3.4 OpenClinica Basics

The following sections provide an introduction to basic information you'll need to use OpenClinica:

Approved for publication by Kerry Tamm. Signed on 2020-11-17 2:07PM

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

3.4.1 OpenClinica Navigation

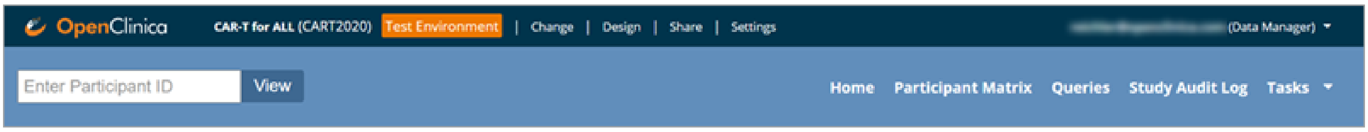
There are two main areas in OpenClinica:

- **Study Runner:** the part of the system where your studies are carried out
- **Study Build System:** where studies are configured, then published to Study Runner

Study Runner:

All users can access Study Runner, but the home screen you will see depends on your user role, as does access to certain features. Features in Study Runner include:

- The **Home** screen, which can be the **Welcome** screen, **Participant Matrix**, or **Source Data Verification** screen (depending on role)
- The **Participant Details** screen
- The **Queries** screen
- The **Study Audit Log**
- The **Tasks** menu and associated tasks
- The **User** menu
- **Quick Access** links to queries assigned to you and recently accessed Participant information

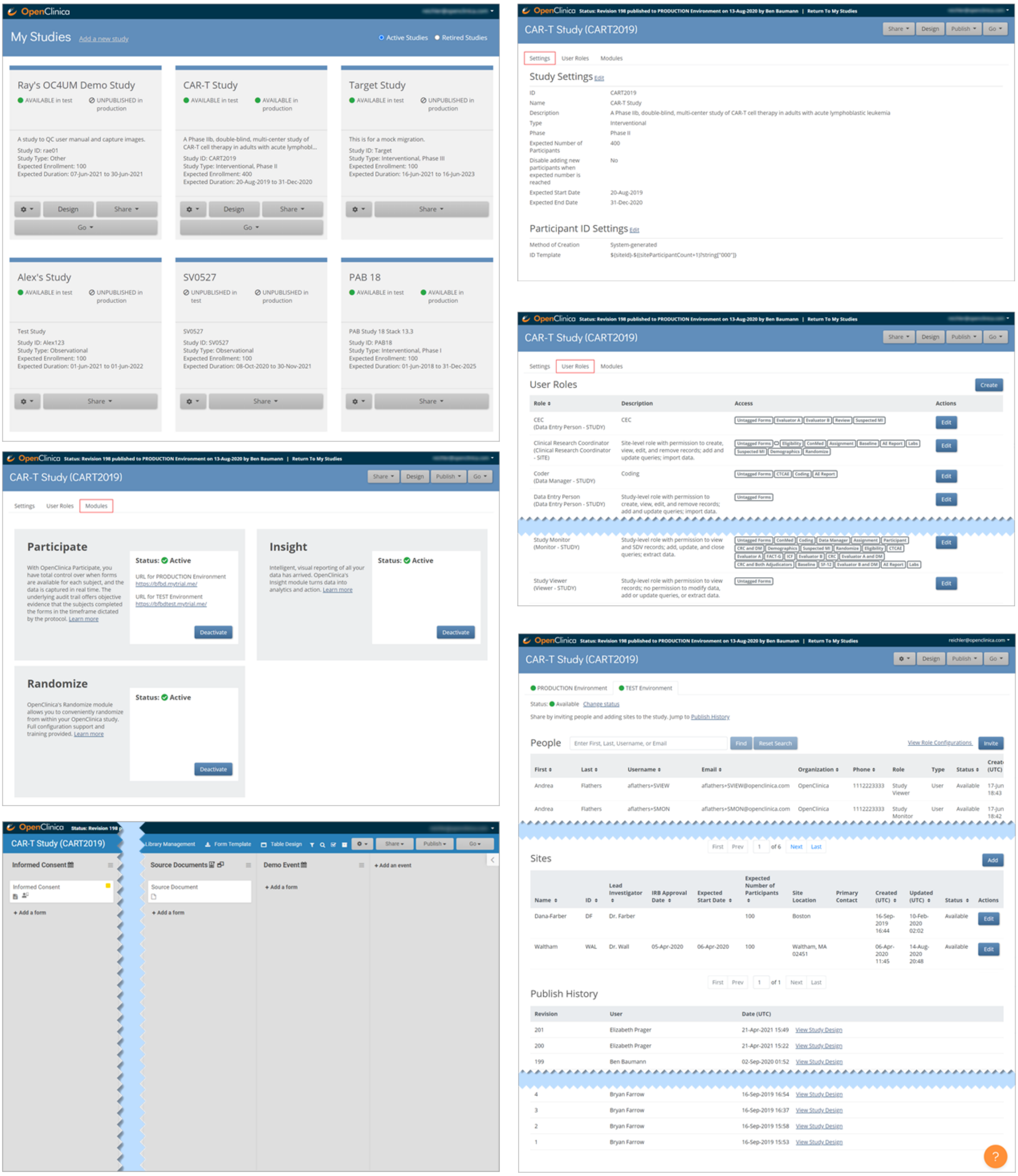


The Header Bar Displays:

- Top Row (from left to right):
  1. The Study Name and Study ID
  2. If you are in the test environment it will display a banner to the right of the study id. This space will be empty in the production environment.
  3. The **Change**, **Share**, and **Settings** buttons. (Only users who are **Data Managers** and **Administrators** see the **Design** button.)
  4. Your user id and the downward arrow that will open your user menu, the contents of which depend on your specific role.
- Second Row (from left to right):
  1. Participant ID Search/Lookup
  2. Links to menus and certain areas within Study Runner

Study Build System:

Only **Data Managers** and **Administrators** can access the **Study Build System**. This includes the following screens, which are presented in detail throughout this guide.

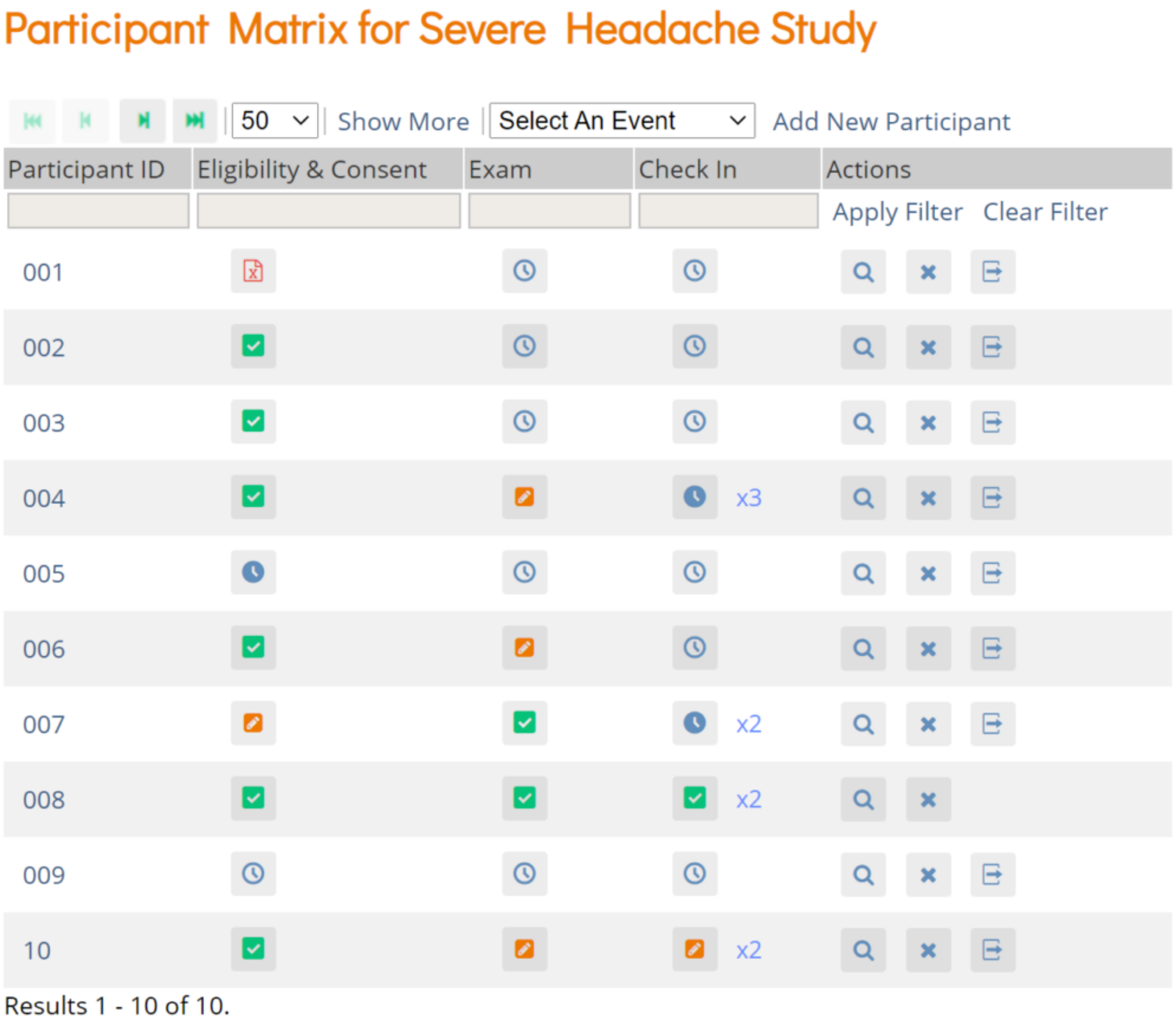


3.4.2 The Participant Matrix

The Participant Matrix displays Participants in the study. This screen is central to the system.

Use the Participant Matrix to:

- Manage Participants:
    - Edit Participant Data
    - Add a Participant
    - Remove a Participant
    - Restore a Participant
    - Sign a Participant Record (Investigators and Data Specialists Only)
    - Reassign a Participant to Another Site (Data Managers Only)
- Schedule Events
- View Participant Details
- View, Enter, or Edit Data (depending on access)



The **Participant Matrix** lists **Visit-Based Events** across the top of the matrix 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 Event.

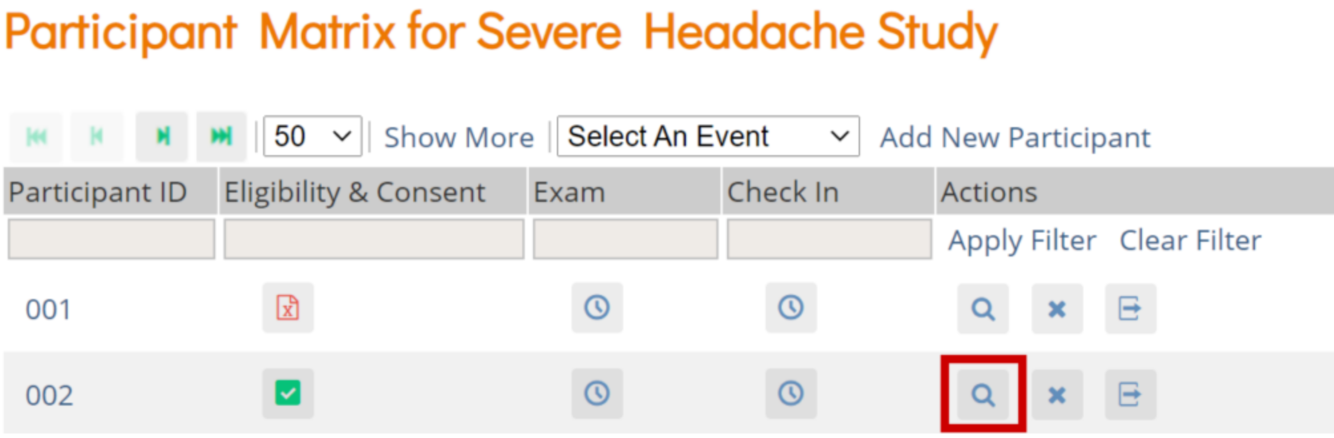
Filters

You can filter Events by the data in any column with a gray box under the header.

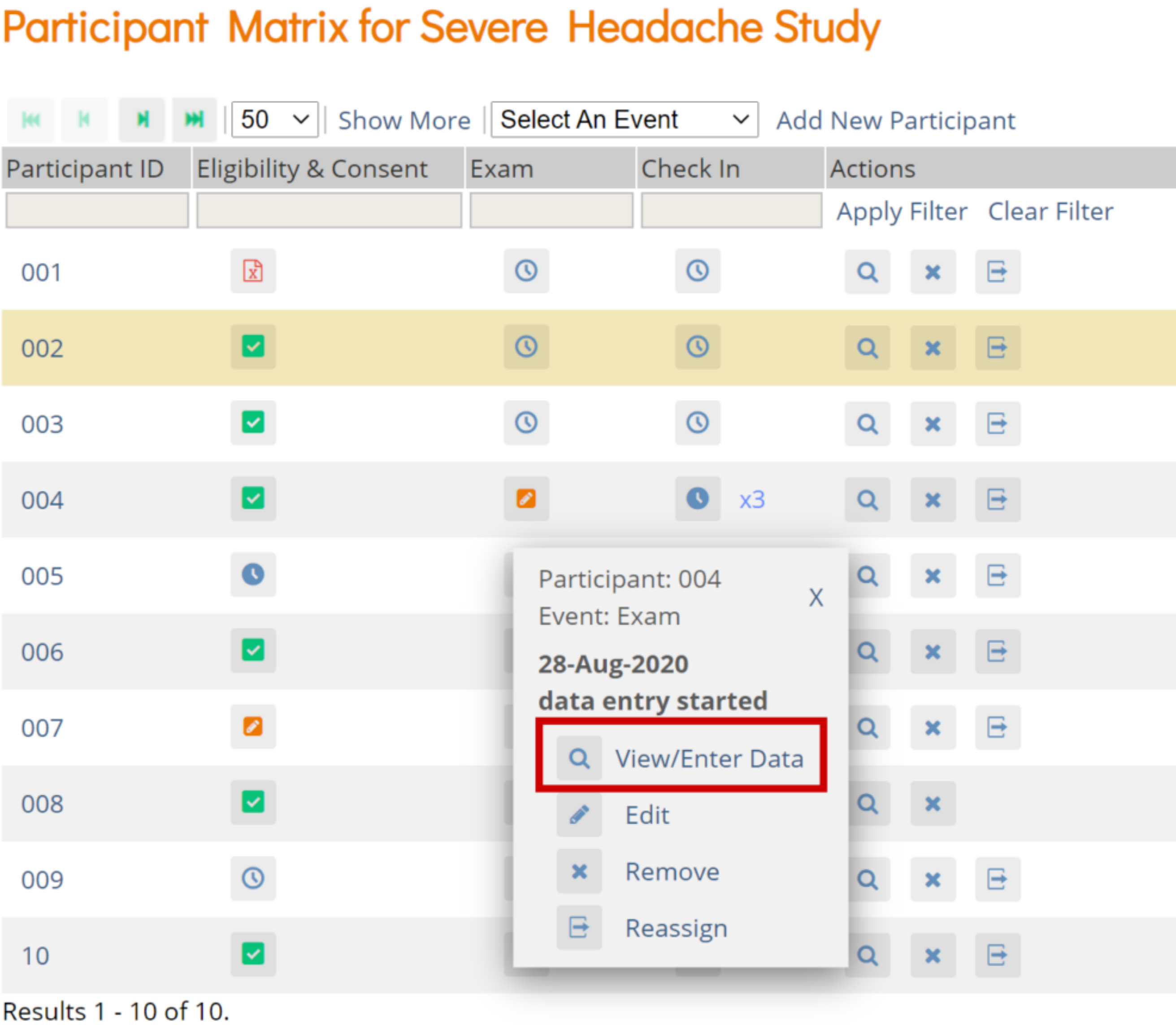
- Use the drop-down menu at the top of the **Participant Matrix** to view Participants by Event.
- Click the gray box in the **Status** column (which appears only if you click **Show More**) to view Participants by status, including the independent statuses of **Locked** and **Signed**. You can also filter Events with **Not Locked** and **Not Signed**.

View and Enter Data

Click the **View** button in the **Actions** column that corresponds to the Participant/Event to view the **Participant Details** screen.

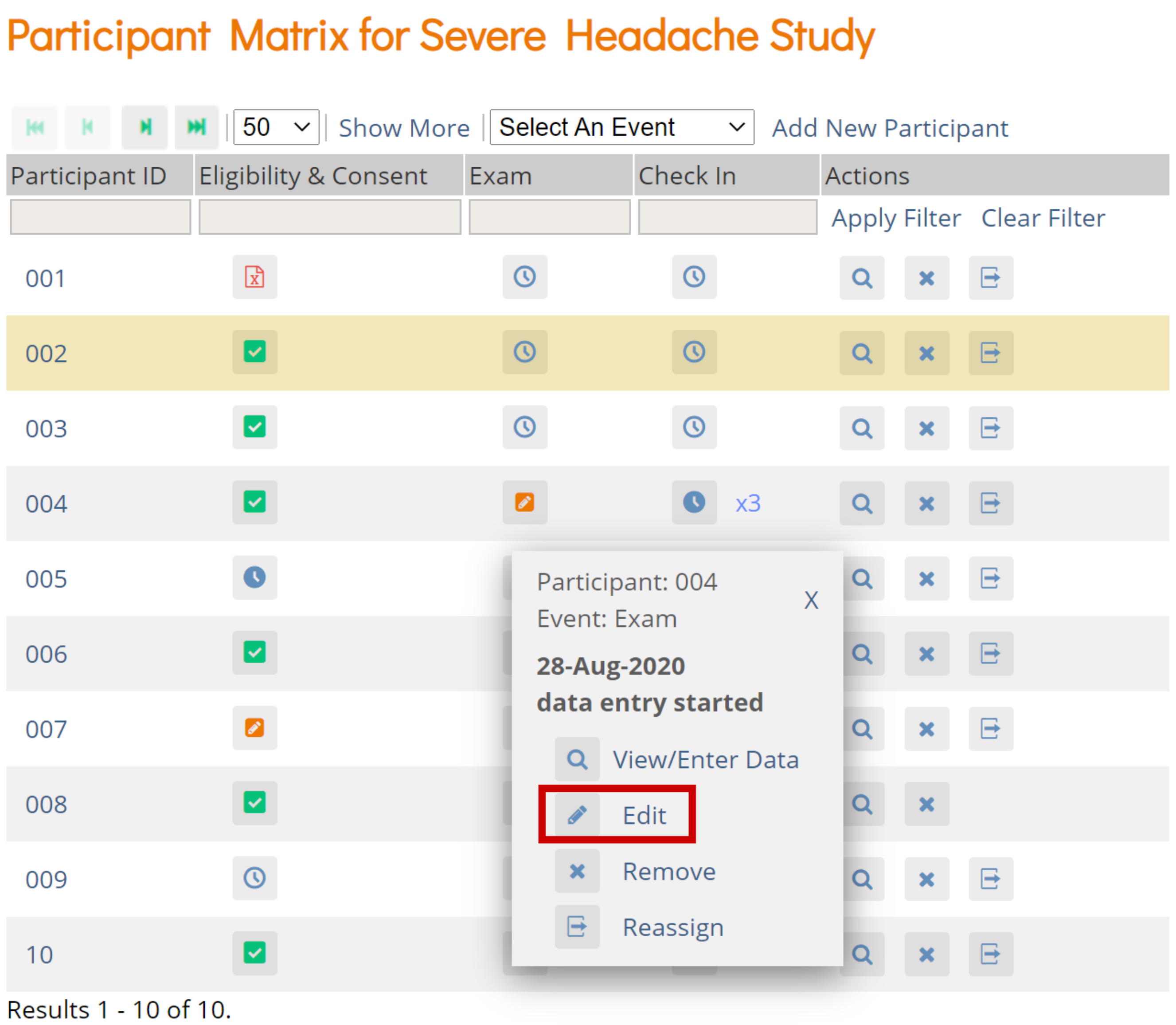


Click the icon for a **scheduled**, **data entry started**, or **completed** Event and select **View/Enter** to view the **Participant Details** screen.



Edit Event

Click the icon for a **scheduled** or **data entry started** Event to edit the **Event.**

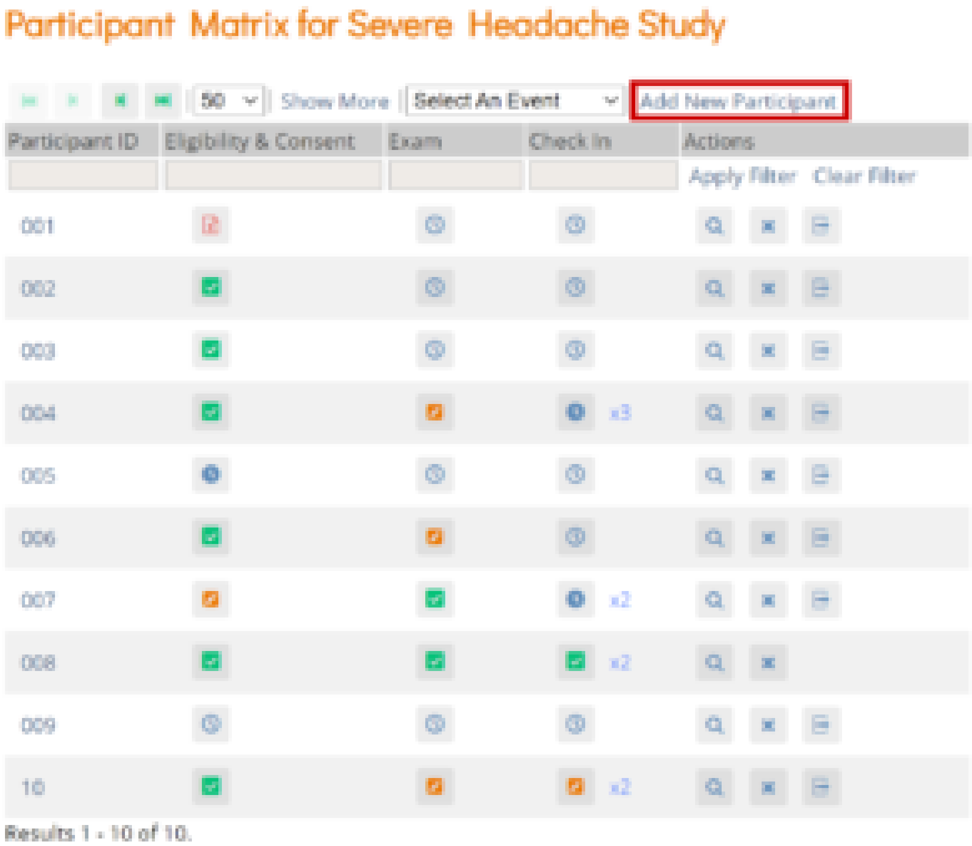


3.4.3 Adding a Participant

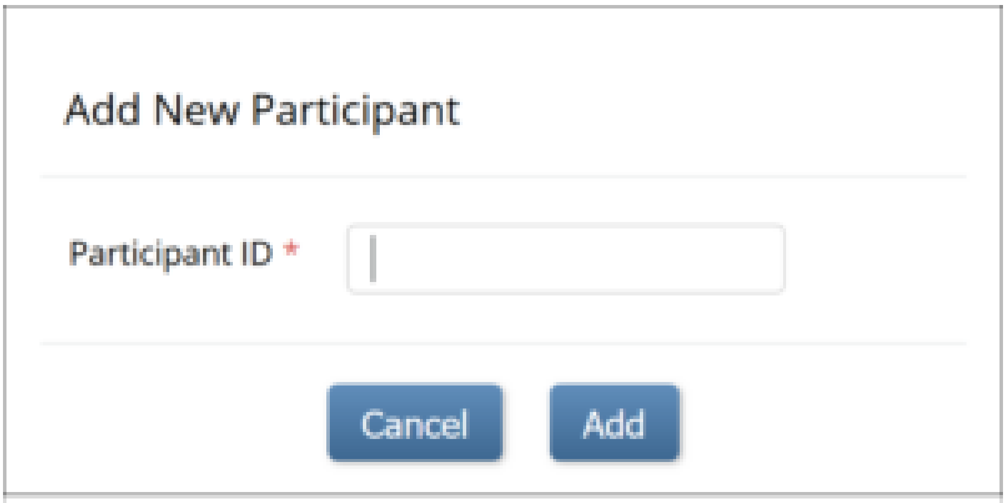
Great! Now that you've logged in, let's add a participant.

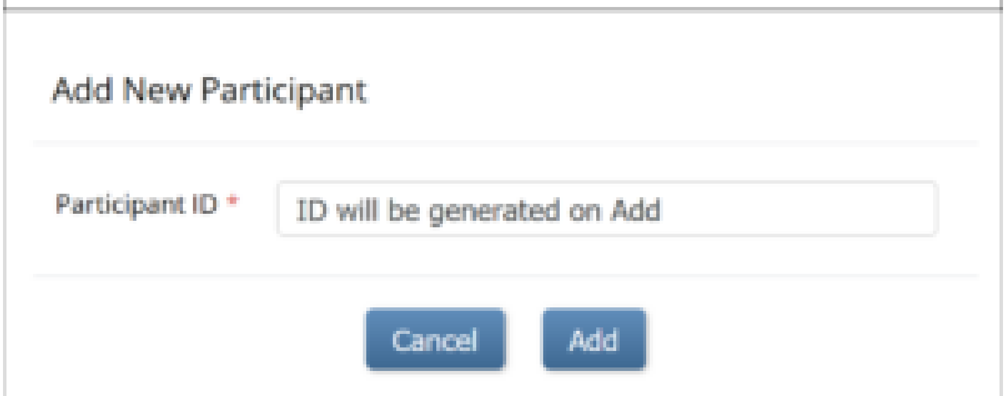
To Add a Participant:

1. On the **Participant Matrix** screen, click the **Add New Participant** link above the matrix.



2. Enter a Participant ID on the **Add New Participant** screen. (This should be a unique identifier, e.g. **001**). If your study is set to auto-generate, an ID based on a pre-defined template appears.
3. Click the **Add** button.





3.4.4 The Participant Details Screen

This screen displays the Participant's general information, Events, and Forms.

Depending on Access, you can:

- View Forms
- Enter/edit Form data
- Lock Events
- Sign Events
- Edit Events
- Add or Schedule Events
- Remove/Restore Events
- Clear Forms
- Reassign a Form to another version

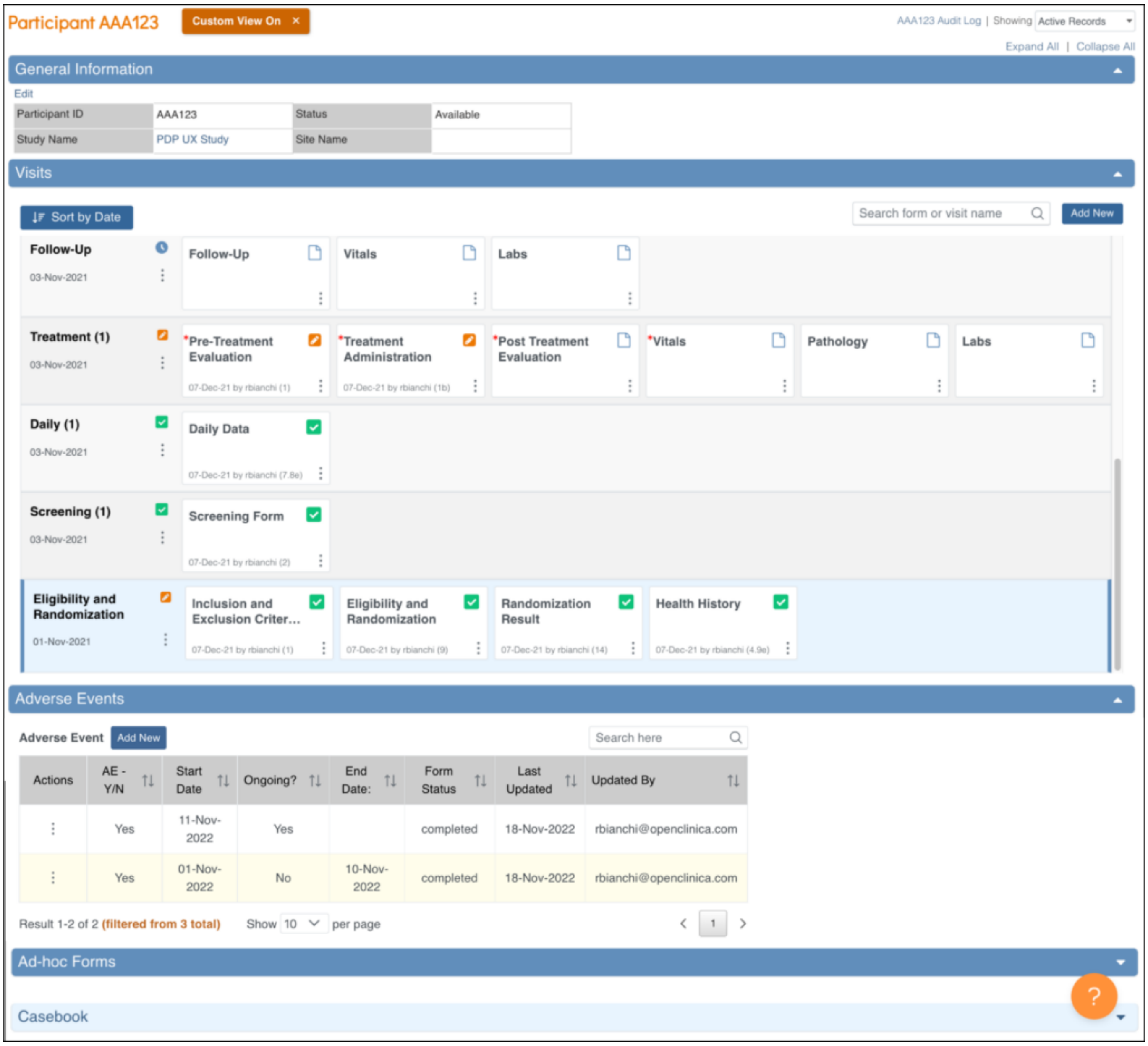
To Access the Participant Details Screen:

On the **Participant Matrix**, click on the **Participant ID** or the **View** button that corresponds to the Participant whose information you want to see.

The Participant Details Screen

The Screen is Divided Into the Following Sections:

- General Information
- Visit-Based Events
- Common Events
- Casebook (Casebook information can be found in the **Downloading Participant Casebooks** section of the **Extract Data** page)



Custom Views

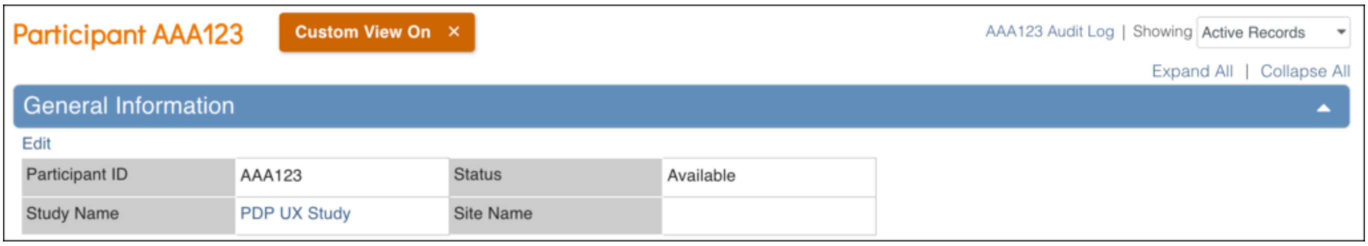
The **Participant Details** screen initially opens with the **Visit-Based Events** displayed and all **Common Events** collapsed. Click the **Expand All** link to expand all **Common Events**, or click an individual **Common Event** section to expand only that section. When you expand sections, the **Custom View On** button appears. To return the screen to its default state, click the **X** on the

Custom View On button. The **Custom View On** button will appear when you expand or collapse any section that is not part of your default view. It will also appear after changing the Showing filter or using the Search feature within Visit and/or Common events. Your custom view will remain on that participant until you update it again or go back to your default view by clicking the **X**.

The General Information Section Displays Information About:

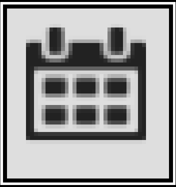
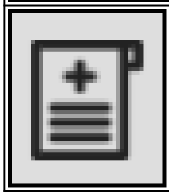
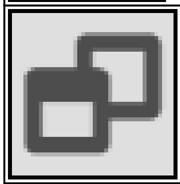
- The participant
- The study

- The site
- The participant status
- The Participate information (if Participate module is active)



3.4.5 Events

An Event is a group of Forms that are used in your Study. An Event might or might not be connected to a real-world visit.

Icon	Event Type	Description	Example(s)
	Visit	An event that is associated with a visit date. The event can be repeating or non-repeating.	Week 2 Visit (non-repeating); Monthly Follow-Up for Disease-Free Survival (repeating)
	Common	An event that is not necessarily associated with a visit date.	Early Withdrawal or Termination (non-repeating); Adverse Events (repeating)
	Repeating	An event that repeats in your study, either a known or unknown, number of times. This icon will appear adjacent to one of the previous two when an event is a repeating event.	Concomitant Medications

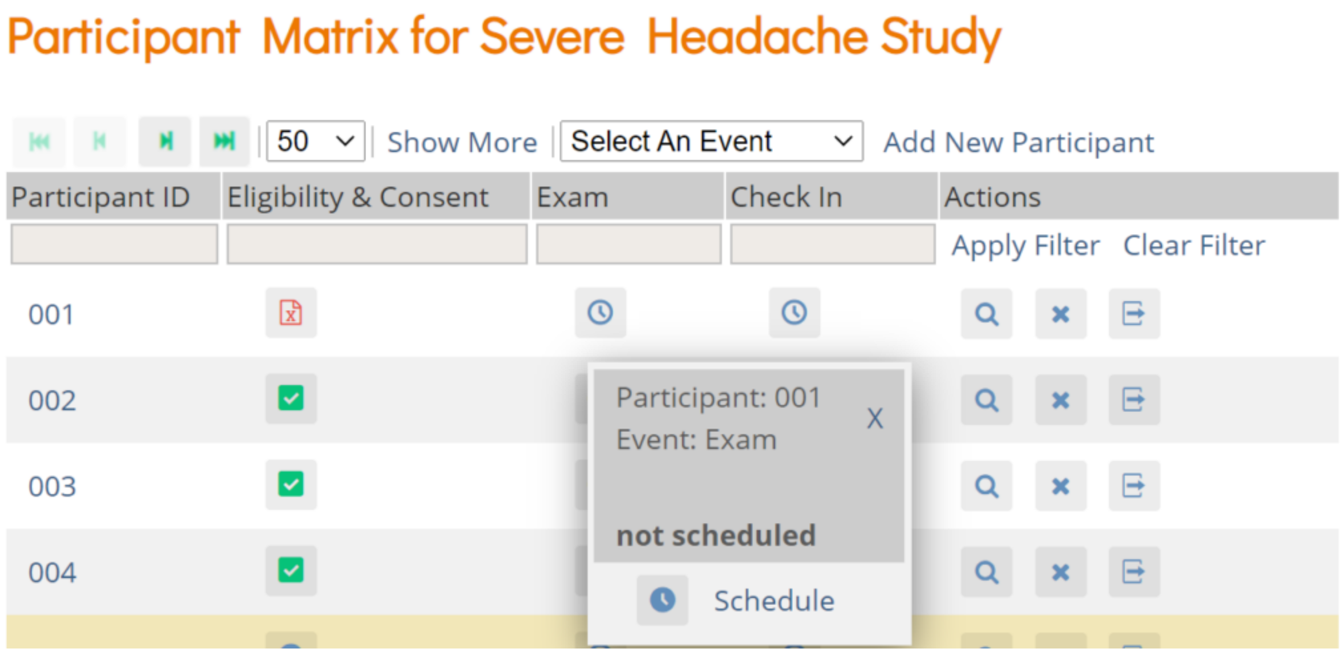
Scheduling an Event

Once a Participant has been added, you can schedule Events.

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**. The recently added visits will be highlighted with a yellow border.

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

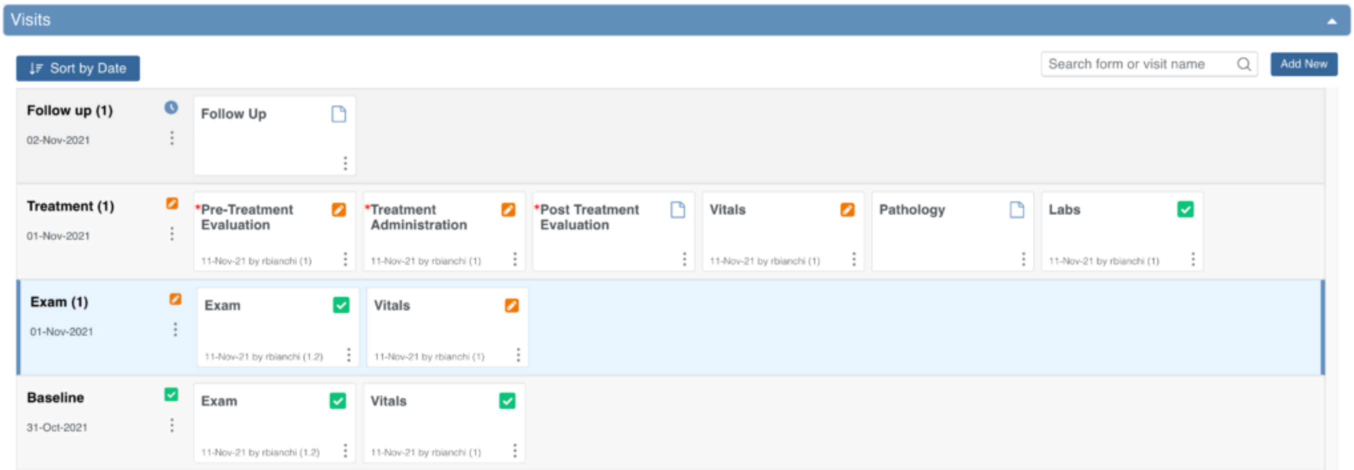
1. Click the **Tasks** button in the header bar of Study Runner.
2. Select **Schedule Event**.
3. Enter a Participant ID in the **Participant ID** field.
4. Select a **Study Event Definition** from the drop-down list.
5. (Optional) Select a **Start Date/Time**. The current date is the start date by default, 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 Schedule 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**.

Visit-Based Events

In a typical clinical trial, most Events are defined as **Visit-Based Events**, such as: Week 2, Week 6, and Monthly Follow-up, in which the Week 2 visit occurs two weeks after the baseline visit, the Week 6 visit occurs six weeks after baseline, etc. These visits are associated with a schedule that is outlined in the Study protocol, and each visit has a specific set of Forms that are collected.



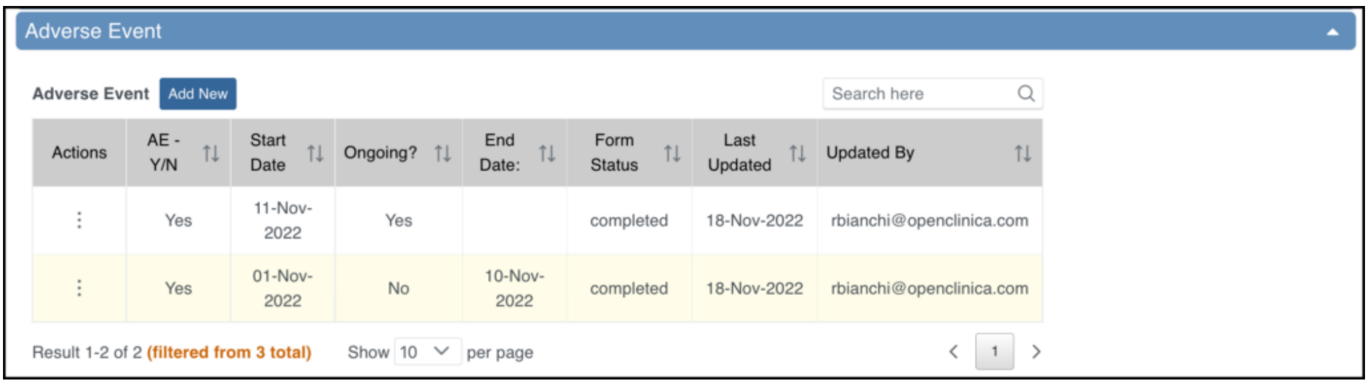
When reviewing the **Visits** section, you are taken to the earliest visit that is not yet complete (Complete, Skipped, Stopped, Removed, or Archived status), displaying with a blue background.

Common Events

However, some Events, such as **Adverse Events**, **Concomitant Medications**, or **Early Termination**, do not occur on schedule and might not be associated with a visit date. These Events should be defined as **Common**.

Common Events are used to collect information that is not necessarily related to a scheduled visit date. For example, Adverse Event (AE), Concomitant Medication (ConMed), or Early Termination forms.

Common Events can be defined as either **Repeating Events** (e.g. AEs and ConMeds, since Participants might have more than one AE or ConMed) or **Non-Repeating Events** (e.g. Early Termination, since a Participant can only terminate once).


Adverse Event

Adverse Event Add New Search here

Actions	AE - Y/N	Start Date	Ongoing?	End Date:	Form Status	Last Updated	Updated By
⋮	Yes	11-Nov-2022	Yes		completed	18-Nov-2022	rbianchi@openclinica.com
⋮	Yes	01-Nov-2022	No	10-Nov-2022	completed	18-Nov-2022	rbianchi@openclinica.com

Result 1-2 of 2 (filtered from 3 total) Show 10 per page 1

Event Statuses

The table below displays Event statuses:

Icon	Status	Description
	Not Scheduled	The Event has not been scheduled. Common Events, such as Adverse Events remain in this status throughout the study.
	Scheduled	The Event has been scheduled, but no data has been entered.
	Data Entry Started	A user has started to enter data, but not all of the Forms in the Event have a status of completed.
	Completed	A user has completed data entry for at least one Form in the Event. If further changes are needed in that Form, you are required to provide a reason for change.
	Skipped	The user has decided not to complete the Event. Any data that has been entered can still be viewed and/or exported. You can select this setting from the dropdown menu on the Update Event screen when the current status is scheduled.
	Stopped	The Participant has temporarily stopped participating in the study. You can select this status from the dropdown menu on the Update Event screen when the current status is data entry started.
	Removed	The Event has been removed. Users can still view Forms. This will supersede any of the other statuses.

Event Attributes

Event Attributes (or Independent Status Attributes) can be used in addition to Event statuses.

Icon	Status	Description
	Signed	The Event has been signed. This icon appears in addition to the status. **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.
	Archived	The Event was archived in Study Designer. This icon appears in addition to the status.
	Locked	A Data Manager locked the Event. No data can be added, and the Event cannot be removed. This icon appears in addition to the status.

Form Actions

Only **Data Managers** can use the **Reassign CRF** action, and only **Investigators** and **Data Specialists** can use the **Sign** action.

Icon	Action	Description
	Enter/Edit	Enter or edit data in the Form.
	View	View data in the Form.
	Remove	Remove the Form from the Event. This is not permanent.

	Restore	Restore a Form that was previously removed. All data is restored.
	Clear Form	Clear all data in the Form. This resets the Form to **Not Started** and closes all associated queries, but audit history is retained.
	Reassign CRF Version	Change the version of the Form if data has already been entered.

Form Statuses and Icons

The following additional Form statuses are represented by the icons indicated on the Participant Details Page:

Icon	Status	Module	Description
	SDV Verified	N/A	The form has been SDV Verified.
	SDV Required, Not Verified	N/A	The form has not yet been SDV Verified, but has at least one SDV Required item.
	SDV Status Changed Since Verified	N/A	The form was SDV Verified, but data changes require it to be verified again.
	Query	N/A	There is at least one open query on at least one item on the form.
	Consent Not Signed	eConsent	The participant has not yet signed this eConsent form.
	Consent Signed	eConsent	The participant has signed this eConsent form, but it has not yet been countersigned by a site user (CRC or Investigator).
	Consent Countersigned	eConsent	The participant has signed this eConsent form and it has been countersigned by a site user (CRC or Investigator).
	Requires Reconsent	eConsent	This eConsent form was signed by the participant (and possibly also countersigned), but a site user (CRC or Investigator) removed the consent. This might be done if a newer version of the eConsent form is being used. The participant will need to sign for consent again.

3.4.6 Viewing and Entering Data on Forms

Next, let's explore how to view and enter data.

Features

The features of OC4 data entry include the following:

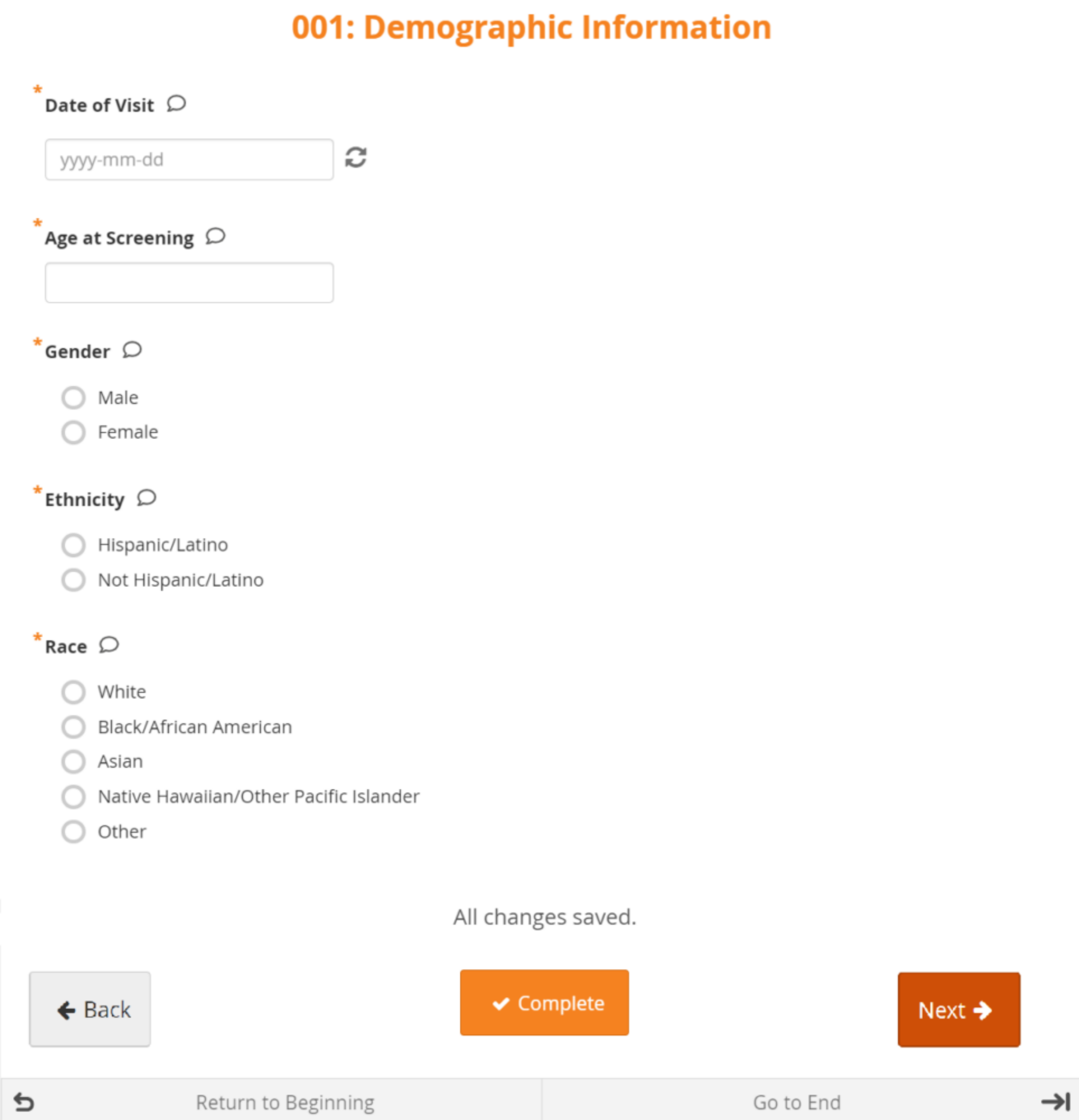
- **Participant Matrix:** Easily see the data entry status of participants.
- **Auto-save:** Automatically save during data entry.
- **Conditional field display:** Only see relevant fields during data entry.
- **Automatic calculations and edit checks:** Automatically use calculations and checks.
- **Queries:**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

Forms

Forms are a collection of data entry fields for an Event or multiple Events. For example, the **First Visit** Event might contain the **Eligibility**, **Consent**, and **Demographics** Forms.

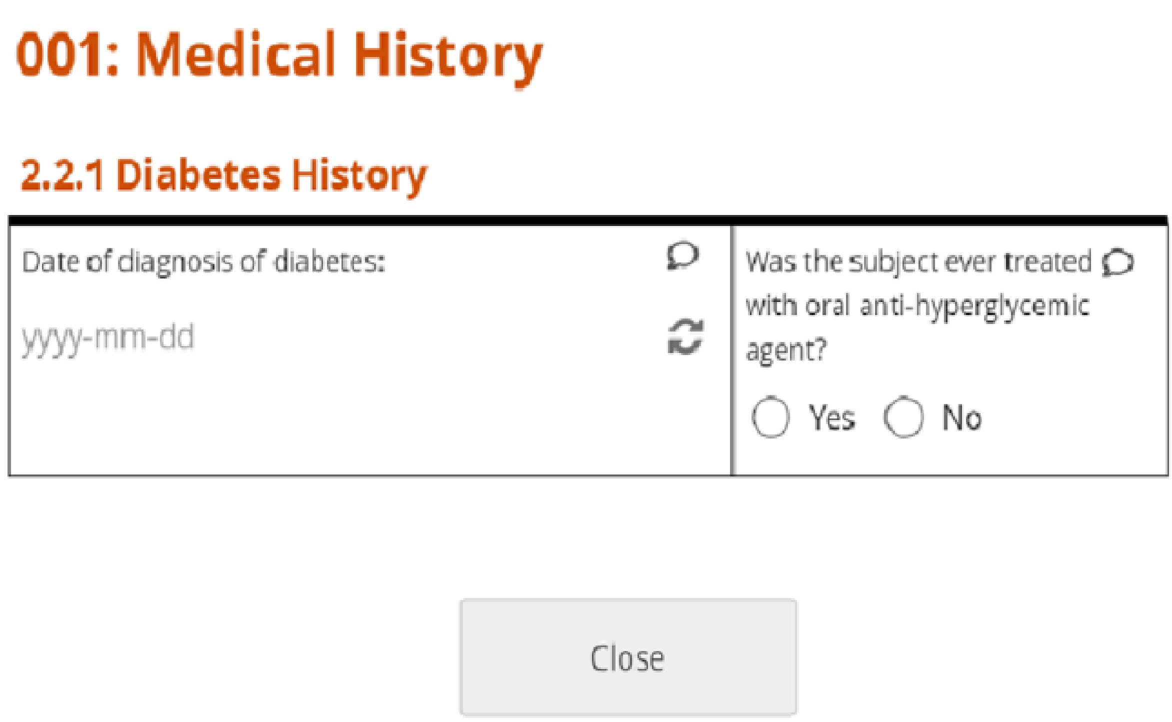
Types

There are different types of fields, such as: **select one**, **select multiple**, **integer**, **date**, **image**, etc. Note that **All changes saved** appears at the bottom of the Form because all changes are saved automatically.



Layout

Forms can be simple (with one question per row) or grid (with one or multiple questions per box).


001: Medical History
2.2.1 Diabetes History
Date of diagnosis of diabetes:
yyyy-mm-dd
Was the subject ever treated with oral anti-hyperglycemic agent?
Yes
No
Close

Grid


001: Medical History
2.2.1 Diabetes History
Date of diagnosis of diabetes:
yyyy-mm-dd
Close
Next

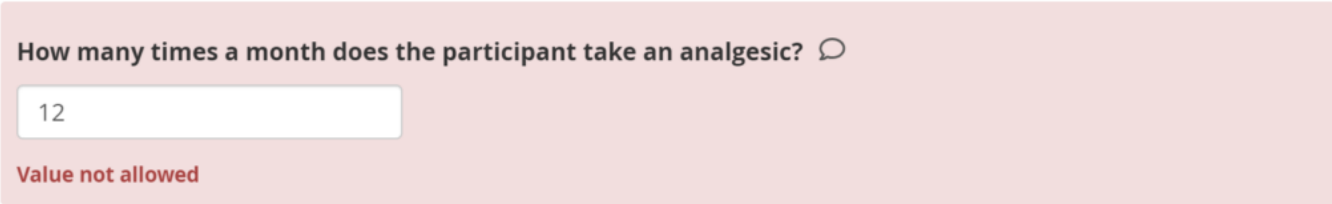
Simple

Conditional Fields

Some fields only appear if you enter a specific response in another field. For example, if the response to **Do you smoke?** is **No**, no related fields appear. If the response to **Do you smoke?** is **Yes**, other fields such as **Packs per day** might appear.

Edit Checks

If you enter a value that is invalid due to a constraint or do not respond to a required field, a message appears on the Form.



Closing or Marking a Form Complete

When you are finished entering data, you can close a Form and continue to enter data later or mark the Form **Complete**.

Before You Enter Data

1. Add a Participant
2. Schedule an Event

Entering Data

To Enter Data Directly into Visit Event Forms:

1. On the **Participant Details** screen, click the Form Card to open the form in its default mode or click the Actions menu (three dot menu in the lower right corner of the Form Card) to select from the available actions on the form.
    a. The default mode for the Form Card will be based on the highest access mode available.
        i. If the form is editable and you have edit permission for the form, the form will open in Edit mode. However, if the form is Completed, it will default to open in Review-only mode, but can still be opened in Edit mode by using the Actions menu.
        ii. If you do not have edit permission, it will open in Review-only mode if you have query editing access, or read-only mode if you do not.
2. Enter information into each field and Submit when ready.

Enter Data Directly into Common Event Forms:

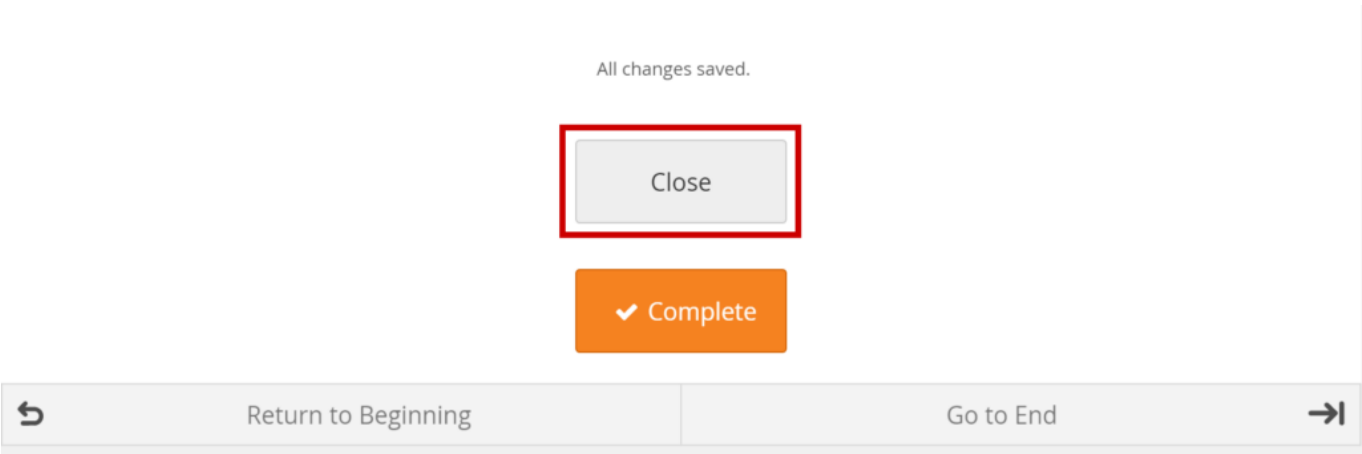
1. On the **Participant Details** screen, click the Common Event header to expand it.
2. Click the **Add New** button.
    a. Or, to enter data in an existing Form, click the menu in the Actions column and select **Edit**.
3. Enter information into each field.

To Continue to the Next Page or Back to the Previous Page of the Form:

Click the **Next** button to proceed on the Form, and click the **Back** button to return to the previous page of the Form.

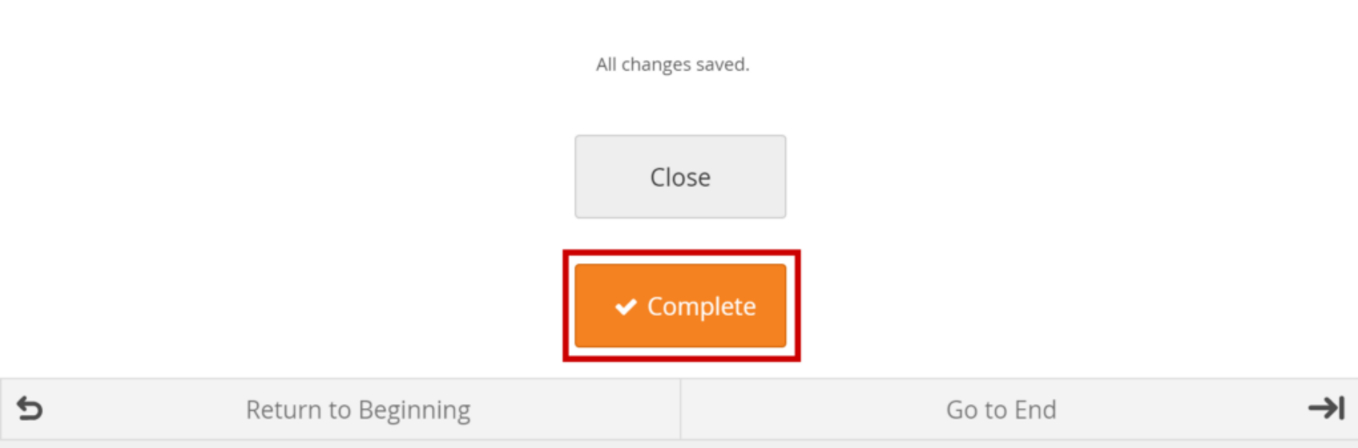
To Close the Form and Continue Data Entry Later:

Click the **Close** button.



Mark Data Entry Complete:

Click the **Complete** button.



Queries

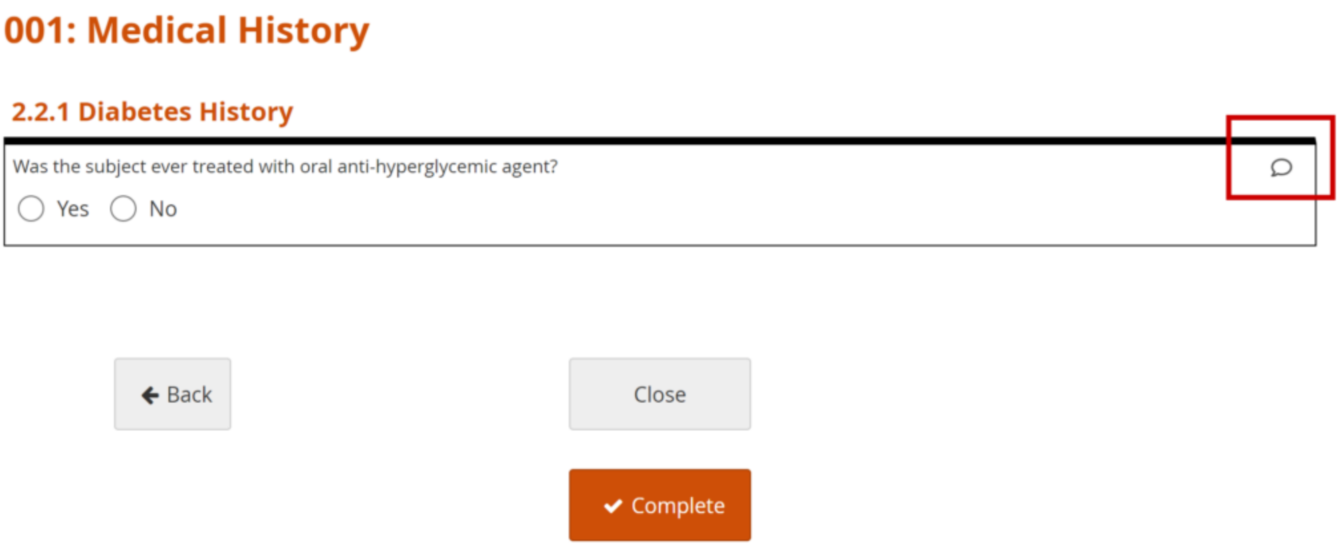
Queries are inquiries or alerts about data that needs to be reviewed.

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

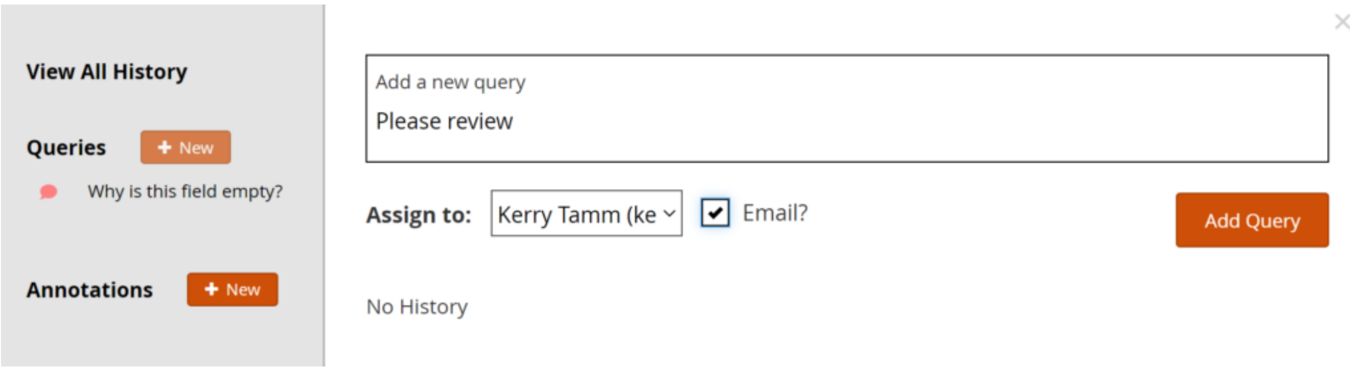
Another user can respond to it and/or change the response in the field. Only **Data Managers** and **Monitors** can close queries.

Add a Manual Query:

1. Click on the **Query Bubble** next to the field you want to inquire about.

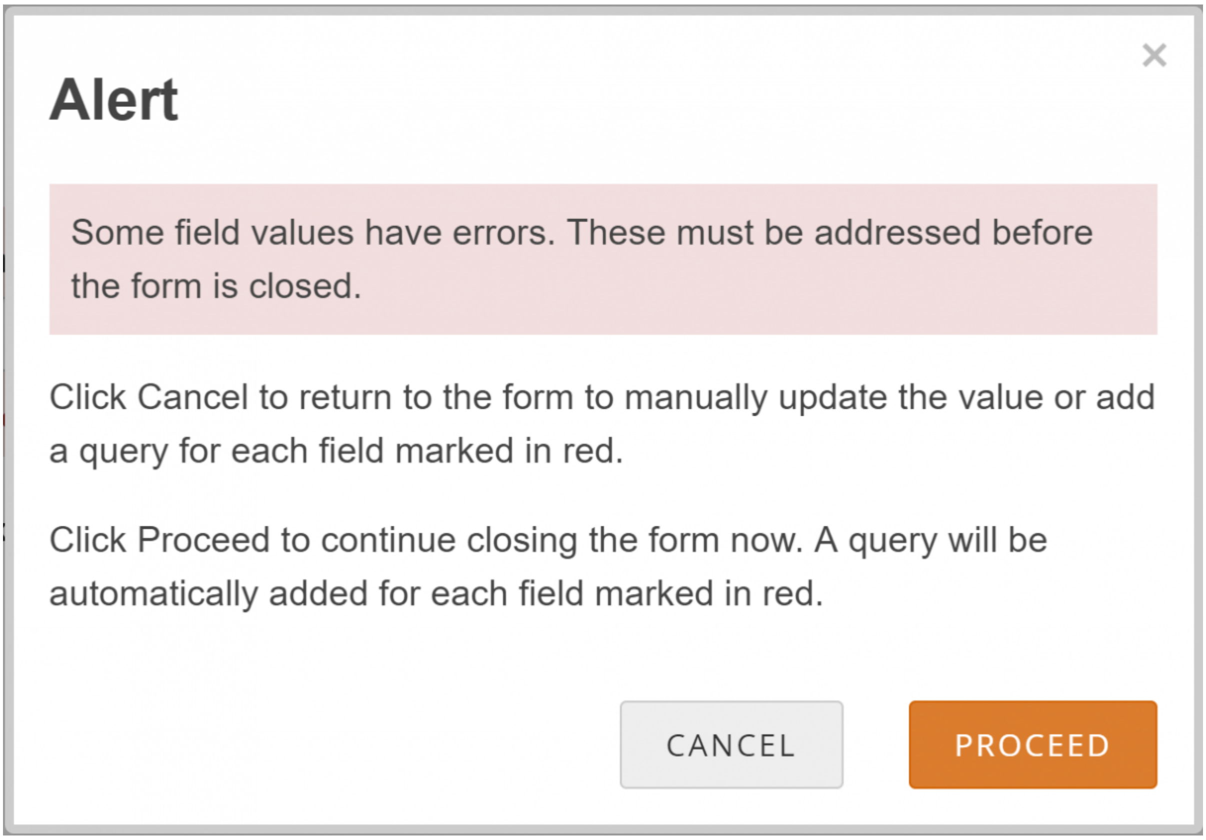


2. Click **+New**.
3. Enter text in the **Add a New Query** text box.
4. (Optional) Select a user to assign the query to.
5. (Optional) Check the **Email?** box to send an email notification.



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

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

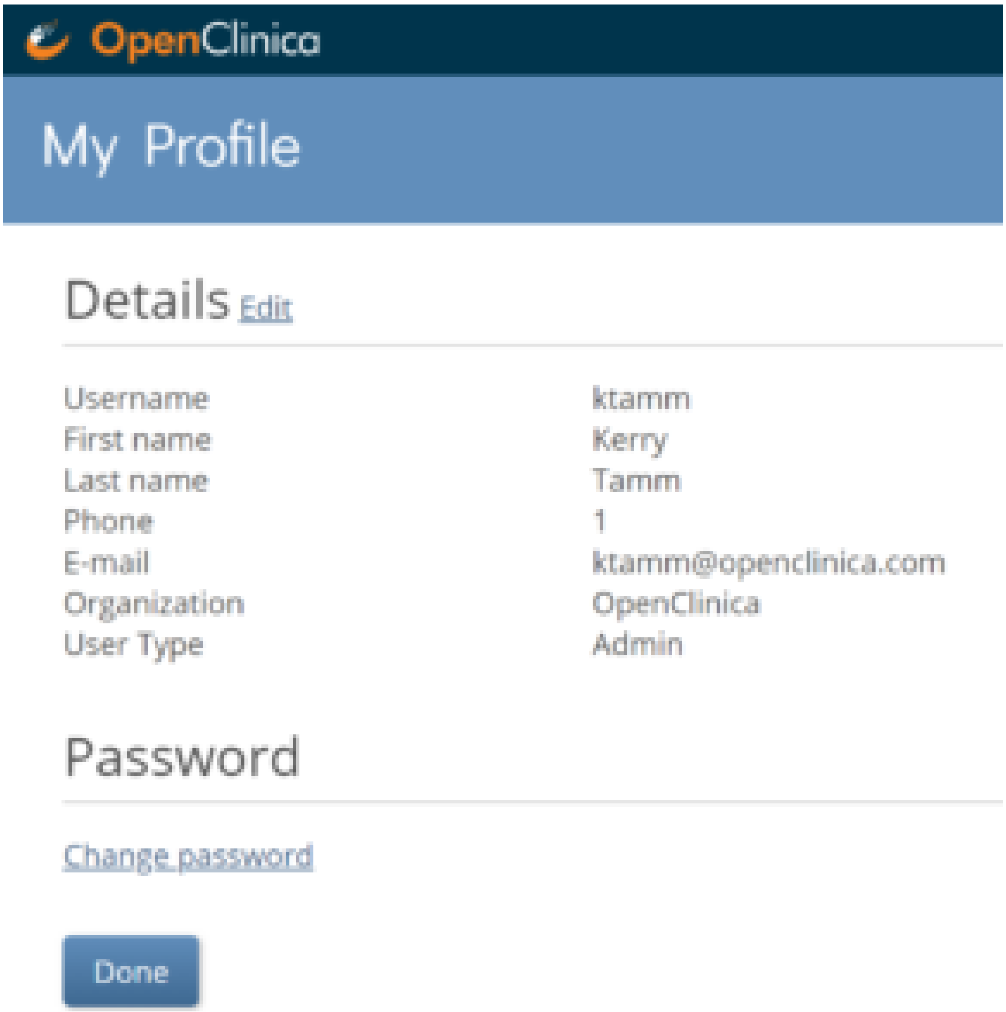


3.4.7 Your Home Screen

Your home screen depends on your **User Role**, as shown in the table below: [table id=3 /] ***Note:*** *If you have a custom* ***User Role****, the role is still based on one of the existing roles. For example, instead of the* ***Monitor*** *role, there might be* ***Monitor Site A*** *and* ***Monitor Site B****. These are based on the* ***Monitor*** *role and have the same home screen and permissions.*

3.4.8 Managing Your Account

All users can update their user profile and password at any time.



To Edit Profile Information:

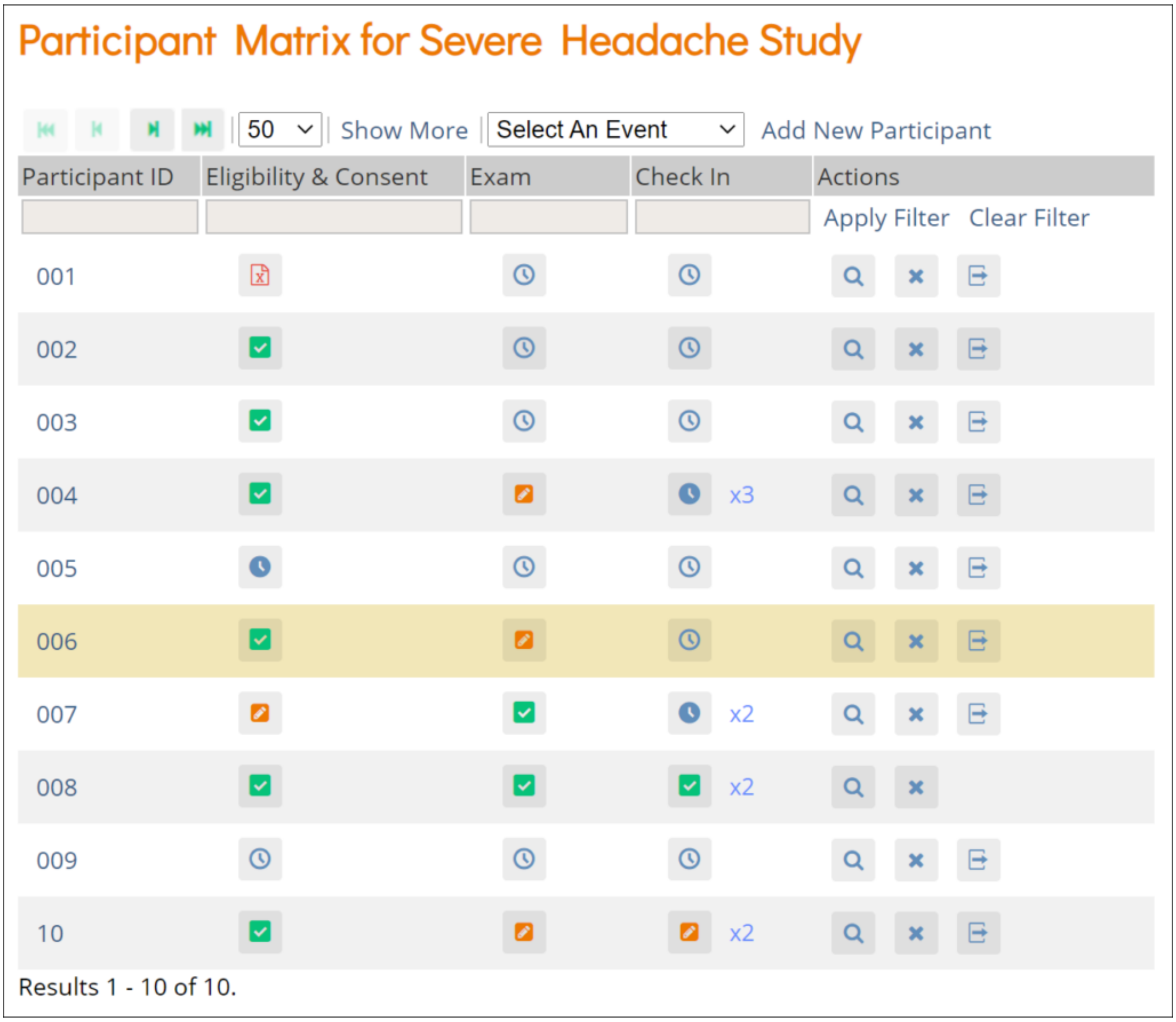
1. From the **User** menu, select **My Profile**.
2. Click the **Edit** link, and update your information as needed:

Note: *You cannot change the email address associated with your account. Please contact your administrator if you need to change your email address. To change your password, click the* ***Change Password*** *link, and update your password.*

3.4.9 Frequently Used Screens

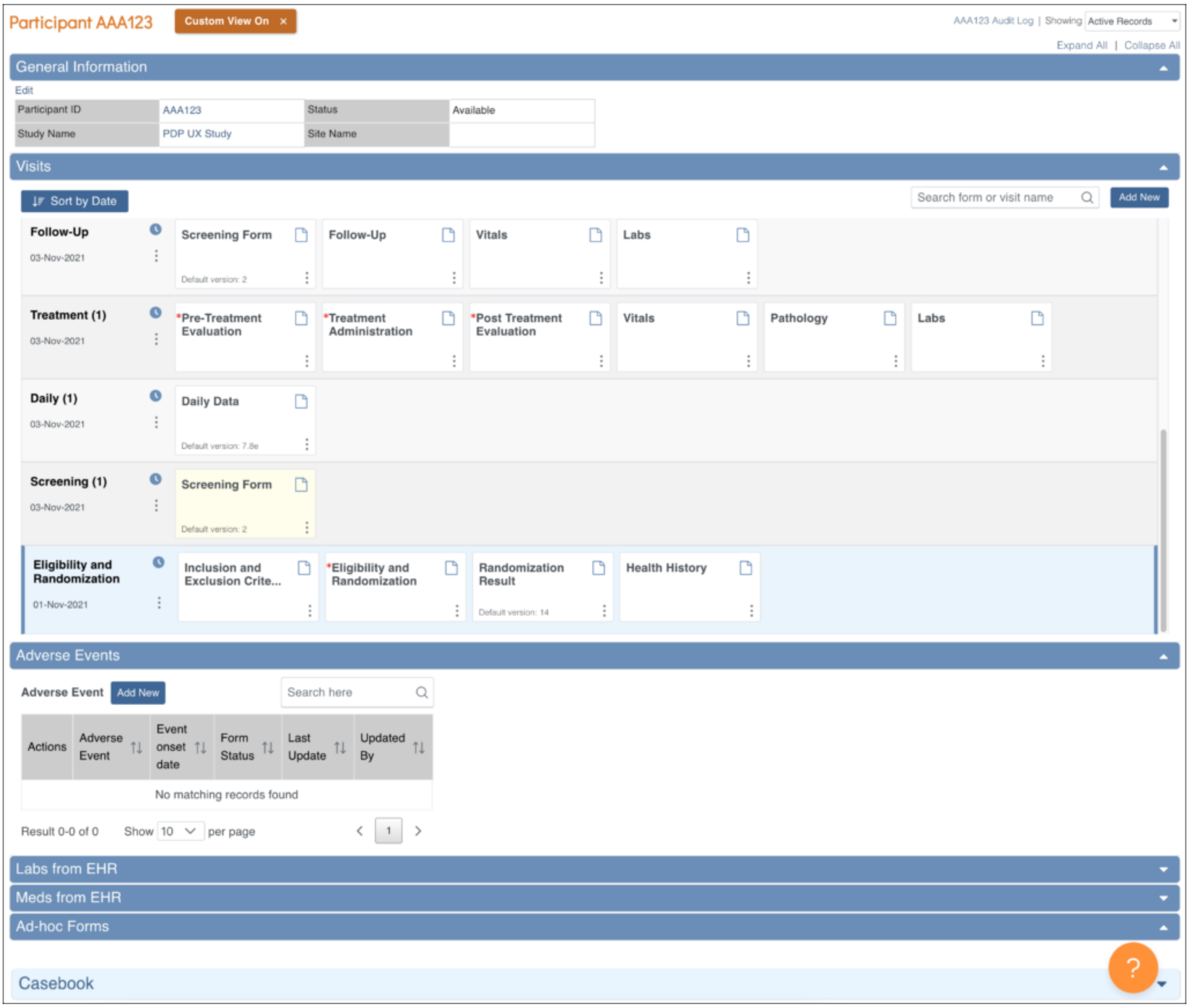
The screens you most frequently use depend on your **User Role**. Below are descriptions of the five main screens in OpenClinica: **Participant Matrix**, **Participant Details**, **Form Data Entry**, **Queries**, **Source Data Verification**. **Participant Matrix:** This screen displays a list of participant IDs, events, and event statuses. From this screen, you can view participant details, schedule events, remove/restore participants, and reassign participants to another site, depending on access.

- The Participant Matrix lists visit-based events across the top of the screen 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.



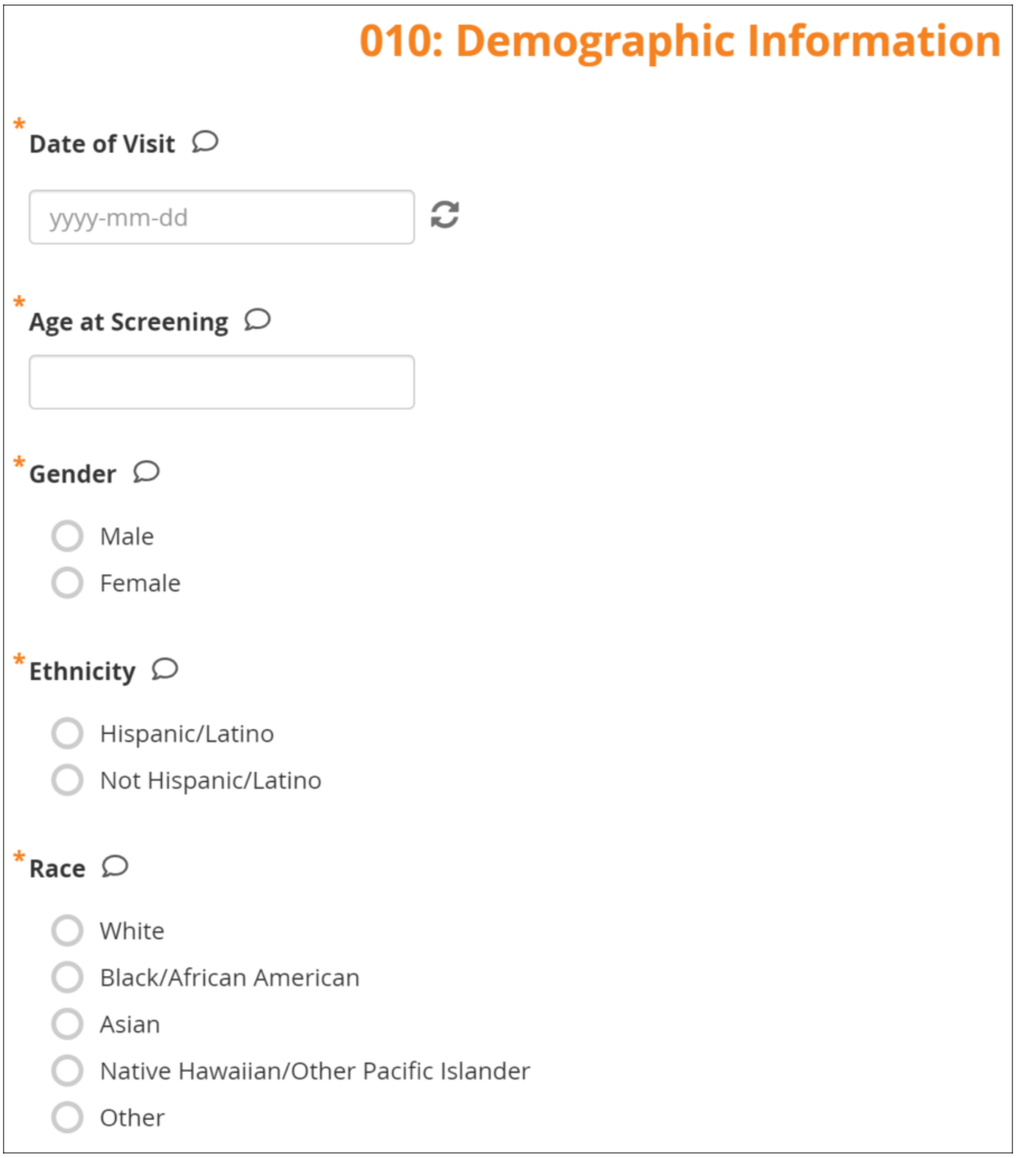
Participant Details: This screen displays the participant's general information, events, and forms. From here you can view Forms, enter data into forms, edit form data, lock events, remove/restore events, clear forms, and reassign a form to another version (depending on access). The Participant Details screen is divided into the following sections:

- General Information
- Visits
- Common Events
- Casebook

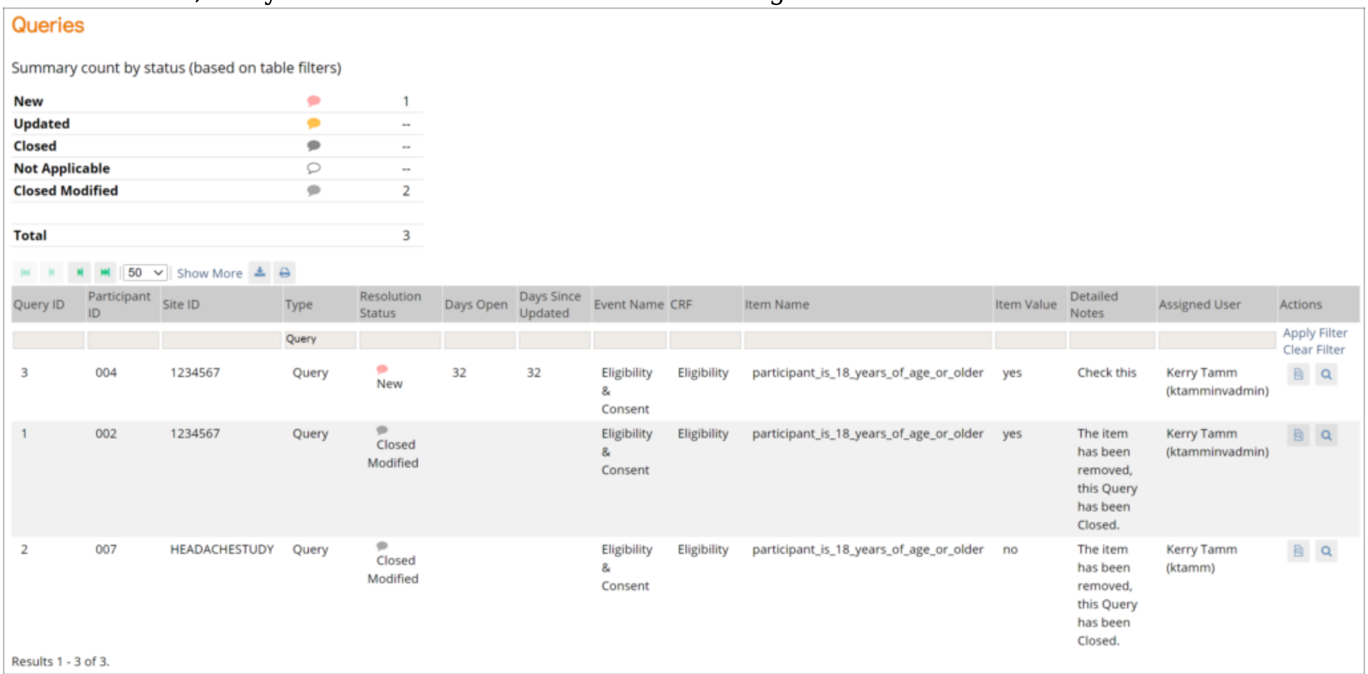


Form Data Entry: When you open a form, you can view, enter data, edit data, add queries or annotations, close, and complete forms. If a user makes a change to the data after the form has been completed, they must enter a Reason for Change. Some features include:

- auto-save
- conditional fields
- calculations and edit checks
- concurrency locking



Queries: This screen displays all queries in the study environment. On this screen, you can view, add, update, and close queries, depending on access. Queries are usually added while reviewing forms from the Participant Details screen, but you can also add them when reviewing forms here.



Queries

Summary count by status (based on table filters)

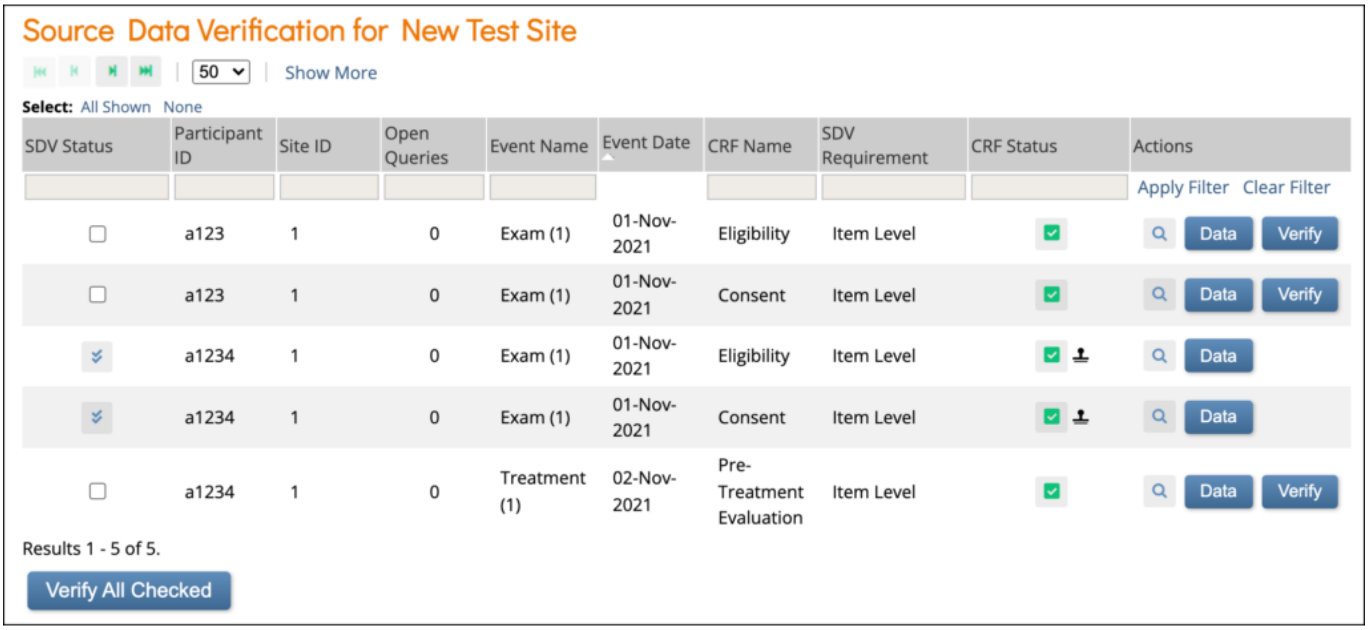
New	1
Updated	--
Closed	--
Not Applicable	--
Closed Modified	2
Total	3

50 Show More

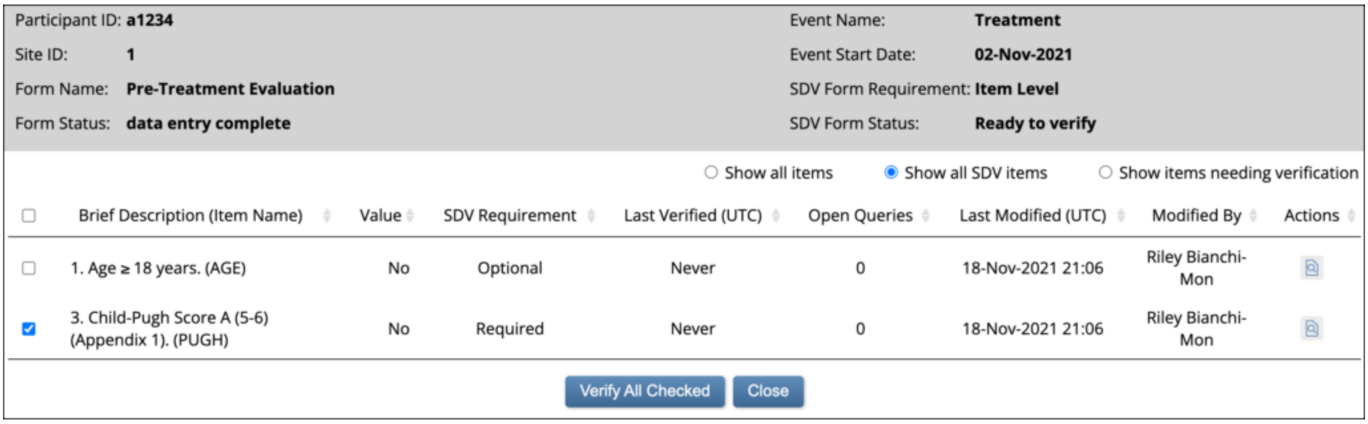
Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
			Query										Apply Filter Clear Filter
3	004	1234567	Query	New	32	32	Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	Check this	Kerry Tamm (ktamminvadmin)	
1	002	1234567	Query	Closed Modified			Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	The item has been removed, this Query has been Closed.	Kerry Tamm (ktamminvadmin)	
2	007	HEADACHESTUDY	Query	Closed Modified			Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	no	The item has been removed, this Query has been Closed.	Kerry Tamm (ktamm)	

Results 1 - 3 of 3.

Source Data Verification: On this screen, you can view forms, view item data, and verify/unverify forms.



Item-Level SDV Screen:



3.4.10 Frequently Used Terms

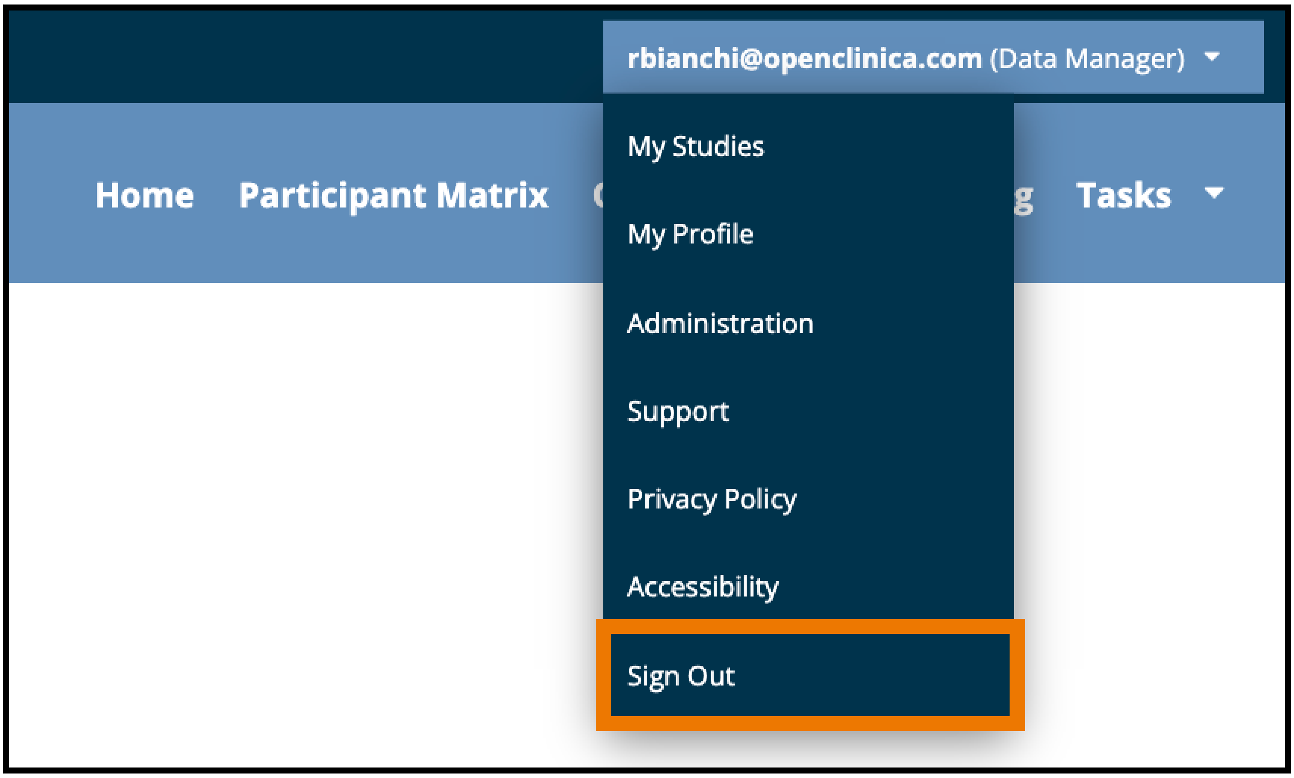
The following table displays terms that are frequently used within OpenClinica. [table id=7 /]

3.4.11 How to Log Out

You can log out of OpenClinica from the **User** menu.

To Log Out of Openclinica:

1. Click the **User** menu.
2. Click **Sign Out**.


rbianchi@openclinica.com (Data Manager)
Home
Participant Matrix
Tasks
My Studies
My Profile
Administration
Support
Privacy Policy
Accessibility
Sign Out