

## 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:

#### Participant Matrix for Severe Headache Study

<div> <span>⏮</span> <span>⏪</span> <span>⏩</span> <span>⏭</span> </div> <div> 50 <span>▼</span> </div> <div> Show More </div> <div> Select An Event <span>▼</span> </div> <div> Add New Participant </div>				
Participant ID	Eligibility & Consent	Exam	Check In	Actions
				Apply Filter Clear Filter
001				  
002				  
003				  
004			 x3	  
005				  
006				  

### 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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
002	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
003	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>

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.

### Participant Matrix for Severe Headache Study

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Show More

Select An Event

Add New Participant

Participant ID	Screening	Baseline	Cycle 1 - 4 (Repeating)	Study Termination	Actions
					Apply Filter Clear Filter
001	<div></div>	<div></div>	<div></div>	<div></div>	<div></div> <div></div> <div></div>
002	<div></div>	<div></div>	<div></div>	<div></div>	<div></div> <div></div> <div></div>
003	<div></div>	<div></div>	<div></div>	<div></div>	<div></div> <div></div>

Results 1 - 3 of 3.

Restore

## 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: \*

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**.

## Participant Matrix for Severe Headache Study

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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.

Reassign

## Reassign Participant

Participant ID	002
Study Name:	Severe Headache Study
Created By:	ktamminvadmin
Date Created:	20-Aug-2020
Last Updated by:	ktamm
Date Updated:	10-Nov-2020

Please choose a site from the following list:

Severe Headache Study

- ☐ MGH  
☒ BOSH (*currently in*)

Reassign Participant

Cancel

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.

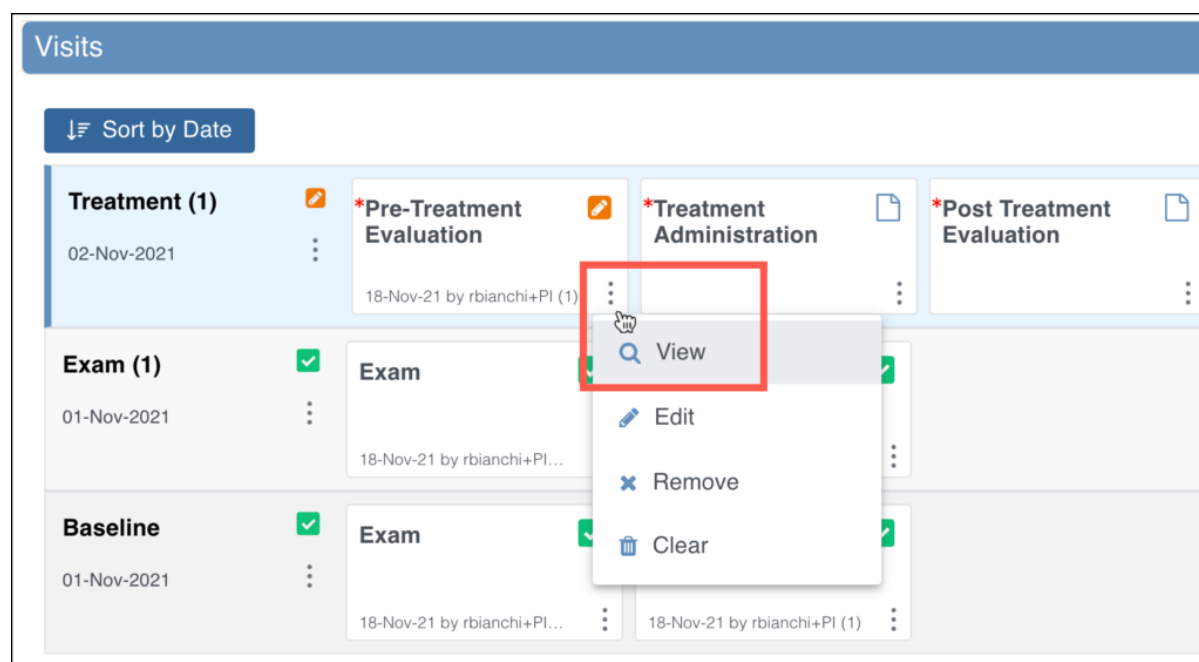
When removing or restoring an event, you will be required to enter a reason for the change.

**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

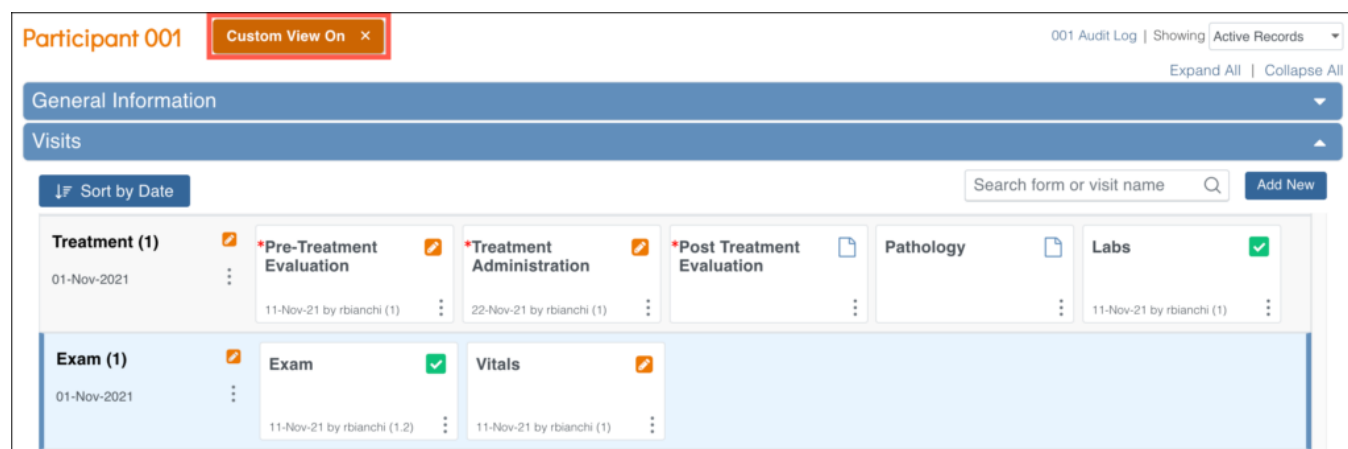
To review data, click the **View** icon for the participant whose data you'd like to review.

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.

Participant a123

a123 Audit Log | Showing **Active Records** ▼

Expand All | Collapse All

General Information

Edit

Participant ID	a123	Status	Available
Study Name	Severe Headache Study	Site Name	New Test Site

Visits

Sort by Date

3 visits filtered from display

Search form or visit name Q

Add New

<b>Exam (3)</b> 23-Nov-2021	<b>Medical History</b> ⋮	<b>Consent</b> ⋮	<b>Eligibility</b> ⋮
<b>Exam (1)</b> 01-Nov-2021 1 form filtered from display	<b>Medical History</b> ✓ 21-Dec-21 by rbianchi (v.01) ⋮	<b>Consent</b> ✓ 02-Dec-21 by rbianchi+mo... ⋮	
<b>Eligibility &amp; Consent</b> ✓ 01-Nov-2021	<b>Eligibility</b> ✓ 18-Nov-21 by... ⋮	<b>Consent</b> ✓ 18-Nov-21 by rbianchi+PI (1) ⋮	

Participant a123
Custom View On
a123 Audit Log | Showing
Removed Records
Expand All | Collapse All

General Information

Edit

Participant ID	a123	Status	Available
Study Name	Severe Headache Study	Site Name	New Test Site

Visits

Sort by Date
2 visits filtered from display
Search form or visit name
Add New

Exam (4)
01-Dec-2021
3 forms filtered from display

No visible forms

Exam (2)
23-Nov-2021

Medical History

Consent

Eligibility

Treatment (1)
02-Nov-2021

Pre-Treatment Evaluation

## Form Migration

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

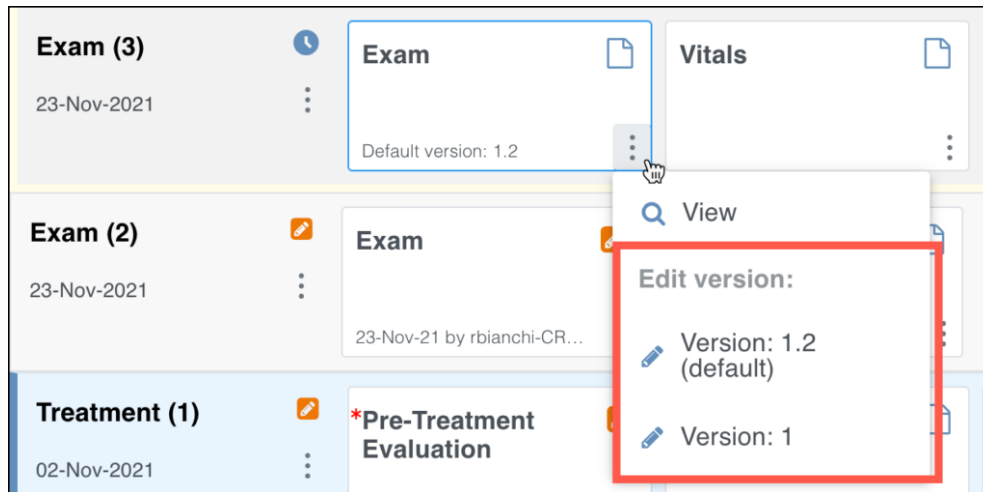
**Example:** A Data Manager might choose to migrate Form data in order to update the Form to a new version.

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:

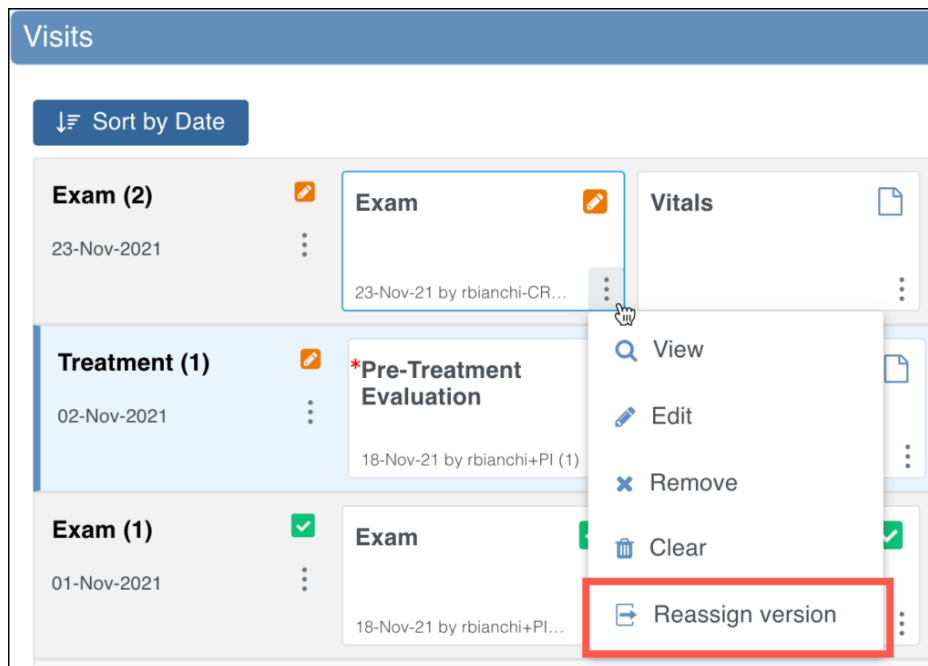
- **Data Entry Status:** Data Entry Started
- **Study Status:** Available
- **User Role:** Data Manager
- **Participant Status:** Active
- **Event Status:** Active (not removed, locked, or skipped)
- **Form Status:** Active (not removed)
- **New Form Version:** Active (not removed)
- **Previous Form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

**Reassign CRF to a New Version**

Participant ID: 001  
 Event: Exam (11-Nov-2021)  
 Occurrence Number: 1  
 CRF Name: Exam  
 Current CRF Version: 1.2  
 New CRF Version:

Version Name	Layout_OID	Date Created	Owner	Default Version	Action
1.2	F_PHYSICALEXAM_12	01-Nov-2021	rbianchi	X	
1	F_PHYSICALEXAM_1	01-Nov-2021	rbianchi		

## 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.

**Manage Case Report Forms (CRFs)**

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Form Name	Date Created	Owner	Form ID	Version	Date Created	Owner	Status	Available	Action
Exam	05-Nov-2021	rbianchi	F_PHYSICALEXAM	(original)	01-Nov-2021	rbianchi	Available		
				1.2	01-Nov-2021	rbianchi	Available	N/A	
				1	01-Nov-2021	rbianchi	Available	N/A	

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.

### Batch CRF Version Migration For Exam

Current version of Exam:

New version of Exam:

Site(s): 

-All-

Study Level Participants Only

New Test Site

Event(s): 

-All-

Baseline

Exam

Adverse Event

Preview

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.

Approved for publication by Riley Bianchi. Signed on 2022-08-22 4:28PM

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