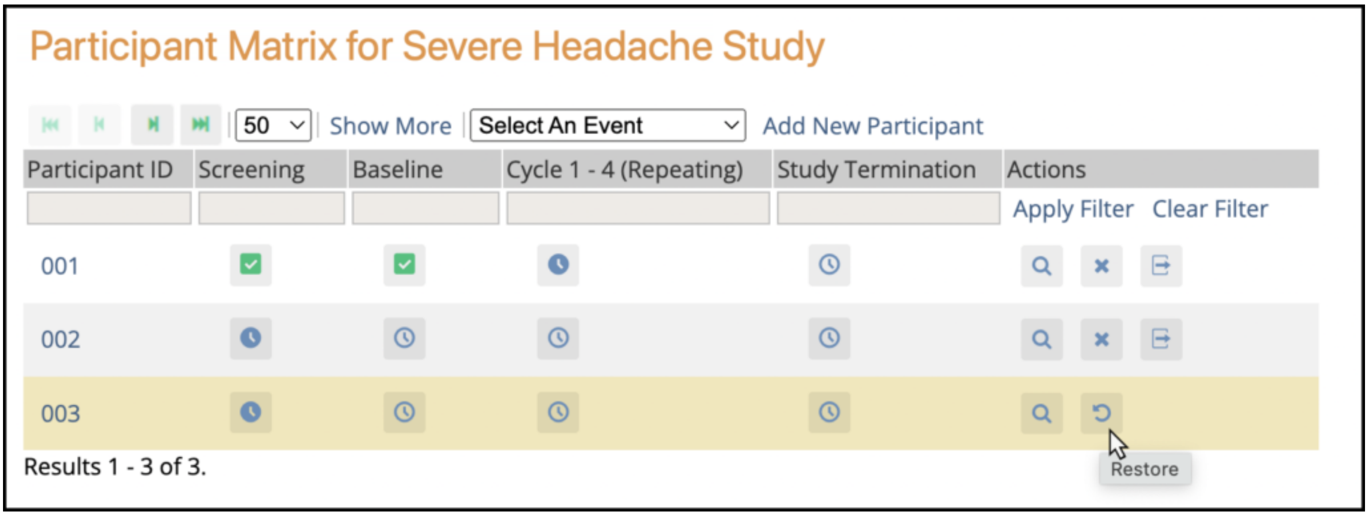
Data Managers have access to remove Participants.

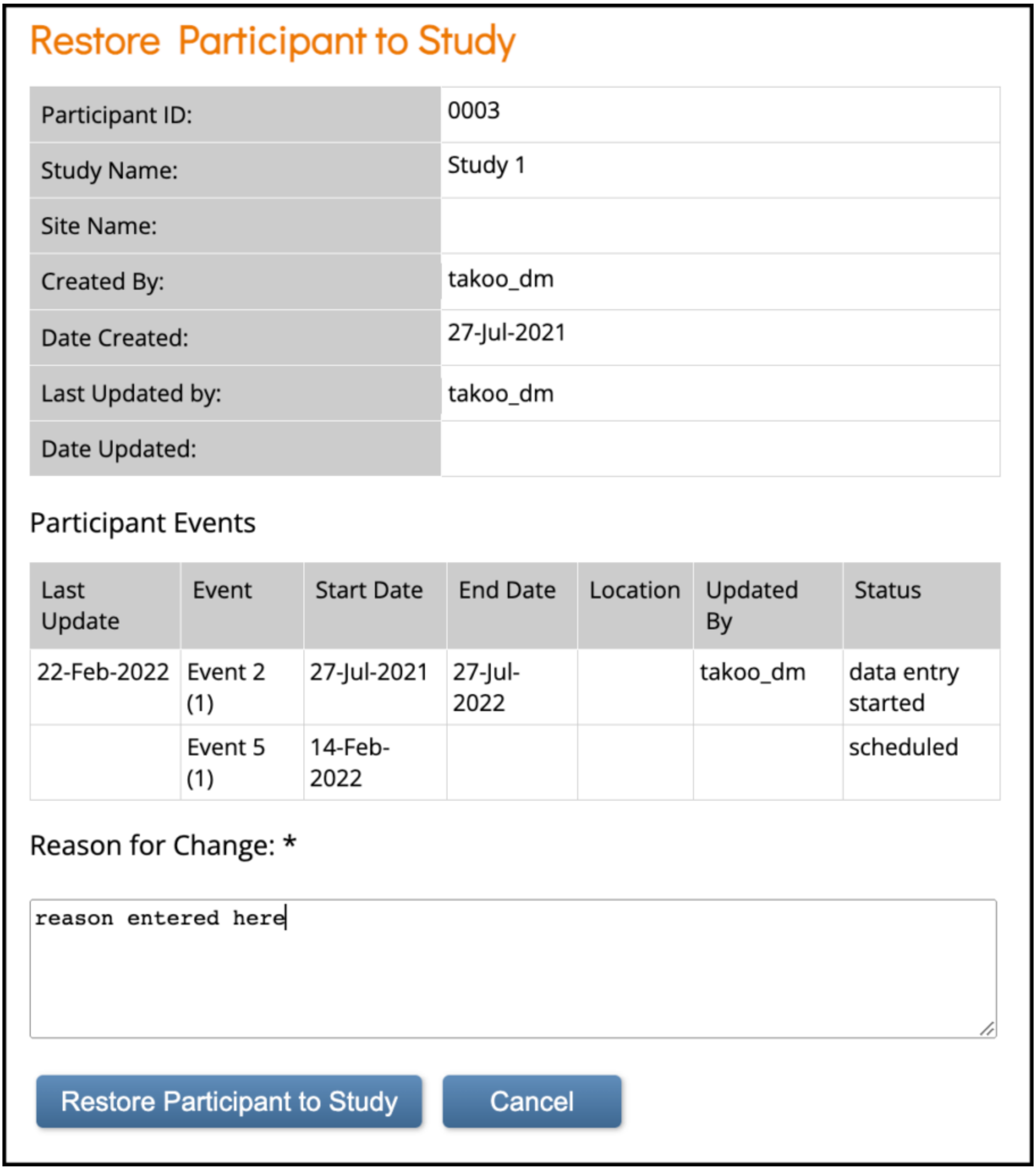
Removing a Participant does not delete the Participant, but instead removes access to that Participant's data. The data for that subject can still be viewed, but cannot be edited and will not be included in data extracts.


Participant Matrix for Severe Headache Study
50
Show More
Select An Event
Add New Participant
Participant ID
Screening
Baseline
Cycle 1 - 4 (Repeating)
Study Termination
Actions
Apply Filter
Clear Filter
001
002
003
Results 1 - 3 of 3.
Remove


Remove Participant from Study
Participant ID: 0003
Study Name: Study 1
Site Name:
Created By:
Date Created: 27-Jul-2021
Last Updated by: takoo_dm
Date Updated: 22-Feb-2022
Participant Events
Last Update | Event | Start Date | End Date | Location | Updated By | Status
22-Feb-2022 | Event 2 (1) | 27-Jul-2021 | 27-Jul-2022 | | takoo_dm | data entry started
| Event 5 (1) | 14-Feb-2022 | | | | scheduled
Reason for Change: *
reason entered here
Remove Participant
Cancel

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.





Restore Participant to Study

Participant ID:	0003
Study Name:	Study 1
Site Name:	
Created By:	takoo_dm
Date Created:	27-Jul-2021
Last Updated by:	takoo_dm
Date Updated:	

Participant Events

Last Update	Event	Start Date	End Date	Location	Updated By	Status
22-Feb-2022	Event 2 (1)	27-Jul-2021	27-Jul-2022		takoo_dm	data entry started
	Event 5 (1)	14-Feb-2022				scheduled

Reason for Change: *

reason entered here

Restore Participant to Study

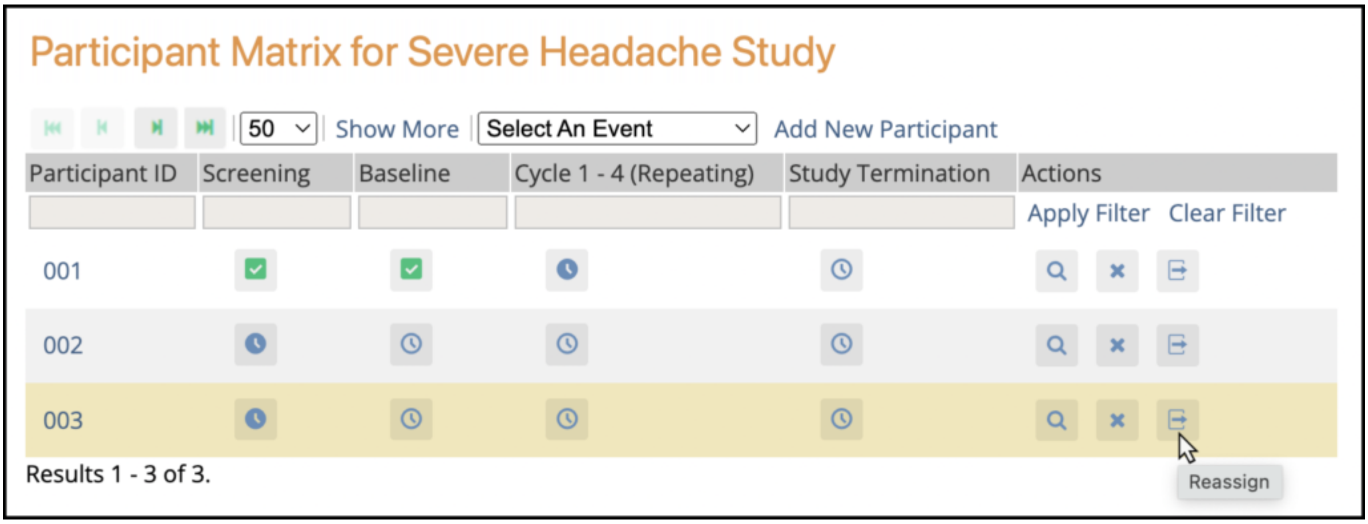
Cancel

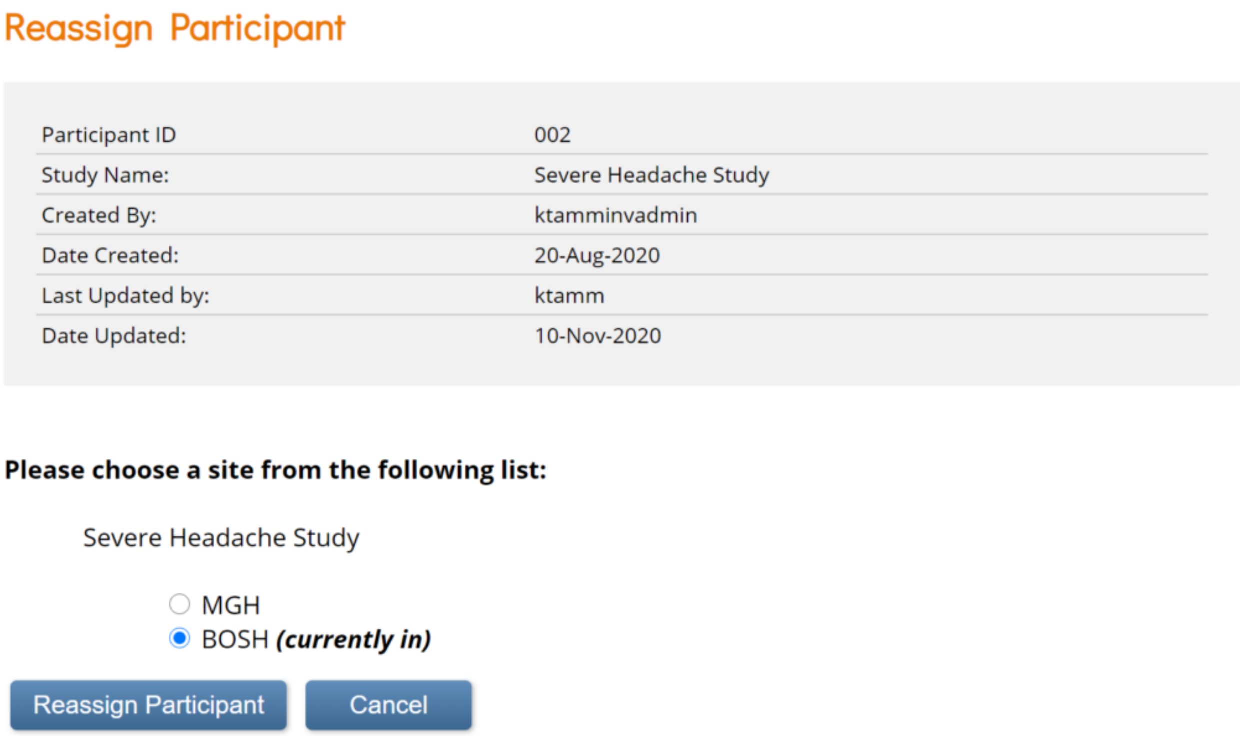
When removing or restoring a participant, you will be required to enter a reason for change.

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.

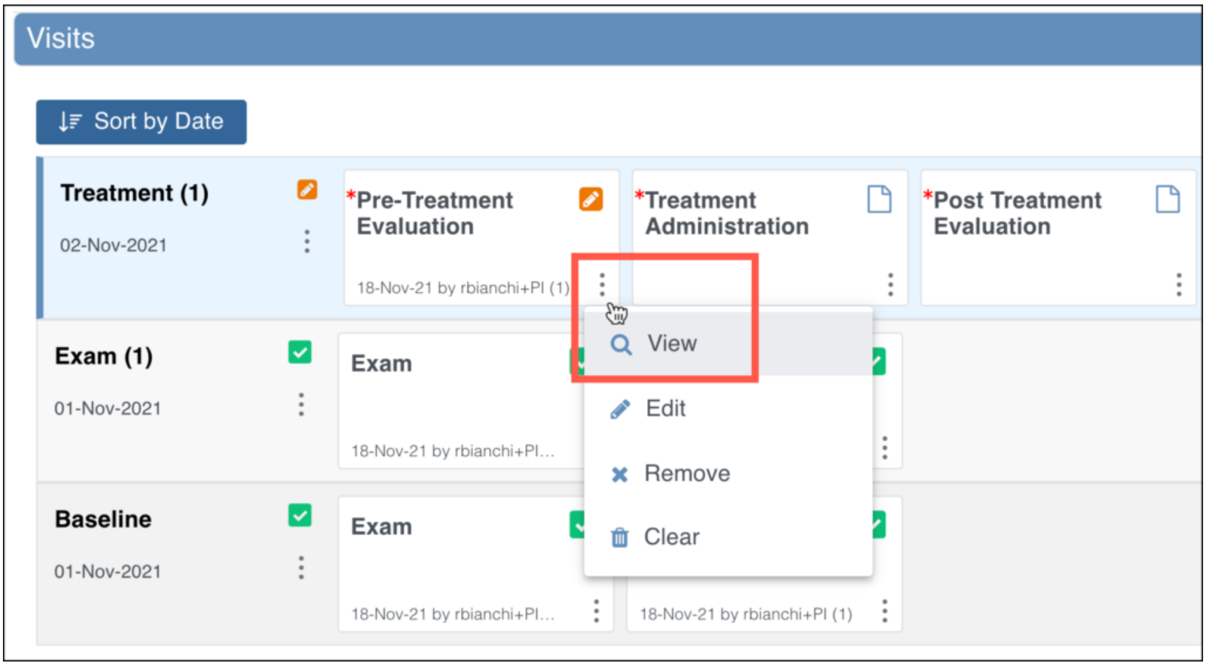
When removing or restoring an event, you will be required to enter a reason for the change.

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

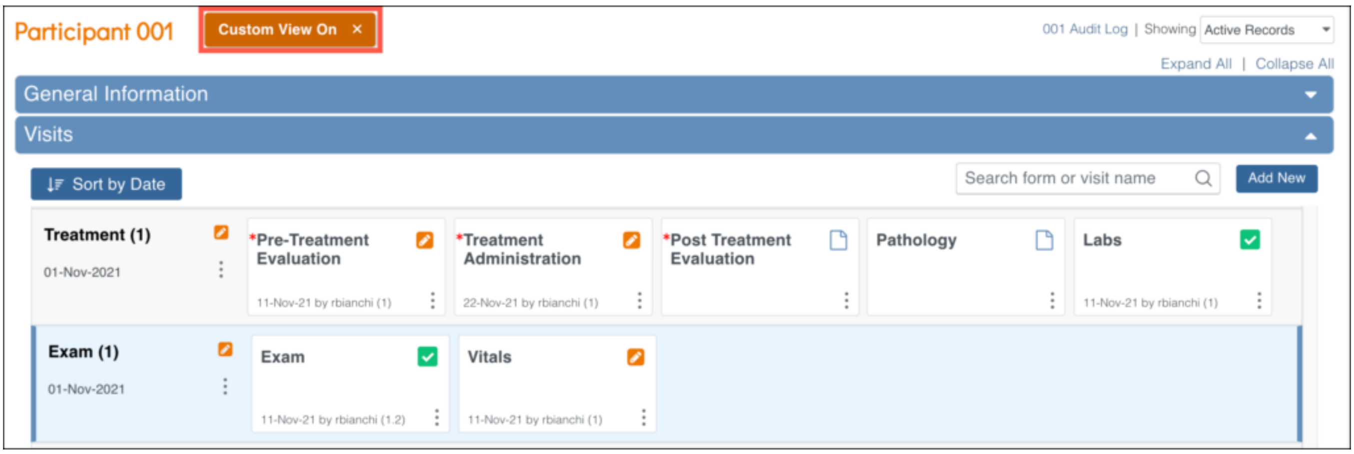
To review data, click the **View** icon for the participant whose data you'd like to review.

To review data on a specific form, click the **View** icon for that form.



Filter Participant Details

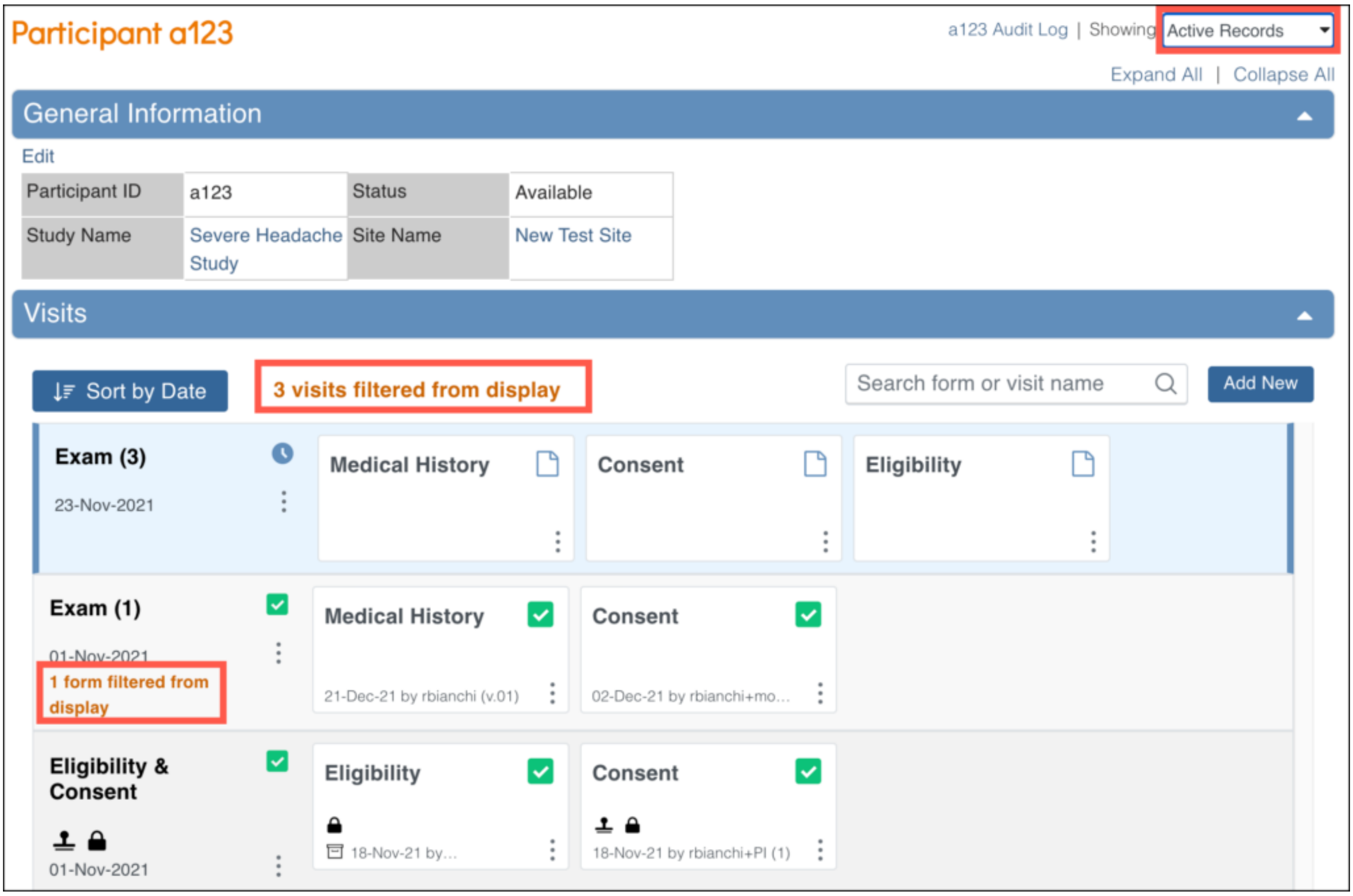
As you review data, you can enter search criteria for the Common Events - for example, to show only AEs that are ongoing. You can also change the number of rows listed for any of the Common Events, and you can sort Common Events by clicking any of the column headings. When you customize anything related 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).

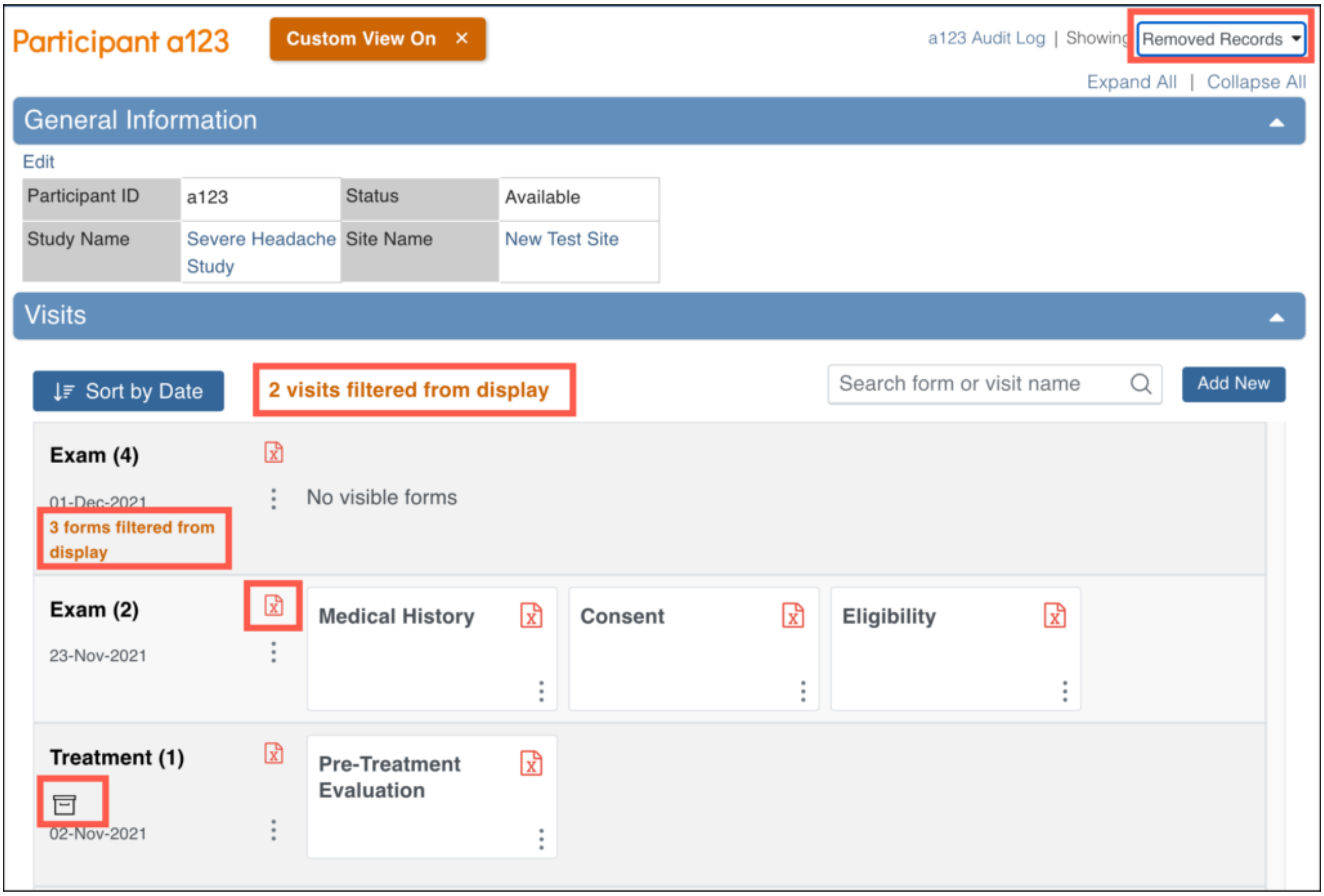


The **Custom View** is active for that participant throughout the time you are logged into OpenClinica. If you view a different Participant's details, the view might not be customized, or it may be a different customization. In the example above, throughout the current session, any time you view participant 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.*

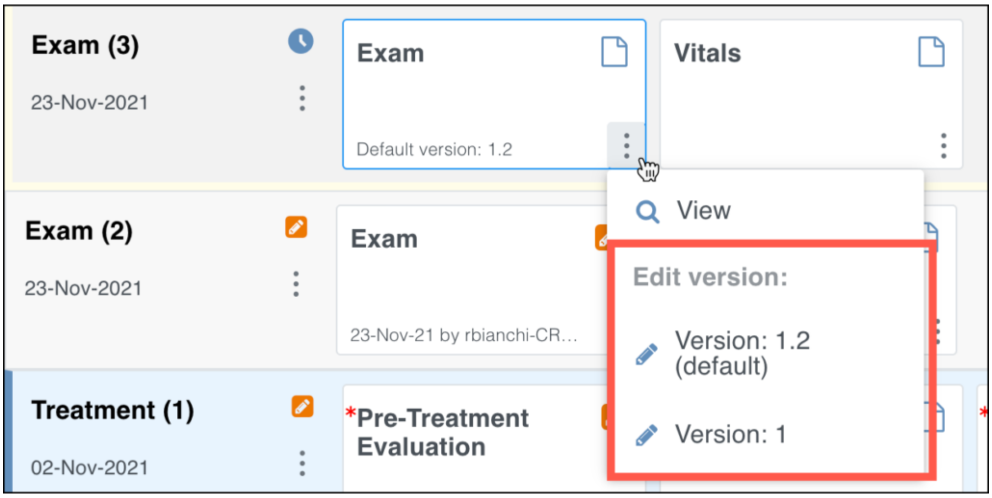
Example: *A Data Manager might choose to migrate Form data in order to update the Form to a new version.*

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:

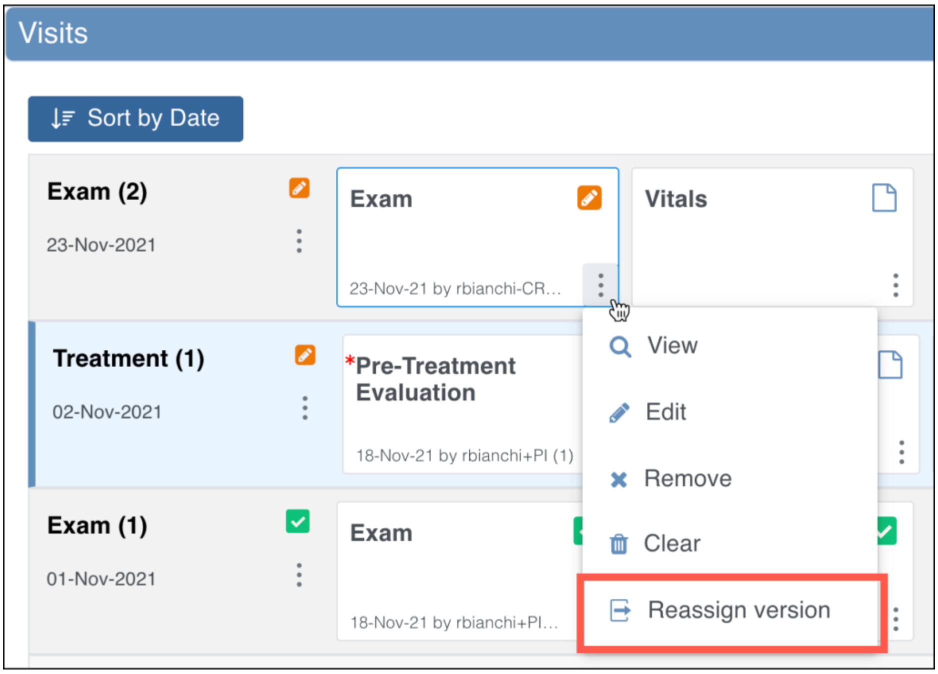
- **Data Entry Status:** Data Entry Started
- **Study Status:** Available
- **User Role:** Data Manager
- **Participant Status:** Active
- **Event Status:** Active (not removed, locked, or skipped)
- **Form Status:** Active (not removed)
- **New Form Version:** Active (not removed)
- **Previous Form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

Prerequisites:

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

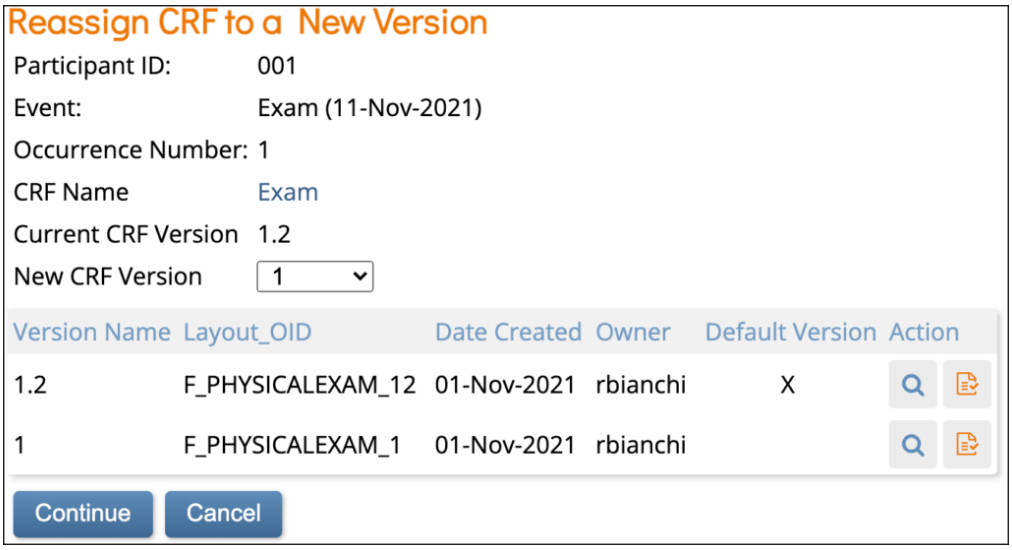
Participant-by-Participant Migration:

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.**



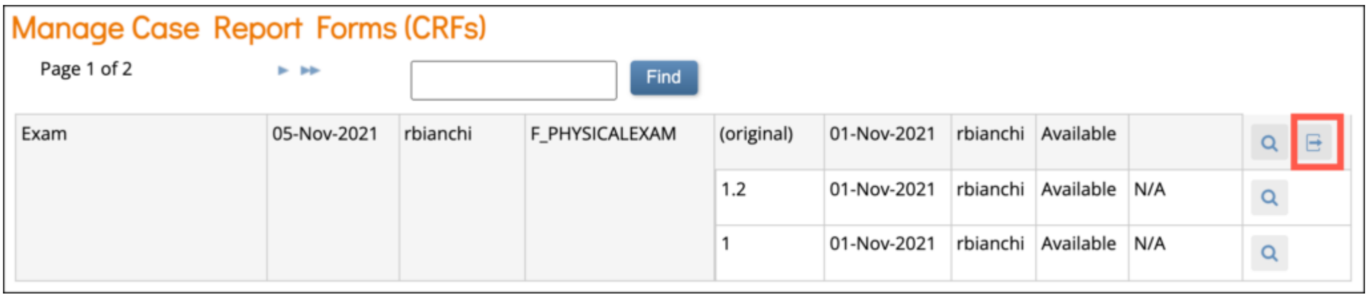
3. Select the new Form version in the **New CRF Version** field.

4. Click the **Continue** button.



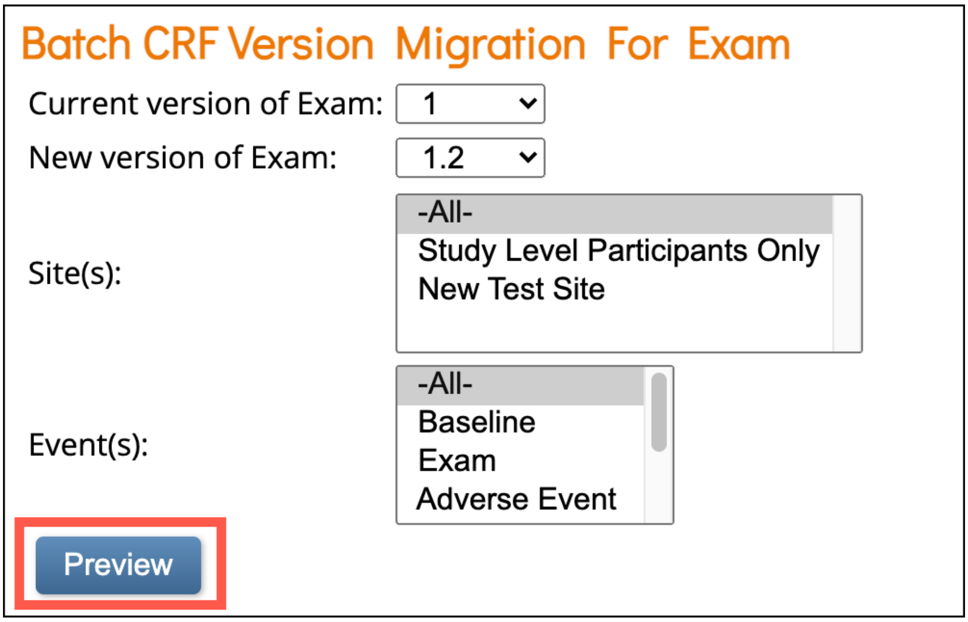
Batch Migration:

1. In the header bar of Study Runner, click **Tasks**.
2. Select **CRFs** under **Monitor and Manage Data**.
3. Click the **Batch CRF Version Migration** button next to the CRF you want to update.



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

2. Select the new version of the Form in the **New Version of (Form Name)** field.
3. (Optional) Select a site to update the version at. (The default is all sites.)
4. (Optional) If the Form is in multiple events, select an Event to update the version in. (The default is all Events.)
5. 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.