6.3 Entering Data

The features of OC4 data entry include the following:

- **Participant Matrix:** Easily see the data entry status of participants.
- **Auto-save:** Automatically save during data entry.
- **Conditional field display:** Only see relevant fields during data entry.
- **Automatic calculations and data checks:** Automatically use calculations and checks.
- **Queries:** Easily create or view queries.

Before You Enter Data

To enter data into OpenClinica, you must do the following:

- Add a Participant
- Schedule an Event

See **Adding Participants** for more information on adding Participants.

Scheduling an Event

Once a Participant has been added, you can schedule events and start to enter data.

You can schedule events from the **Participant Matrix**, **Participant Details** screen, or the **Tasks** menu.

To Schedule a Visit-Based Event from the Participant Matrix:

1. Click the **Schedule** button for the Participant and the Event that you want to schedule.
2. Select **Schedule**.
3. Select a **Study Event Definition** from the drop-down list.
4. (Optional) Select a **Start Date/Time**. The current date is the start date by default, but you can change it.
5. (Optional) Select an **End Date/Time**.
6. (Optional) To schedule additional Events, click **Schedule Another Event**, and enter information for that Event. Repeat as needed.
7. To go to the **Participant Details** screen to enter data, click the **Proceed to Enter Data** button.

To Schedule a Visit-Based Event from the Participant Details screen:

1. Click the Participant ID or **View** button next to a Participant on the Participant Matrix.
2. Under the **Visits** header on the **Participant Details** screen, click **Add New**.
3. Select a **Visit Name** from the drop-down list.
4. The current date is the start date by default, but you can change it.
5. (Optional) Click **Show advanced options** to change the **Start Time** or **End Date/Time**.
6. (Optional) To schedule additional Visits, click **+ Add another visit**, and enter the new visit information. Repeat as needed.
7. When you are ready, click **Add visits**.

Note: Once a non-repeating event has been scheduled, it will no longer be available in the **Add Visits** window for that participant.

To Schedule a Visit-Based Event from the Tasks Menu:

1. Click the **Tasks** button in the header bar of Study Runner.
2. Select **Schedule Event**.
3. Enter a Participant ID in the **Participant ID** field.
4. Select a **Study Event Definition** from the drop-down list.
5. (Optional) Select a **Start Date/Time**. The current date is the start date by default, but you can change it.
6. (Optional) Select an **End Date/Time**.
7. (Optional) To schedule additional Events, click **Schedule Another Event**, and enter information for that Event. Repeat as needed.
8. To go to the **Participant Details** screen to enter data, click the Proceed to **Enter Data** button.

To Add a Common Event from the Participant Details screen:

1. Click the Participant ID or **View** button next to a Participant.
2. Under a header for a common event on the **Participant Details** screen, click **Add New**.

Note: *For Common Events, such as Adverse Events and Concomitant Medications, a visit date is not required, and the* ***Add New*** *button opens the form directly.*

Entering Data

To Enter Data Directly into Forms:

1. Click the **Add New** button to add a form associated with the Event. This will open the form directly for you to document.
2. Click the **Edit** button in the **three dots** menu to open the form.
3. Enter information into each field.

To Continue to the Next Page of the Form:

Click the **Next** button.

To Mark Data Entry Complete:

Click the **Complete** button.

To Close the Form and Continue Data Entry Later:

Click the **Close** button.

Note: *If you cannot access a Form, the access to that Form might be restricted in your Study.*

To Download Data for Files, Audio Recordings, Videos, Images, Annotations, Drawings, or Signatures

Click the **Download** button that appears in the field. This button is available in **Edit**, **Review-Only**, and **Read-Only** modes.

Event/Form Independent Attributes

Event/Form Independent Attributes are separate from the **Event/Form Statuses**. Each Event or Form has a single status, but can have multiple attributes. For example, an Event might be **Completed**, **Signed**, and **Locked**.

The Participant Matrix

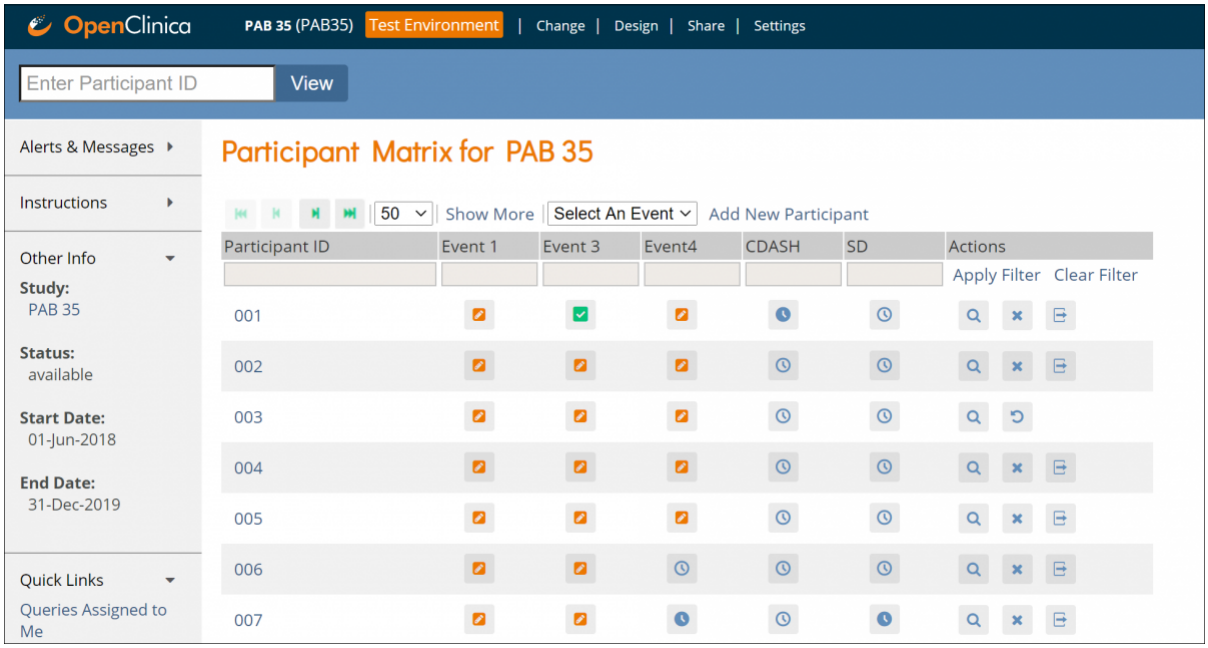
Once you have entered data for Participants, use the **Participant Matrix** to view and navigate Participant records.

The Participant Matrix lists visit-based events across the top and participant IDs down the side. Each icon represents the status of the participant/event combination.

A legend of the icons is listed on the left side of the screen.

Hover over the icons in the **Participant Matrix** to see more details about the participant event. Click an icon for options to view and/or edit data, depending on your access.

You can filter Events by status, including the independent statuses of **Locked** and **Signed**. You can also filter Events with **Not Locked** and **Not Signed**.



Note: *If you filter Events with a status of* ***Not Started****, the Participant Matrix only includes Events that were previously started and then deleted, i.e. Events that have never been started are excluded.*

If you have a repeating Event for a Participant, the ***Participant Matrix*** *shows the least complete status. For example, if the first event is* ***data entry started*** *and the second event is* ***completed****, only the status of* ***data entry started*** *will display.*

For information on removing, reassigning, and restoring Participants, see **Reviewing and Managing Data**.

The Participant Details Page

To access the **Participant Details Page**, click on the Participant ID or the **View** button that corresponds to that Participant.

The **Participant Details Page** is divided into sections. Below the **General Information** section, there are sections for **Visits** and repeating or non-repeating **Common Repeating**.

The **General Information** section displays information about the Participant, the study, the site, and the Participant status.

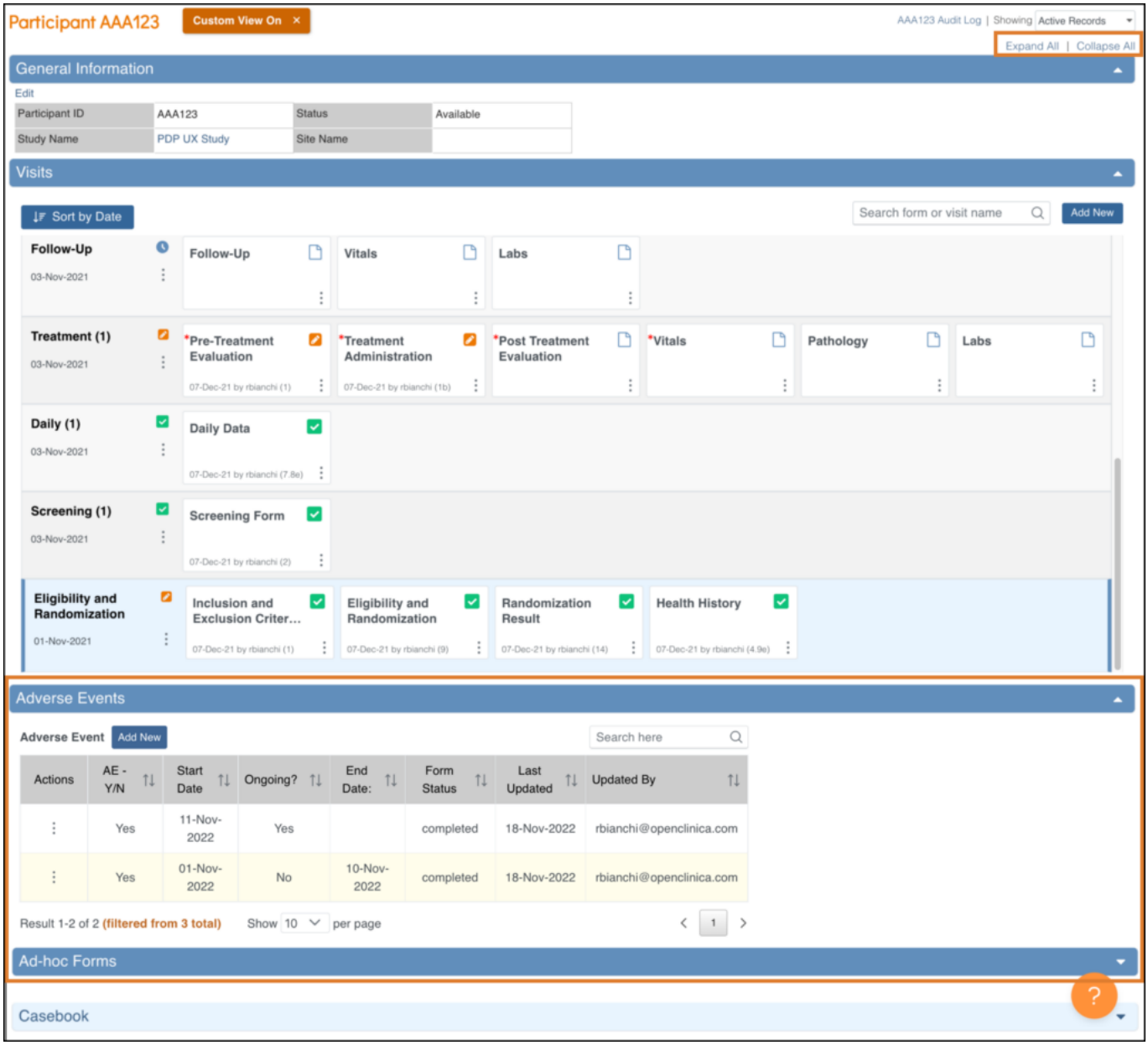
Common Events collect data that is not necessarily related to a specific visit, but may occur between visits (e.g., adverse events, concomitant medications, or early termination). When you view the **Participant Details** screen, all **Visit-Based Events** are listed first, followed by the **Common Events**.

The **Participant Details Page** includes **Visit-based Events** and related forms followed by any common events and related forms.

The page initially opens with the **Visit-Based Events** displayed and all **Common Events** collapsed.

To Expand the Common Events Section:

Click the **Expand All** link to expand all sections including **Common Events** or click an individual common event section to expand only that section.

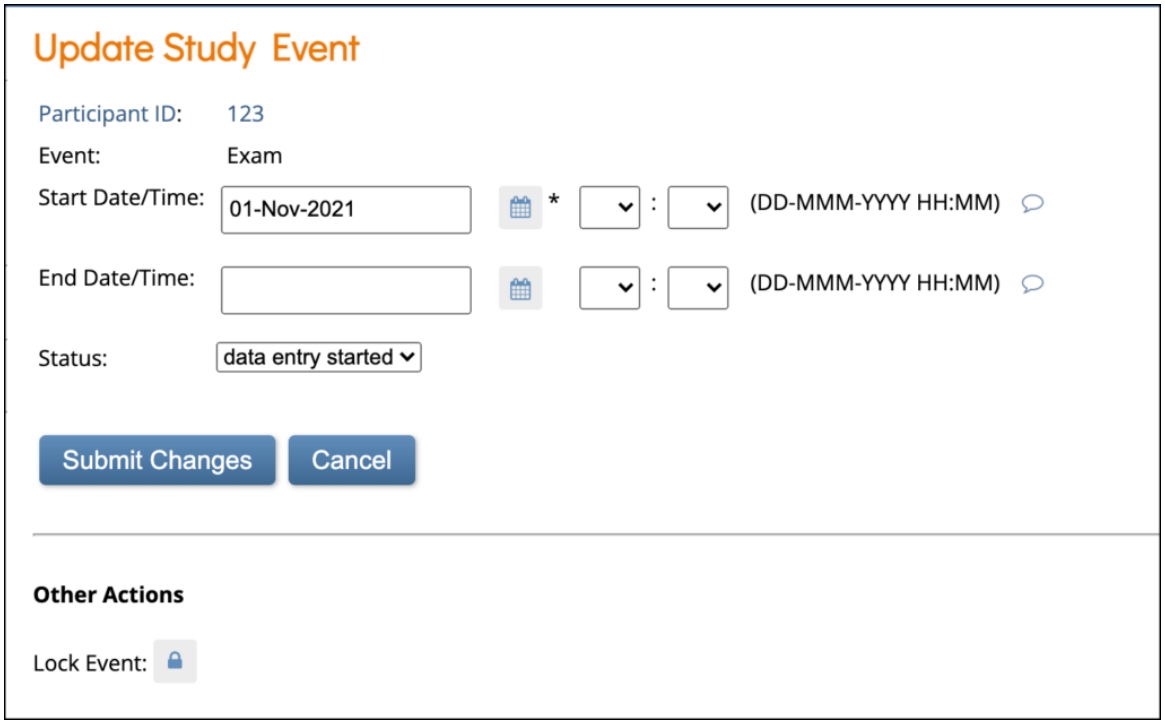


The Update Event Screen

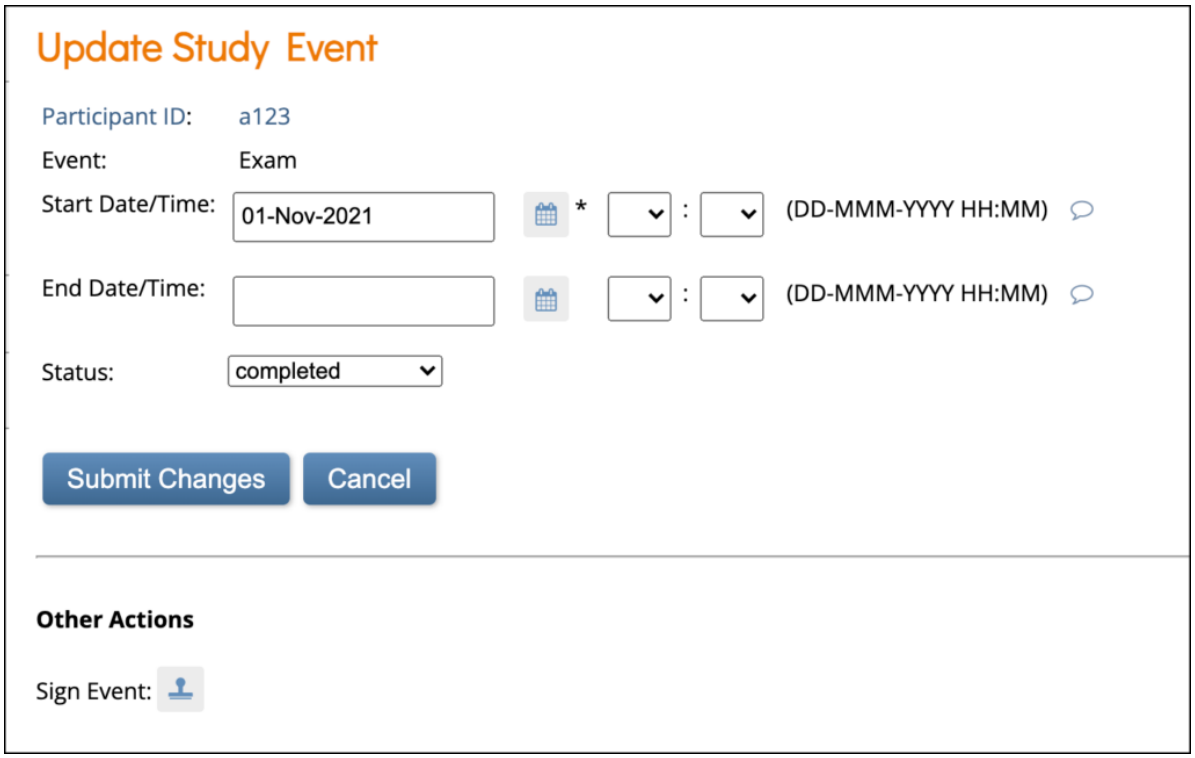
To update an Event status from the **Participant Details** screen, click the three-dot menu on the event and select **Edit**.

Available statuses are **Data Entry Started**, **Completed**, **Stopped**, and **Skipped**.

If you are a Data Manager or Administrator, you can click the **Lock Event** button at the bottom of the screen to lock the Event.



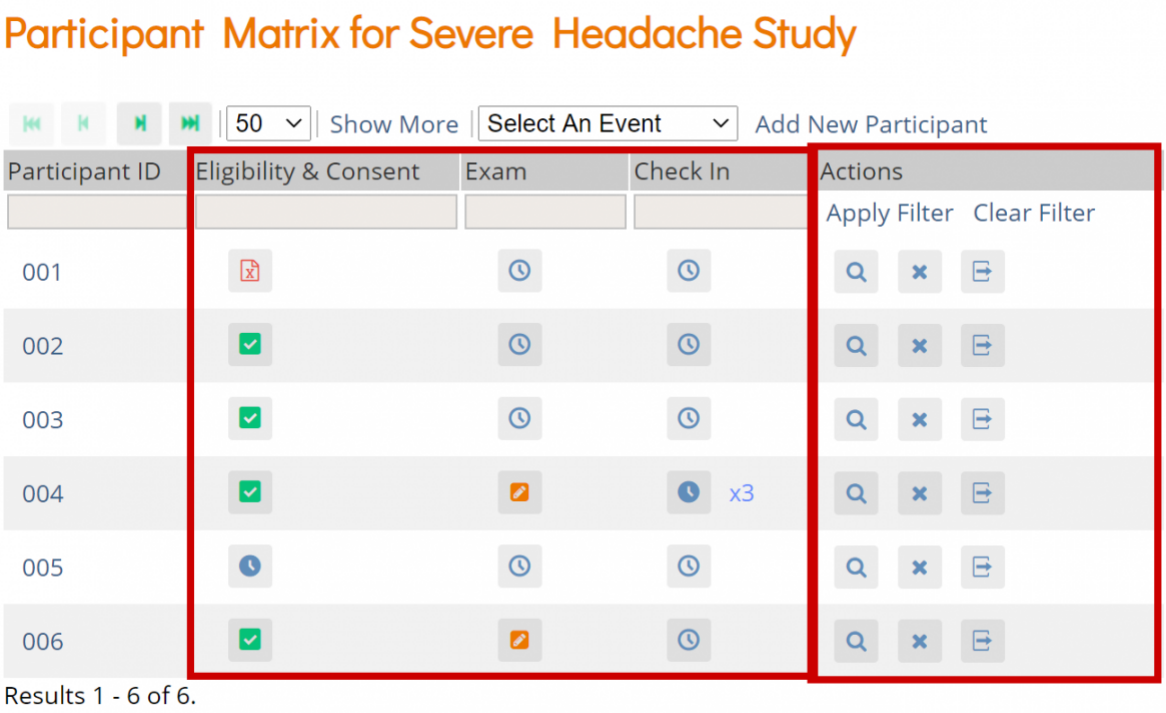
If you are an Investigator or Data Specialist, you can click the **Sign Event** button to sign. You cannot remove an Event from this screen.



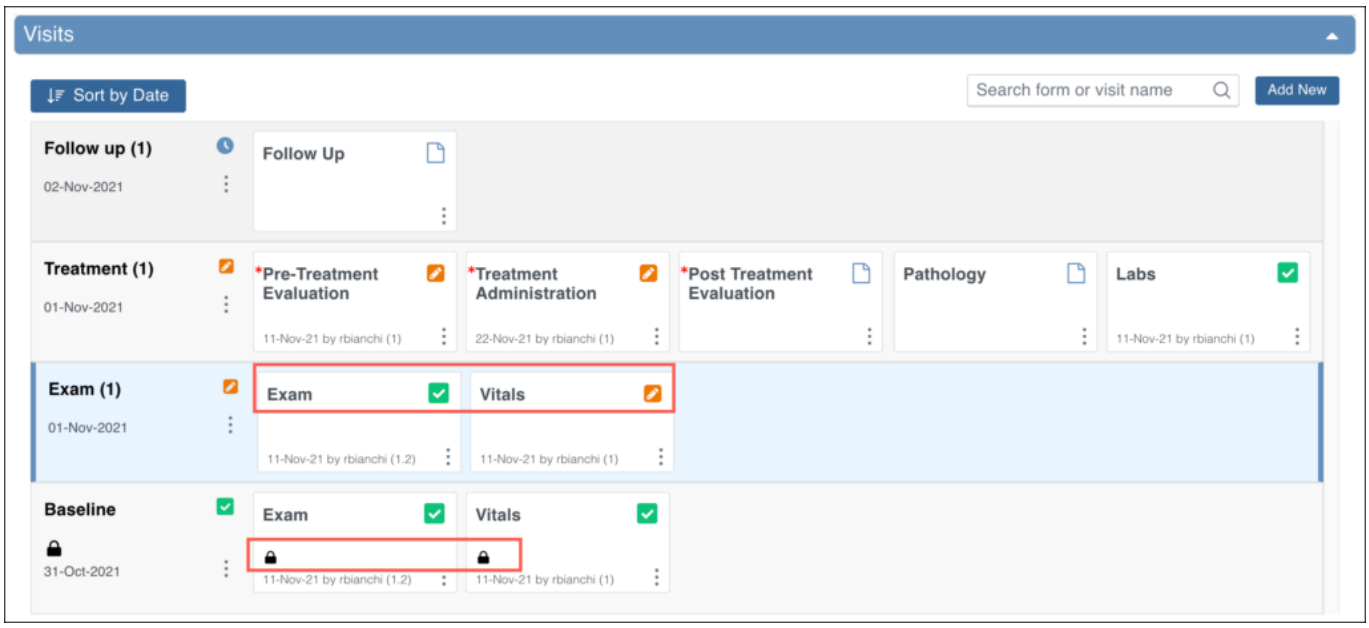
Event and Form Statuses/Actions

Events appear on the **Participant Matrix**, **Participant Details** screen, and many other screens throughout Study Runner. If you click on the Event on the **Participant Matrix**, you can choose from some of the actions.

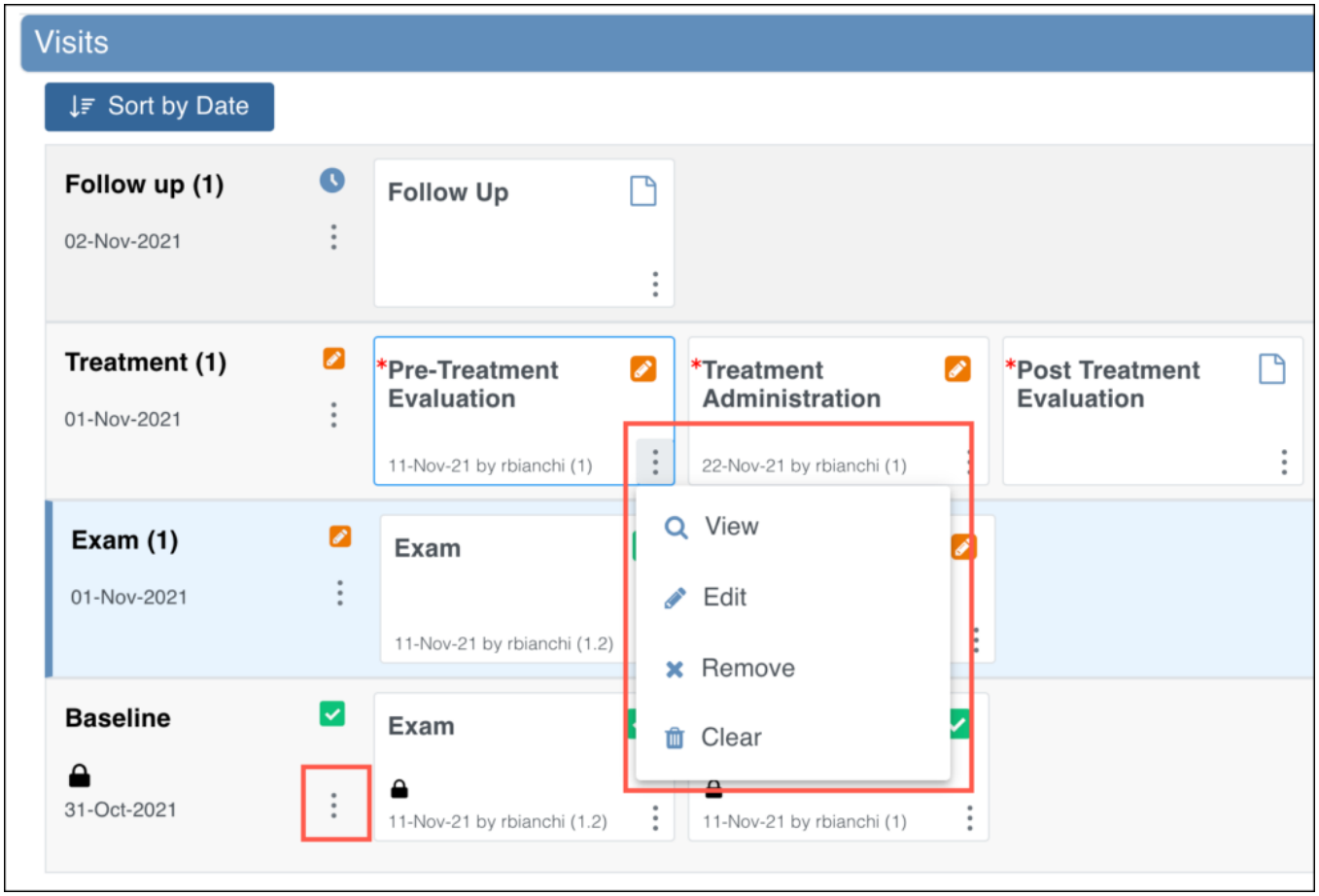
Note: If you filter Events with a status of **Not Started**, the **Participant Matrix** only includes Events that were previously started and then deleted, i.e. Events that have never been started are excluded.



Form Statuses and **Attributes** do not appear on the **Participant Matrix**, but do appear on the **Participant Details** screen, and many other screens throughout Study Runner.

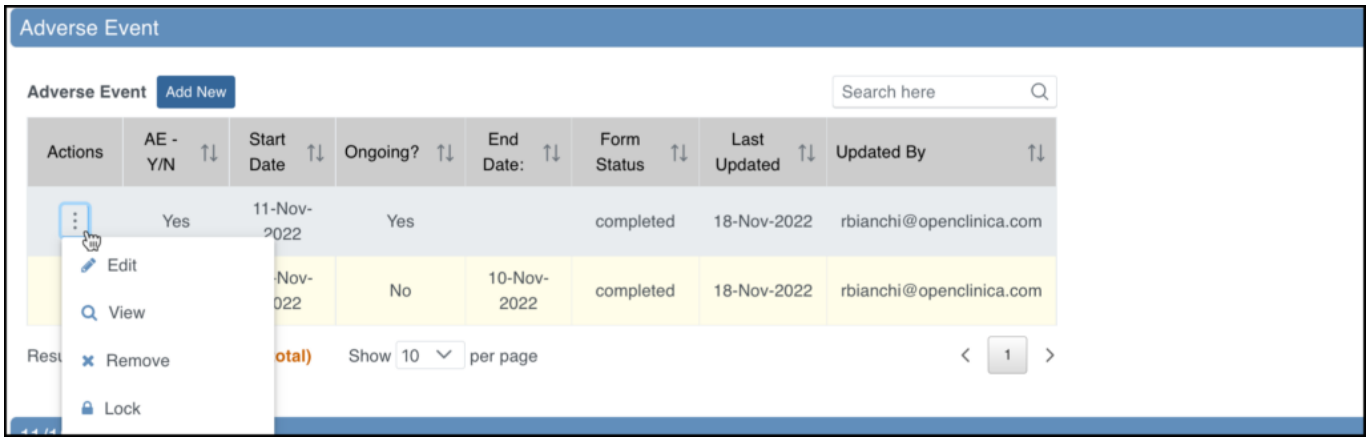


Use the three-dot **Actions** menu to view all available actions for the Events and Forms.



Alternatively, hover over the form card to view the default action for the form and click the form card to take the default action. The default action is based off of your role and the status of the form.

For **Common Events** on the **Participant Details screen**, the Independent Attributes appear in the **Form Status** column. **Actions** are available within the menu in the first column in the table.



The form that was opened most recently is indicated by the yellow background.

Below are tables that display the statuses and actions you can take on Events and Forms. Below the tables are instructions on how to perform each action.

Event Statuses

[table id=20 /]

Event Attributes

[table id=21 /]

Event Actions

[table id=22 /]

Form Statuses

[table id=52 /]

Form Attributes

[table id=53 /] A red asterisk (*) on a form card indicates that the form is required.

Form Actions

[table id=54 /]

Events

To View an Event:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

Edit an Event:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

To Lock an Event:

If you are a Data Manager you can lock an Event so that no Form data can be entered or edited and Forms cannot be removed, restored, or cleared.

Click the **Lock** button in the **three dots** menu on the **Participant Details** screen.

or

Click the **Edit** button in the **three dots** menu on the **Participant Details** screen. On the **Update Study Event** screen, click the **Lock** button under **Other Actions**.

To Sign an Event:

If you are an Investigator or Data Specialist, you can sign an Event to indicate that all Forms have been reviewed and approved.

Events must have a status of **completed**, **stopped**, or **skipped** before they can be signed. The Event cannot have been archived or removed. To sign a participant event, first review the data captured in the event, then change the status to **signed**.

Click the **Sign** button in the **three dots** menu on the **Participant Details** screen.

or

Click the **Edit** button in the **three dots** menu on the **Participant Details** screen. On the **Update Study Event** screen, click the **Sign** button under **Other Actions**.

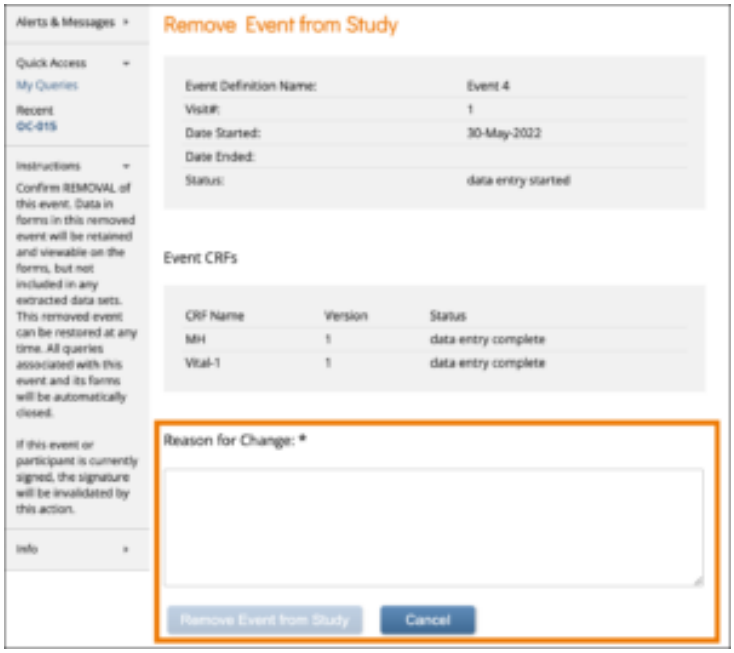
Note: *If an Event is signed, changes to an item in a Form in that Event removes the signature. This also occurs if an Event status is changed from completed, stopped, skipped or* ***Not Scheduled*** *after being signed. In addition, this changes the Participant Status from* ***signed*** *to* ***available*** *and the Event Status to* ***completed****.* Archiving/unarchiving or removing a form will unsign the Event. The exception is that when archiving/unarchiving, a form with a status of **Not Started** will not be unsigned.

Multiple users can sign an Event, so even if an Event has already been signed, the **Sign** action will still be available. If there are multiple signatures, the most recent one appears on the Form, and the others appear in the Audit Log.

To Remove an Event:

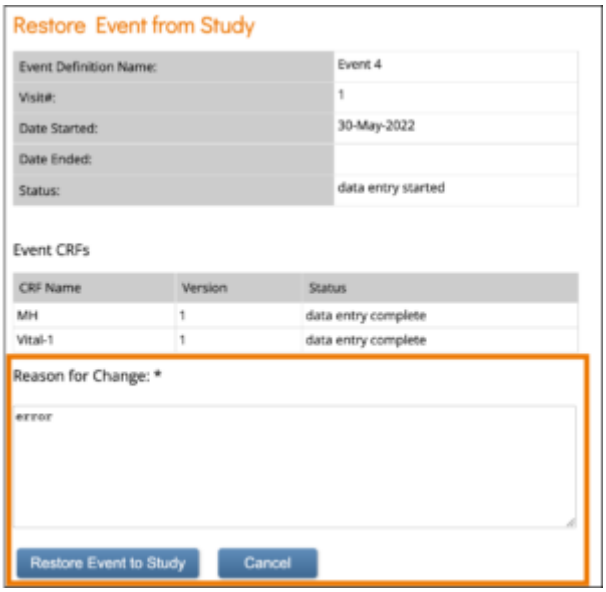
Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Remove Event from Study**.

Note: If an Event is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.



To Restore an Event:

If you have removed an Event you want to restore, click the **Restore** button in the three dot **Event Actions** menu on the **Participant Details** screen. Enter a Reason for Change and click Restore Event to Study.



Note: *If an Event is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again. When data was entered on the Form prior to the Event being removed,* ***The event this form is in has been removed*** *appears at the top of the Form.*

Forms

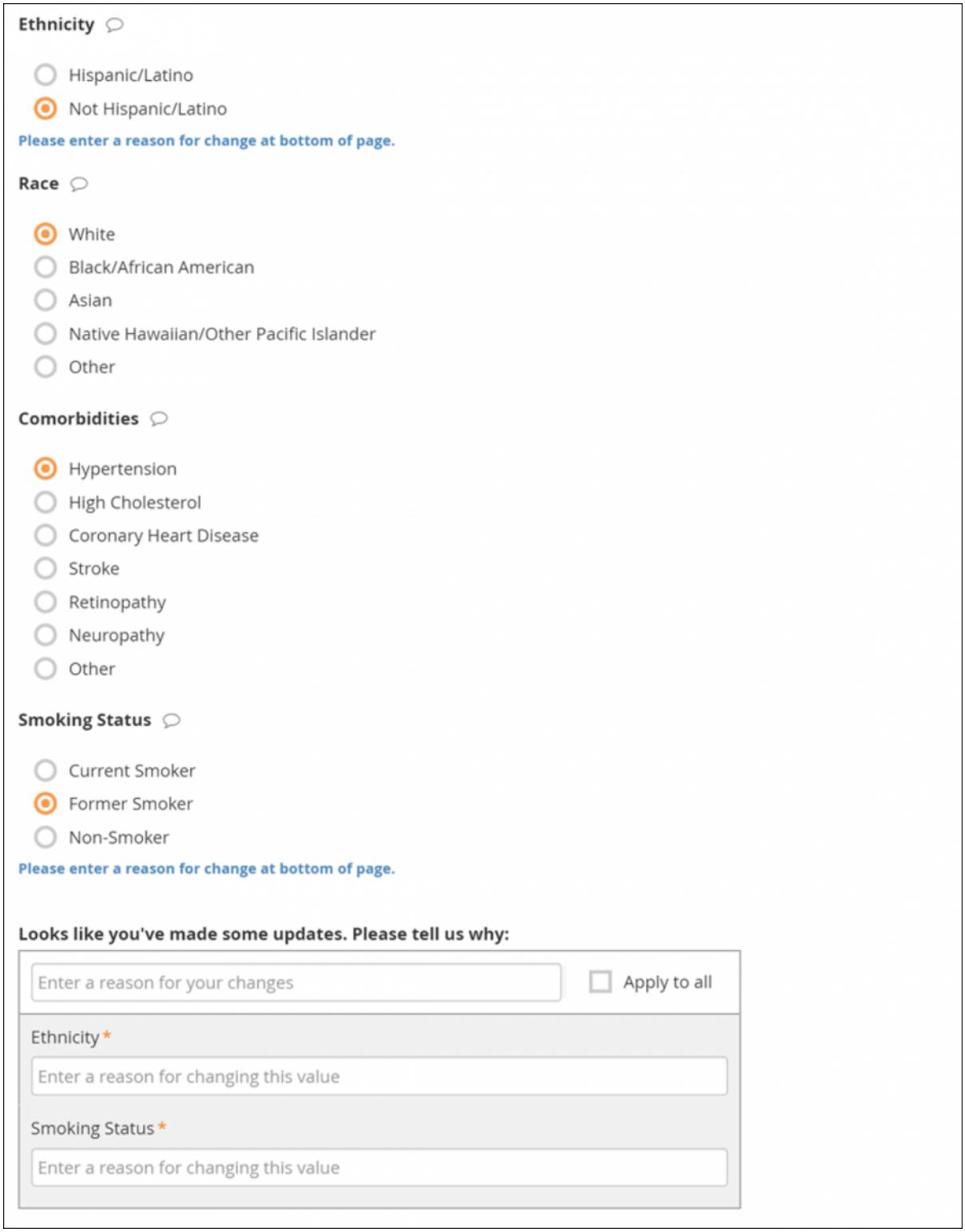
To View a Form:

Click the **View** button in the **three dots** menu on the **Participant Details** screen.

To Enter/Edit Form Data:

Click **Edit** in the **three dots** menu on the **Participant Details** screen. If you have permission to access the Form, you can start entering or editing data.

If you edit a form that has already been completed, you must enter a reason for change.

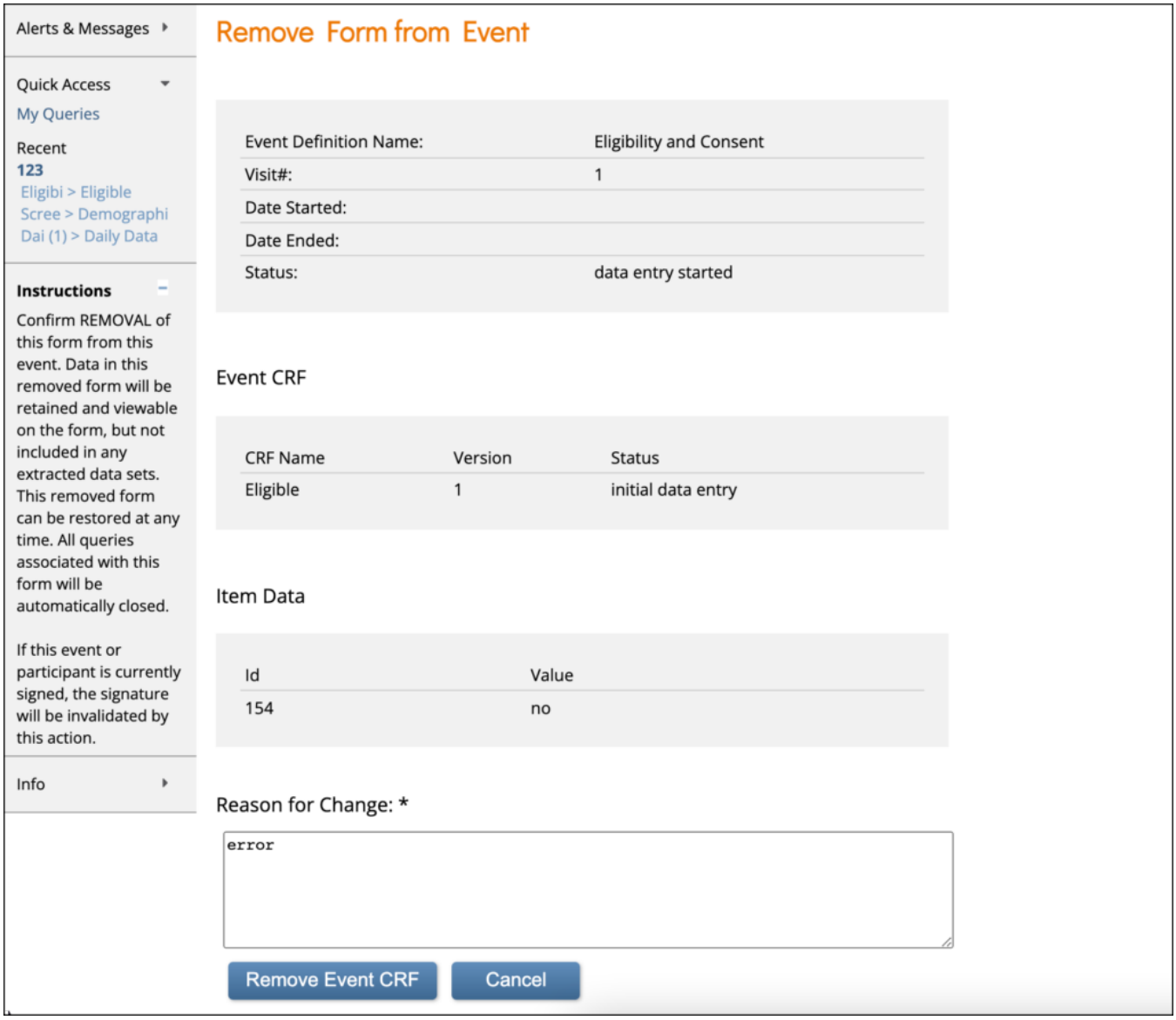


If your changes do not meet form requirements, such as constraints, you will see a message alerting you that specific values have errors and must be changed.

To Remove a Form:

Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Remove Event CRF**.

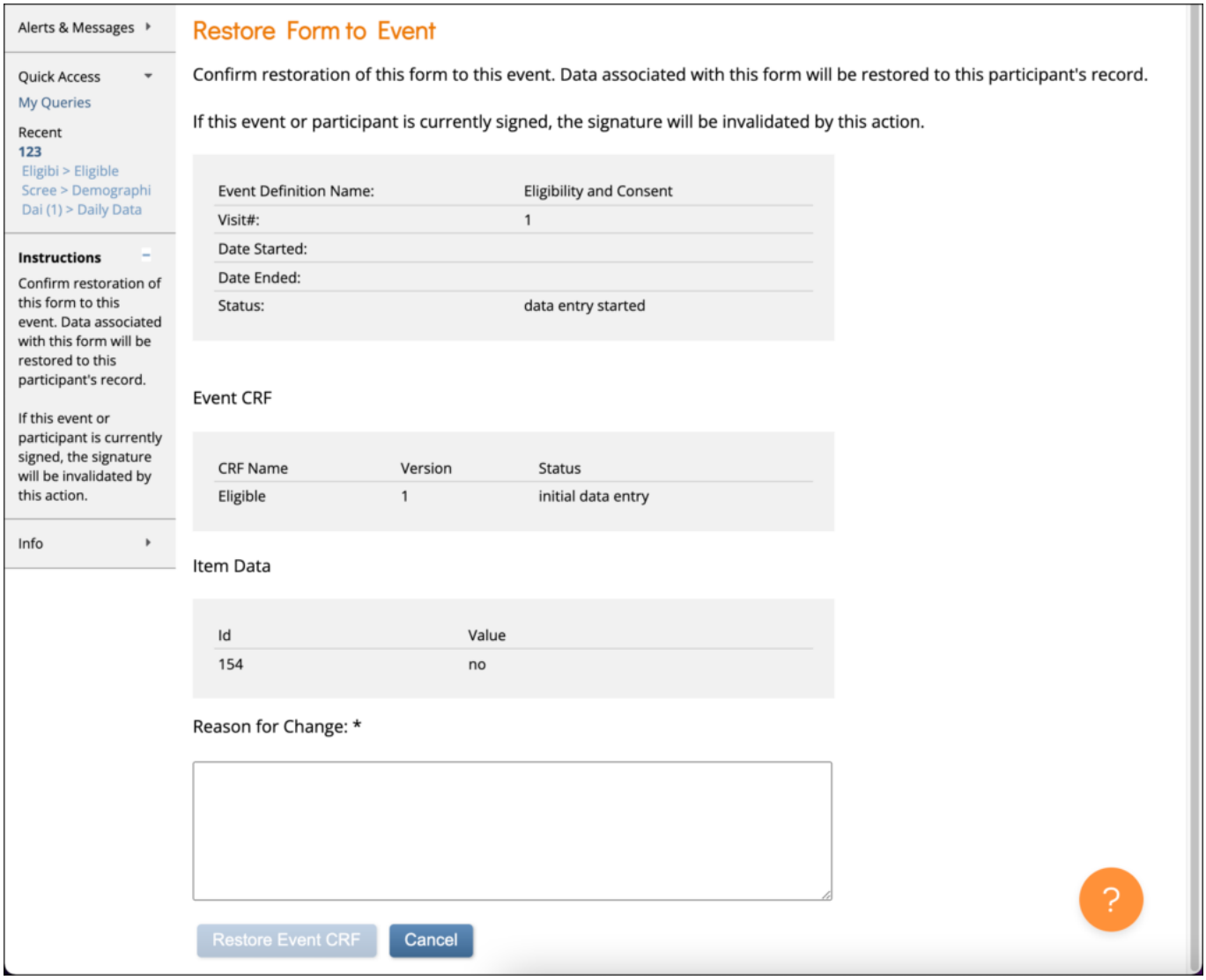
Note: *If a Form is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.*



To Restore a Form:

Click the **Restore** button in the **three dots** menu on the **Participant Details** screen. Enter a *Reason for Change* and click **Restore Event CRF**.

Note: *If a Form is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again.*



To Clear a Form:

To clear form data, click the **Clear Form** button in the **three dots** menu on the **Participant Details** screen. The system does the following:

- Clears all data from the Form
- Closes all queries associated with the Form
- Removes a signature, if present
- Sets the **Status** of the Form to **Not Started**
- Records this action in the Participants Audit Log.

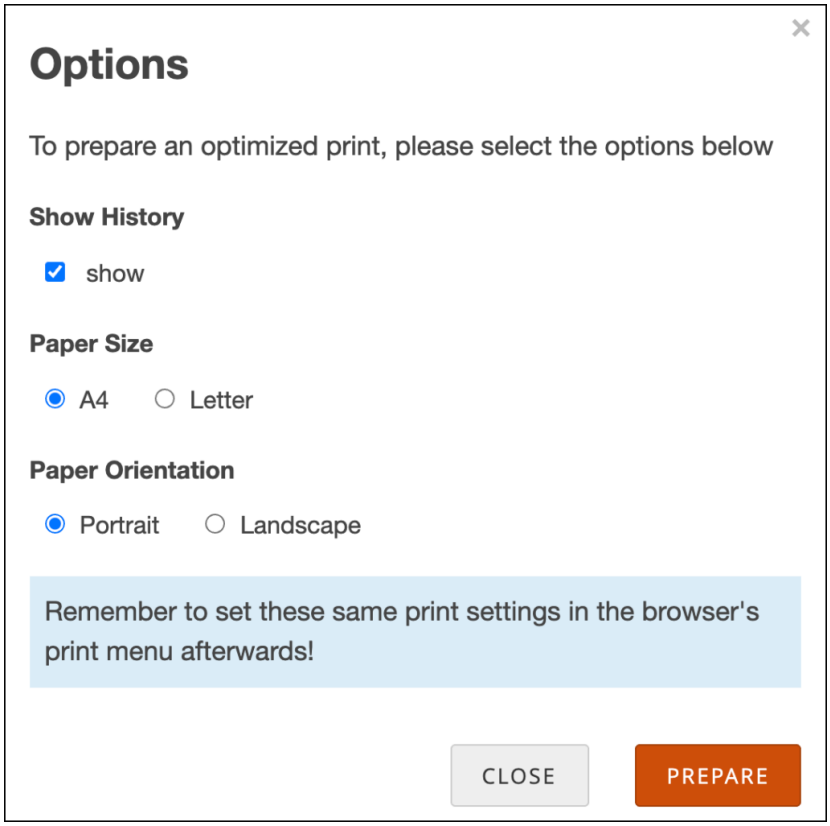
To Print a Form:

1. Click the **Print** button that appears at the top of the screen for each Form.
2. Enter information on the Options screen
    a. (Optional) Check the checkbox next to **Show** to include Query and Edit History on the printed Form.
    b. Select a Paper Size.
    c. Select a Paper Orientation.

Note: *The **Paper Size** and **Paper Orientation** fields appear only for Forms with the **Style** of **theme-grid** and printing options must be set correctly in your browser for these settings to take*

effect.

3. Click the **Prepare** button to show a preview.
4. Click the **Print** button.



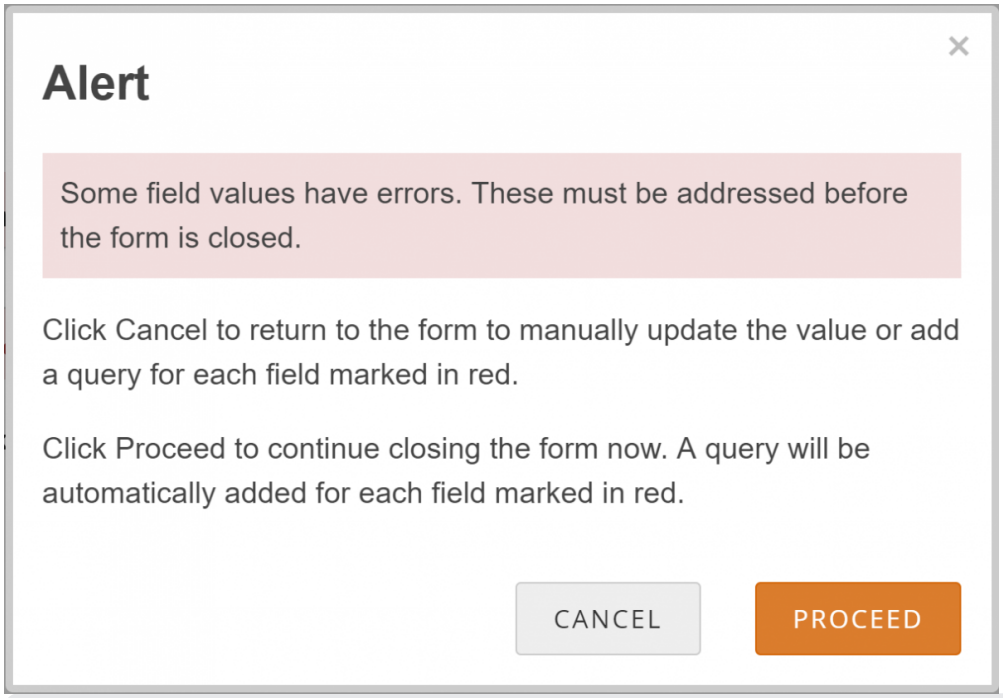
Queries

Review the Data and/or Add a Manual Query:

1. Click the **Cancel** button.
2. Review the value to make sure you entered it correctly.
3. If the value is correct, create the query that includes an appropriate message for that value. Otherwise, change the value.

Allow the System to Automatically Create a Query for the Value in Question:

1. Click the **Proceed** button.
2. The system auto-generates a query based on the default message text defined in the Form.



Approved for publication by Riley Bianchi. Signed on 2023-03-09 3:59PM

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