

1 Getting Started

Welcome! The OpenClinica 4 (OC4) User Guide provides detailed information on how to build studies and forms, operate your study, manage your data, and support your study team and sites. It also includes details about our add-on modules: Recruit (for patient recruitment), Participate (for patient engagement and electronic patient reported outcomes, or ePRO), Consent (21 CFR Part 11-compliant electronic consent forms), Insight (reporting, visualization, and data warehousing), Randomize (for clinical trial randomization and supply management), and Code (standardized medical terminology coding) to enhance your experience. OpenClinica is trusted in thousands of studies around the world to capture and organize critical research data, and to enhance the productivity of your research. We hope you'll find your OpenClinica experience to be friendly, intuitive, and of the highest quality. The team here at OpenClinica is committed to your success.

For Information on Logging In and Getting Started, See the Following Sections:

Approved for publication by Kate Lambert. Signed on 2025-09-08 4:14PM

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1.1 How to Get Help

Who Can Request Support?

We provide support on a named user basis to users who have completed the OpenClinica Super User Training. Your contract with us will specify how many supported users you are entitled to. Additional supported users can be added as needed. *Note:* The number of supported users has no bearing on the number of users you can have in your OpenClinica system.

To Access the OpenClinica Support Team (Contract-Based, Named Users Only):

- 1. From the **User** menu, select **Support**. The **Support Portal** appears. You must log into the **Support Portal** separately from **OpenClinica**.
- Click the Create Request, View Request, or Email Support buttons, or click the Regulatory Resources button to go to OpenClinica social documentation site and view information on Regulatory Resources.

Updates

We provide release announcements and updates on downtime within OpenClinica through HelpScout. Release Announcements are provided two weeks prior to the release. These include brief descriptions of the changes, screenshots, and occasionally short videos. After the release, the Release Announcement is updated with a link to the full release notes. You can also view our OC4 release notes <a href="https://www.nct.nct/heart-sep-en-link-nct/heart-sep-en-l

The Doc Site

Our goal is to provide information that is easy to find and understand on this website. To find information, you can:

- Click OC4 User Manual on the sidebar, and select a heading related to the information you
 want to find.
- Click Self-Service Training on the sidebar, and select the course related to the information you want to find. You will always have access to information, screenshots, videos, and quizzes, regardless of whether you have completed the training.
- Enter search terms in the Search bar in the upper left-hand corner of the screen. This includes anything on the website, including information from the User Manual and from the Self-Service Training. You can also filter search results by OC4 or OC3.

Resources on Our Website

- Request support
- Contact us
- Request a demo
- Check our blog
- Check us out on Youtube, LinkedIn, Twitter, or Facebook!
- Register to receive access to our newsletter and free resources, such as <u>The Ultimate eCRF</u> <u>Design Guide</u>.

Tips for Submitting a Ticket

The more information we have, the more likely we will be able to quickly diagnose and resolve your issues. To keep things organized, please create one ticket per issue. If you want to submit multiple issues, please create a separate ticket for each. Here is some information that might be helpful to include in your description of the problem:

- The date and time when you first encountered the issue
- The username(s) of the user(s) who encountered and/or are affected by this issue
- Whether the problem occurred in Test or Production, or both
- The version of the software you are using
- A description of the problem with steps on how to reproduce
- Whether or not the issue can be reproduced for other sites, participants, browsers, etc.
- Whether you attempted a work-around; if so, what was it and what was the result?
- The study name
- The forms (If you uploaded the Form with the Form Definition Spreadsheet, include that file)
- The rules in use
- Screenshots of the issue

Approved for publication by Kerry Tamm. Signed on 2020-12-17 3:59PM

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1.2 For OC3 Users

OpenClinica 4 has a modern, user-friendly interface that is easy to use and includes built-in, context-sensitive help. Customer accustomed to working in OpenClinica 3.x will see many familiar screens and concepts, but in many areas a brand new user interface--including new study and form building tools. This toolset can deliver dramatically shorter timelines for your study builds, and allow you to deploy case report forms that are highly dynamic, mobile-friendly, and autosave your data. Click here to see a more complete comparison between the different editions. Contact us for bridge training.

Approved for publication by Ben Baumann. Signed on 2021-05-14 3:21PM

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1.3 Logging In

Getting Invited

You will receive an email inviting you to participate in a study.

To Accept an Invitation:

- 1. Open the email.
- 2. Click **Let's Go**.

Welcome to New Cancer Drug!

Dear Kerry,

You've been invited to join New Cancer Drug in OpenClinica. We'll get you started in a few quick steps.

Let's Go ->

The above link will allow you to set up your login, and will only work the first time you access OpenClinica. After you've done this, you may return to OpenClinica by bookmarking the following URL: https://cust2.openclinica-dev.io/OpenClinica/MainMenu

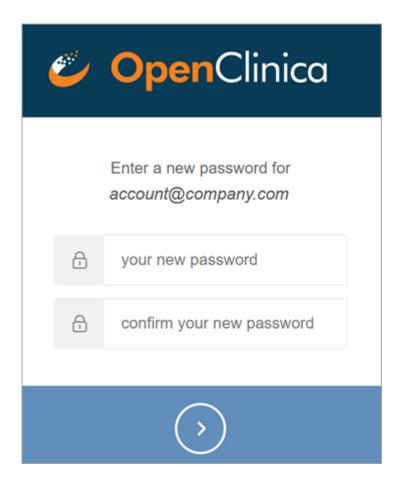
OpenClinica is a simple and powerful tool for capturing and organizing your research data. It's trusted in more than 10,000 studies around the world.

Thanks!

The New Cancer Drug Team



After clicking **Let's Go**, you will be redirected to a screen asking you to set your password.



Your Password Must:

- Be at least 8 characters in length
- Contain at least one of each of the following types of characters:
 - Lower case letters (a-z)
 - ∘ Upper case letters (**A-Z**)
 - Numbers (**0-9**)
 - ∘ Special characters (!@#\$%^&*)

Note: Your environment may have different password requirements than shown above.

In Addition:

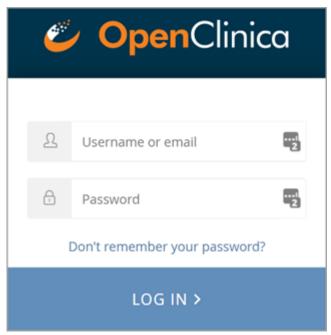
- Passwords expire every 180 days, and users are automatically prompted to create a new password.
- User accounts are locked after **ten failed login attempts** from the same IP address.
 - The lockout resets after **15 minutes**. The login failure count resets every **24 hours**.
 - When a user tries to login after their account has been locked, it is included in the User
 Audit Log as a failed login attempt.
- If a user resets a password, it cannot be the same as the previous password.
- The password reset link is available for **24 hours**, after which, if a user has not reset the password, they must request a password reset again.
 - All reset requests are logged in the **User Audit Log**.
- Invitations to studies expire in 14 days if they have not been accessed.
- Users are automatically logged out of OpenClinica after **one hour** of inactivity.

Note: Your environment may be configured for different behavior than shown above (except for the one hour inactivity timeout). Once you have entered a password that meets the requirements, you

will be prompted to log into OpenClinica using a supported browser. If you want to create an OpenClinica bookmark, make sure to bookmark the **Home** screen after you login instead of bookmarking the **Login** screen. After you log in for the first time, you can no longer click the **Let's Go** button on the invitation.

To Log into OpenClinica After Your First Login:

- 1. Enter the URL for OpenClinica into the search bar at the top of your supported browser. You can find the URL on your invitation to the study. Or, if you have bookmarked the **Home** screen, click on the bookmark.
- 2. Enter your username.
- 3. Enter your password.



OpenClinica supports using recent versions of the

following browsers:

- a. Google Chrome, Microsoft Edge, Firefox, and Safari for desktop devices
- b. Google Chrome for Android devices
- c. Safari for iOS and iPadOS (Apple) devices

OpenClinica does not support Internet Explorer (IE11) or Edge Legacy (the original version of Microsoft Edge). If the environment you're working with requires multi-factor authentication (MFA), the login process has an additional step.

Multi-factor Log In

In addition to entering your **username** and **password**, you must scan a barcode and enter an access code generated by the **FreeOTP** or **Google Authenticator** app on your smartphone.

To Log In with Multi-factor Authentication:

- Download either the FreeOTP (iOS or Android) app or the Google Authenticator (iOS or Android) app to your smartphone.
- 2. Scan the barcode.



You are required to set-up multi-factor authentication.

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

Step 1: Install one of the following applications on your mobile device:

- Google Authenticator (recommended) (Android iOS)
- FreeOTP (Android iOS)

Step 2: Open the application and scan the barcode:



Unable to scan?

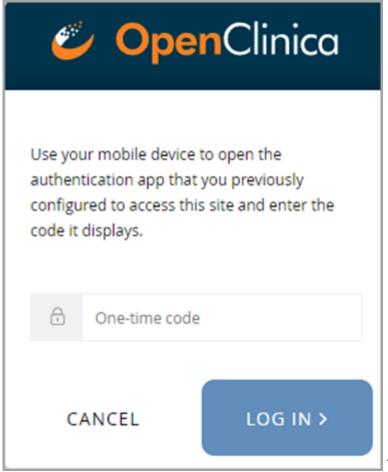
Step 3: Enter the one-time code provided by the application in the box below and click Log In to finish the setup.



One-time code

LOG IN >

3. Enter an access code.



Whenever prompted in the future, use the same mobile device you previously set up to receive the one-time passcode from either **Google Authenticator** or **FreeOTP**.

Functional approval by Paul Bowen. Signed on 2023-10-04 4:46PM

Approved for publication by Laura Keita. Signed on 2023-10-04 4:48PM

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1.4 OpenClinica Basics

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

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1.4.1 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.

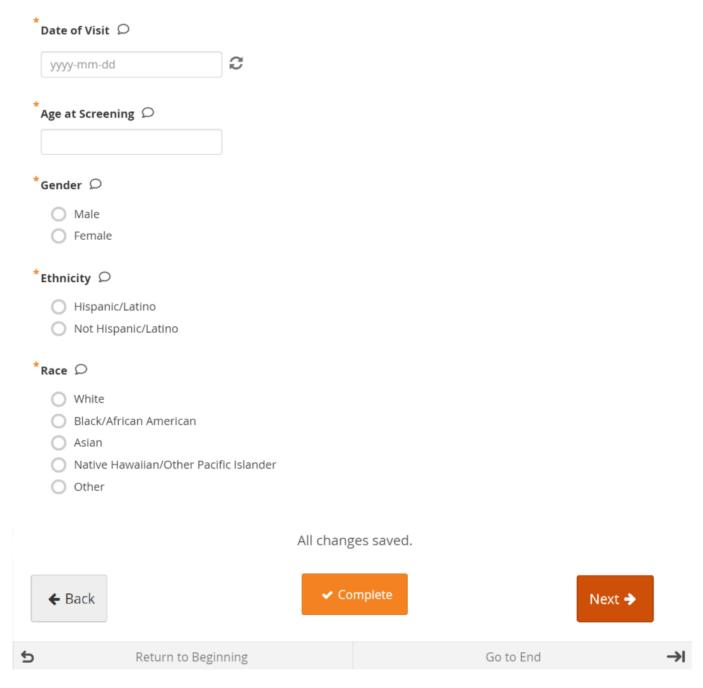
Forms

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

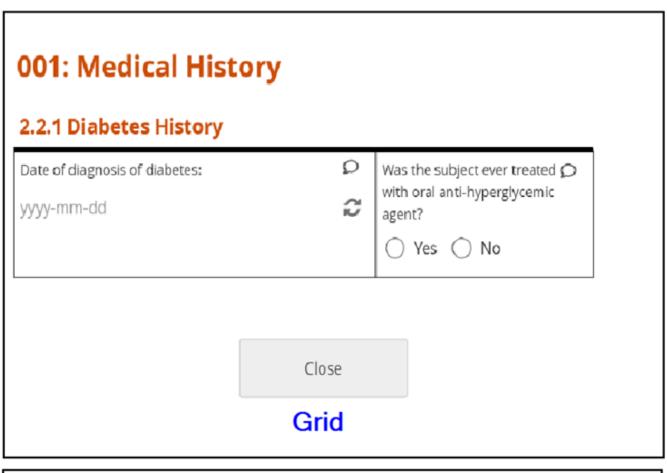
There are different types of fields, such as: **select one**, **select multiple**, **integer**, **date**, **image**, etc. Note that **All changes saved** appears at the bottom of the Form because all changes are saved automatically.

001: Demographic Information



Layout

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





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.

ı	How many times a month does the participant take an analgesic? $ $			
	12			
١	/alue not allowed			

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

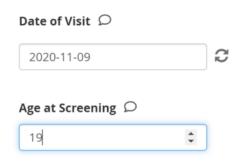
To Enter Data Directly into Visit Event Forms:

- 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
- 3. Enter information into each field.

001: Demographic Information



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.

001: Medical History

2.2.1 Diabetes History Was the subject ever treated with oral anti-hyperglycemic agent? ✓ Yes ✓ No Close

To Close the Form and Continue Data Entry Later:

Click the Close button.

All changes saved.

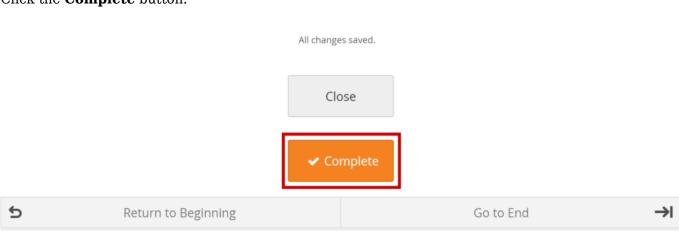
Close

Close

5 Return to Beginning Go to End →

Mark Data Entry Complete:

Click the **Complete** button.



Queries

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

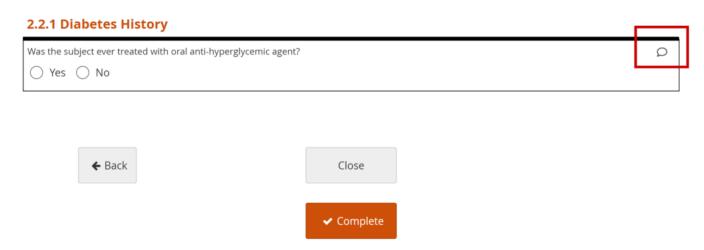
The system creates queries automatically if you close a Form that has unaddressed errors or you can manually create a query.

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.

001: Medical History

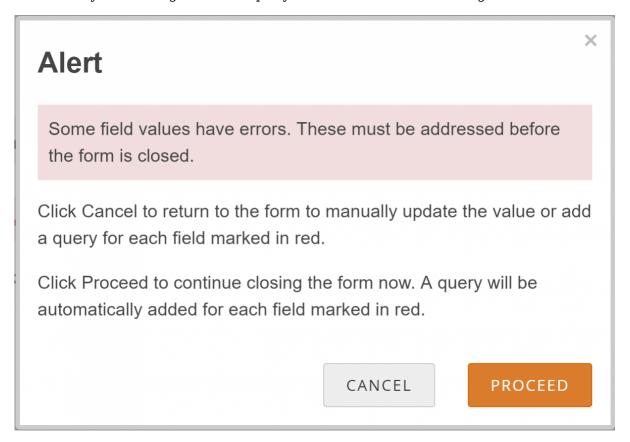


- 2. Click +New.
- 3. Enter text in the **Add a New Query** text box.
- 4. (Optional) Select a user to assign the query to.
- 5. (Optional) Check the **Email?** box to send an email notification.



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.



1.4.2 Your Home Screen

Your home screen depends on your **User Role**, as shown in the table below:

User Role	Home Screen	Displays
Data Manager/Admin	Welcome	Graphs of Study Progress
Investigator	Participant Matrix	Participants and Events
Clinical Research Coordinator	Participant Matrix	Participants and Events
Data Specialist	Participant Matrix	Participants and Events

Data Entry Person Participant Matrix Participants and

Events

Study or Site Monitor Source Data

Forms to Review and

Verification

Verification Verify

Study or Site Viewer Participant Matrix Participants and

Events

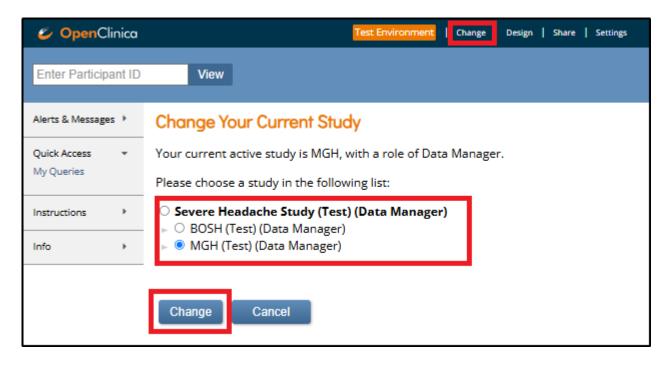
Note: If you have a custom **User Role**, the role is still based on one of the existing roles. For example, instead of the **Monitor** role, there might be **Monitor Site A** and **Monitor Site B**. These are based on the **Monitor** role and have the same home screen and permissions.

1.4.3 Change Study

If you have access to multiple studies or sites, you can switch your active study based on your assigned role.

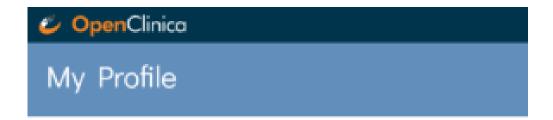
To switch between studies or sites:

- Click **Change** in the top navigation.
- Select the study or site you want to view from the list.
- Click **Change** to confirm your selection.



1.4.4 Managing Your Account

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



Details Edit

Username ktamm
First name Kerry
Last name Tamm
Phone 1

E-mail ktamm@openclinica.com

Organization OpenClinica User Type Admin

Password

Change password



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.

1.4.5 Frequently Used Screens

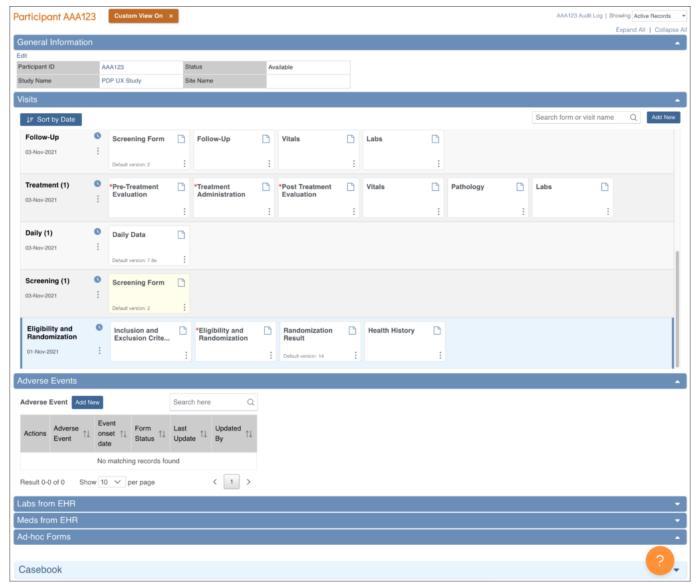
The screens you most frequently use depend on your **User Role**. Below are descriptions of the five main screens in OpenClinica: **Participant Matrix**, **Participant Details**, **Form Data Entry**, **Queries**, **Source Data Verification**. **Participant Matrix**: This screen displays a list of participant 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 Matrix for Severe Headache Study				
44 H H	₩ 50 ∨ Show Mor	e Select An	Event V Add	New Participant
Participant ID	Eligibility & Consent	Exam	Check In	Actions
				Apply Filter Clear Filter
001		0	0	Q * E
002		0	0	Q x E
003		0	0	Q × E
004			o x3	Q x =
005	•	0	0	Q x =
006			0	Q x =
007			o x2	Q x =
008			☑ x2	Q x
009	0	0	0	Q * =
10			2 x2	Q × E
Results 1 - 10 of 10.				

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

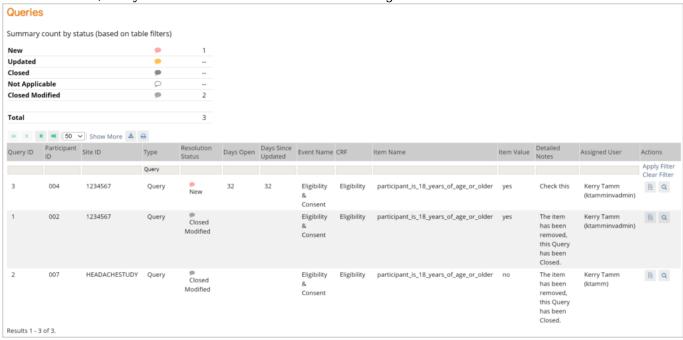


Form Data Entry: When you open a form, you can view, enter data, edit data, add queries or annotations, close, and complete forms. If a user makes a change to the data after the form has been completed, they must enter a Reason for Change. Some features include:

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

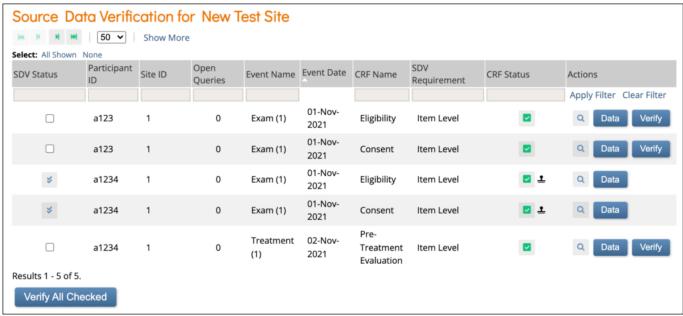
	010: Demographic Information
*Date of Visit	
yyyy-mm-dd	$\boldsymbol{\varepsilon}$
*Age at Screening \wp	
*Gender \wp	
Male	
Female	
*Ethnicity \wp	
O Hispanic/Latino	
Not Hispanic/Latino	
*Race Ω	
White	
Black/African American	n
Asian	
Native Hawaiian/Other	Pacific Islander
Other	

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.

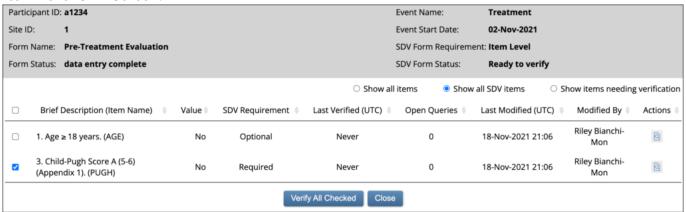


Source Data Verification: On this screen, you can view forms, view item data, and verify/unverify

forms.



Item-Level SDV Screen:



1.4.6 Frequently Used Terms

The following table displays terms that are frequently used within OpenClinica.

Definition Term

A study is a collection of **events** and **forms** that contain participant data. Study

> A participant (sometimes referred to as a *subject*) is a person who provides data for the study.

- Participant
 If the Participate module is activated, participants can enter data themselves.
 If the Randomize module is activated, participants can be randomly assigned to groups (e.g., placebo or treatment) without bias from demographics such as age, sex, or gender.

An event is a collection of one or more **forms**. Events can be:

- **Visit-based, non-repeating**: A scheduled occurrence (e.g., *Baseline*)
- Visit-based, repeating: A repeatable scheduled or unscheduled occurrence (e.g., Cycles in Oncology trials, Unscheduled Visits)
- Common, repeating: An unscheduled but repeatable occurrence (e.g., Adverse Event)
- Common, non-repeating: An unscheduled, one-time occurrence (e.g., Termination)

Event

A form (or CRF) is an electronic record of participant data that can include:

- **Items** individual data fields (e.g., blood pressure, date of visit).
- **Constraints** rules that define acceptable input values (e.g., numeric ranges, required fields).
- **Relevance logic** conditional rules that show or hide fields based on prior responses.

Form

- Calculations auto-derived values (e.g., BMI from height and weight).
- **Metadata** labels, instructions, and coding standards to ensure consistent data entry.

Users with the appropriate level of form access can enter data into a Form.

- If the **Participate** module is activated, a form can be published as a *Participate Form*, allowing participants to enter data from their own devices.
- If the **Consent** module is activated, a form can be published as an *eConsent Form*, allowing participants to provide consent in a manner compliant with **21 CFR Part 11**.

Study Designer

Study Designer is the interface where Data Managers create Events and Forms.

Study Runner is the interface where users enter data into the study in either **Test** or **Production** environments. Depending on your access level, you may be able to:

• Manage participants / events

Study Runner

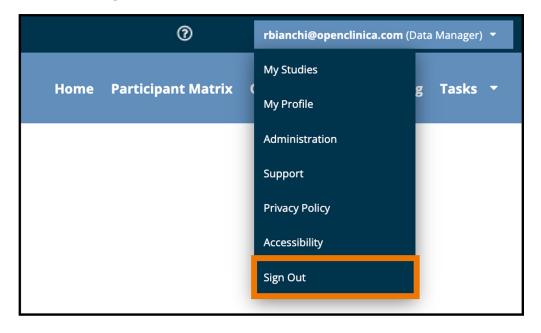
- View/enter data
- Create, update or close queries
- Perform Source Data Verification (SDV)
- Import data
- Extract data

1.4.7 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**.



1.4.8 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

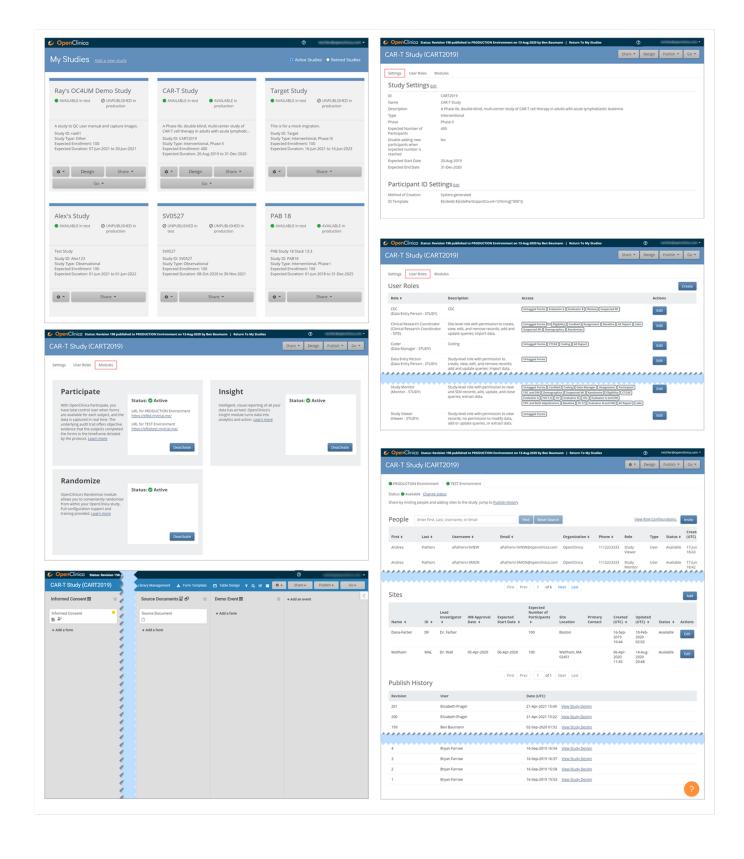


The Header Bar Displays:

- 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.



1.4.9 The Participant Matrix

The Participant Matrix provides a centralized view of participants enrolled in your study or site. It helps you track participant status, identify records that require action, and navigate directly to related tasks.

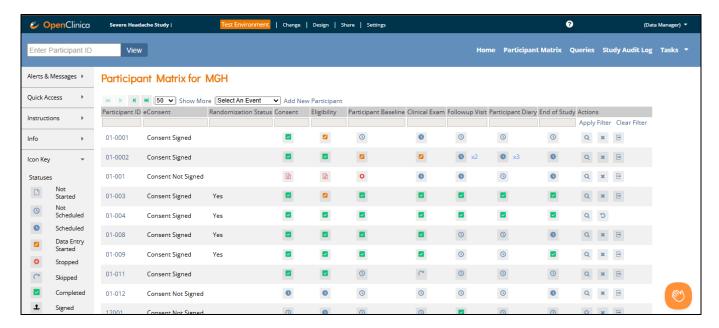
If accessed at the **study level**, the Participant Matrix displays all participants in the study.

If accessed at the **site level**, it displays only participants at your assigned site.

There are two main views:

- All Events View Columns represent visit-based events (e.g., Screening, Baseline, Follow-up)
- Single Event View Columns represent forms within the selected event

Each row in either view represents a participant. You can hover over icons to see more details about event or form status. A legend appears on the left side of the screen as a quick reference for icon meanings.



Common Actions

You can use the Participant Matrix to:

Manage Participants:

- Add a participant (For more information, refer to <u>Adding a Participant</u>)
- Edit participant data
- Remove a participant
- Restore a participant
- Sign a participant record (Investigators and data specialists only. For more information, refer to **Signing Participant Records.**)
- Reassign a participant to another site (data managers only)

Manage Events and Forms:

- Schedule events
- View participant details
- View, enter, or edit forms (depending on access)

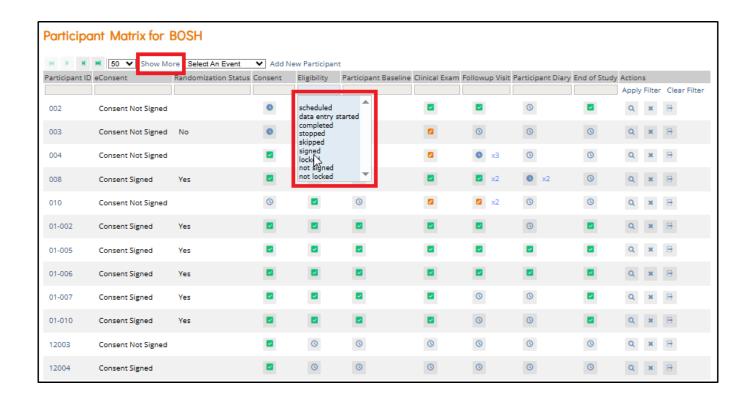
Matrix Layout

- In **All Events View**, the columns are the **visit-based events** defined in your study design.
- In **Single Event View**, the columns are the **forms** within the selected visit-based event.
- **Common Events** are not displayed in the matrix.
- The **eConsent Status** column appears if the Consent module is enabled and configured.
- Additional **custom columns** may be configured in the Study Designer. For more information on configuring Custom Column Headers, refer to *Defining Custom Column Headers on the Participant Matrix and Queries Table* within **Design a Study.**

Filtering Participants

You can filter participants using:

- The **Select an Event** dropdown at the top of the matrix
- Gray filter boxes under each column header
 - Participant ID: Type partial or full ID
 - Visit-Based Event Columns: Filter by status
 - Custom Columns: Filter options vary by data type
 - **Status Column**: (Visible when *Show More* is enabled) View participants by overall status: *Available, Removed, Signed*, etc.

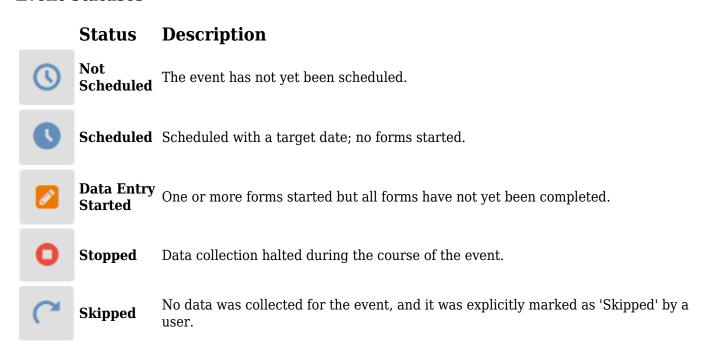


Status Icons

The Participant Matrix uses icons to visually indicate the status of each **event** and **form**. These icons help you quickly assess participant progress, identify where action may be needed, and understand system-imposed restrictions like locks or archival.

Each icon is associated with a specific state in the data collection process. The meaning of each icon varies depending on whether you are viewing **events** (in All Events View) or **forms** (in Single Event View).

Event Statuses



	Completed	All required forms completed
<u>•</u>	Signed	Reviewed and signed by investigator. Resets if data changes For more information on event-level signatures, refer to <u>Signing Participant Records</u> .
	Locked	Locked by a data manager; no changes allowed unless it is explicitly unlocked. Events are generally locked after data entry and verification are complete to ensure that no more data changes occur.
	Archived	Archived in study configuration. When you click 'All Records', any archived events with or without data will be displayed.
X	Removed	Removed from record; viewable/restorable via All Records.

Form Statuses

	Status	Description
	Not Started	Data entry has not started for the form.
	Data Entry Started	Data entry has been initiated for the form, but it has not yet been marked as complete by the user.
<u>~</u>	Completed	The user has entered data or queries for all required items and has marked the form as complete. Form data can still be edited.
	Archived	Archived forms with data appear in <i>All Records</i> .
x	Removed	The form was removed from the participant's record. Form data can be restored if needed.

Actions

The Participant Matrix allows you to perform key actions on participants, events, and forms—depending on your role and current view (All Events vs Single Event). These actions let you manage the study workflow by updating participant records, handling visit schedules, and modifying form data.

Available actions vary by context:

- Participant-level actions are always available for each participant row.
- Event-level actions appear only in All Events View.
- Form-level actions appear only in Single Event View.

Participant-Level Actions

These actions allow you to manage participants directly from the matrix, such as removing or restoring a participant, reassigning them to a different site, or applying a signature.

	Action	Description	Location
Q	View	Opens the Participant Details Page.	Clicking on Participant ID
×	Remove	Opens the Remove Participant screen. Prompts for a reason for change. Participant remains visible on Participant Matrix.	Actions column
C	Restore	Opens the Restore Participant screen. Prompts for a reason for change. Restores participant to Active status.	Actions column
₽	Reassign	Transfers participant to another site. The participant will then be associated with the new site. Note that only users with the appropriate role can perform a reassignment.	Actions column
<u>•</u>	Sign	Opens the signature screen. For more information about Signing Participants, refer to Signing Participant Records	Actions column

Event-Level Actions

Available in **All Events View**

These actions allow you to manage visit-level data, including updating the schedule, locking the event, or signing it once complete. They are accessed by clicking on the participant event icon.

Status Description

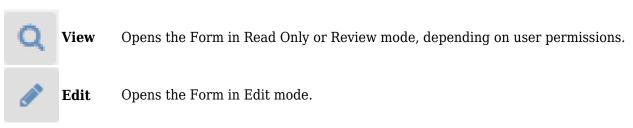
		•
C	View	Opens the Participant Details Page to the selected visit.
ø	Edit	Opens the Update Study Event page, where you can modify the details of the event.
3	Remove	Removes event from the Participant's record.
5	Restore	Restores previously removed event.
1	Sign	Opens the signature screen for the selected event. For more information about Signing Participants, refer to <u>Signing Participant Records</u>
	Lock	Locks the selected event, preventing further changes.
	Unlock	Unlocks the event, allowing data entry or corrections to resume.

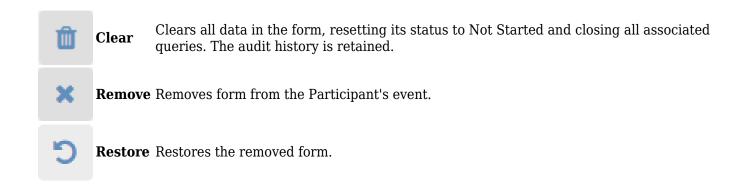
Form-Level Actions

Available in **Single Event View**

These actions allow you to manage individual data collection forms within an event. They are accessed by clicking on the participant form icon.

Status Description





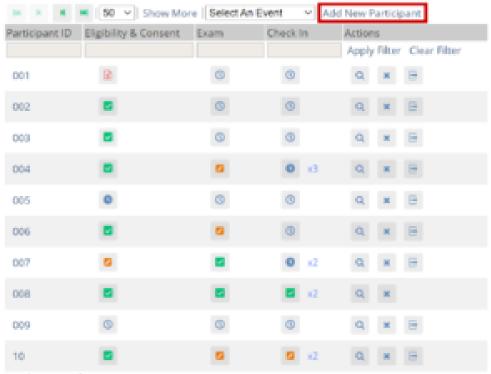
1.4.10 Adding a Participant

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

To Add a Participant:

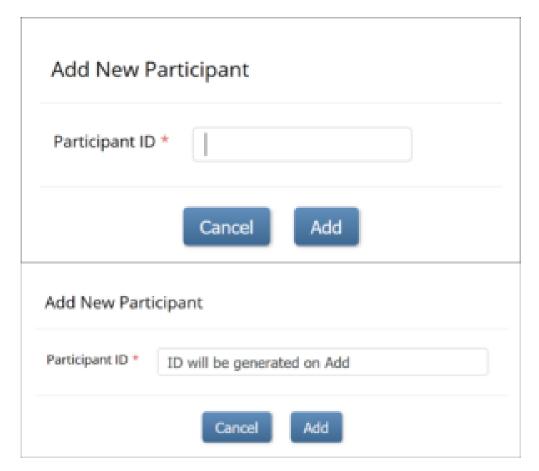
1. On the **Participant Matrix** screen, click the **Add New Participant** link above the matrix.

Participant Matrix for Severe Headache Study



Results 1 - 10 of 10.

- 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.



1.4.11 The Participant Details Screen

The **Participant Details page (PDP)** provides a comprehensive overview of all information related to a specific study participant in one location. This page allows you to review key participant details, enrollment status, study event progress, and track form completion and data entry for each visit. It helps ensure that required activities have been completed, and facilitates entering new data or updating existing information as the study progresses.

Depending on your level of access, you can:

- View, Add or Update Participant data, including the Participant Audit Log
- 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

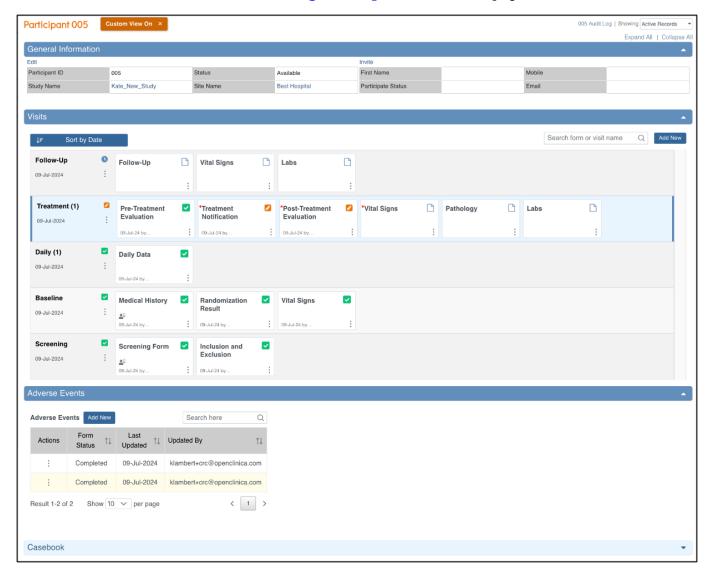
Accessing the Participant Details Screen

On the **Participant Matrix**, click on the **Participant ID** or the **View** button corresponding to the participant whose information you want to view.

PDP Sections

The PDP is divided into the following sections:

- General Information
- Visit-Based Events
- Common Events
- Casebook (Casebook information can be found in the Download Single Participant Casebooks section of the Generating Participant Casebooks page)

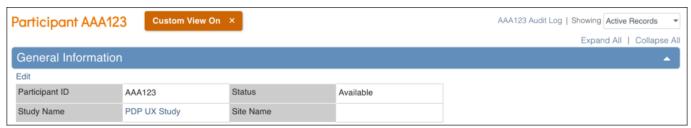


General Information

The **General Information** section displays information about:

- · The participant
- The study
- The site
- The participant status
- **Participate** information (if **Participate** module is active)
- eConsent status (if Consent module is active)
- Participant Audit Log
- Whether All, only Active, or only Removed records are displayed. (Active records displayed

by default)



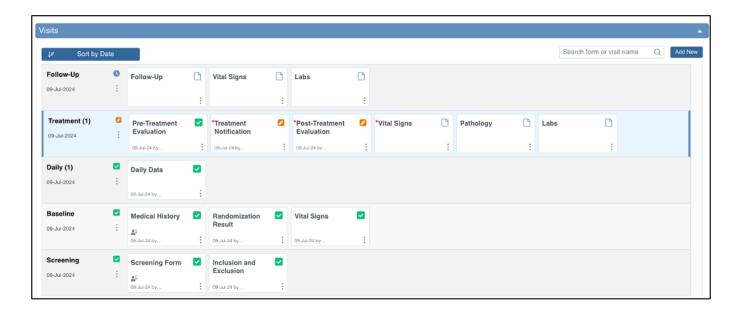
□ Note: If the Participant ID Method of Creation is set to System-generated, only Data Managers can edit the Participant ID. If it is set to Manual Entry, Data Managers, Clinical Research Coordinators (CRCs), Investigators, and Data Specialists can edit the Participant ID. For more information on adding or editing participants, refer to Add Participant.

Visit-Based Events

Based on user permissions, the **Visit-Based Events** section allows users to:

- Schedule Visit-Based Events by clicking the Add New button on the right side of the Visits
 header. For more information, refer to Scheduling an Event.
- Easily view the status of **Visit-Based Events** and **Forms** for the Participant
 - The icon legend on the left (**Icon Key**) provides a quick reminder of these meanings onscreen, or you can refer to the **Status Icons** section below for more information.
 - If an event is repeating, the name may include an occurrence number in parentheses (for example, "Followup Visit (1)" indicates the first instance of a repeating visit).
- Perform actions on the Event via the three dots menu next to the Event:
 - **View or Edit** the Event
 - Lock the Event
 - **Sign** the Event
 - **Remove or Restore** the Event
- View or Edit a Form by clicking the middle of a Form card
- Perform actions on a Form in the Event via the three dots menu on the Form card:
 - View or Edit Form
 - **Clear** Form (set all values back to blank)
 - **Verify** Form (SDV)
 - **Reassign** Form to other form version
 - Remove or Restore Form
- Search for a specific Event or Form name
- Sort the Visit-Based Events by Date

□ **Note**: For all Completed forms, clicking the form card on the PDP will always open the form in **View** mode only—regardless of the user's role. This design helps prevent accidental changes to data in forms that were already completed. These forms can be edited via the three dots menu on the Form card. □ **Note**: For all Participate-enabled forms, clicking the form card on the PDP will always open the form in **View** mode only—regardless of the user's role or the form's workflow status. This design helps prevent accidental changes to data entered by participants themselves. These forms can be edited via the three dots menu on the Form card. For more information about Visit-Based Events, refer to **Events**.



Common Events

The **Common Events** section allows users to:

- Add new occurrences of Common Events
 - Some common events are repeating, meaning you can have multiple occurrences (e.g., many Adverse Events).
- Perform actions on Common Event occurrences via the three dots menu in the Actions column:
 - Lock the Event
 - **Sign** the Event
 - Remove or Restore the Event
- Perform actions on a Form instance in the Common Event via the three dots menu in the Actions column:
 - View or Edit Form
 - **Verify** Form
 - **Reassign** Form to other form version
- View a table with data from all instances of Forms within Common Events
- Search for a specific instance of a Form within a Repeating Common Event

Columns for each Common Event form include:

- Actions that can be taken on the form instance
- Event and form name
- Form status
- Last updated date
- Updated by
- Custom columns containing form data. For more information on configuring custom columns, refer to Events & Forms.

For more information about Common Events, refer to **Events**.



Custom Views

The **Participant Details screen** opens by default 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.

Custom View On ×

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 for that participant until you update it again, go back to your default view by clicking the **X**, or log out of OpenClinica.

Status Icons

Status icons and colored symbols are used throughout the **Participant Details Page** to provide ata-glance information about the progress of data entry for each event and form.

Icon Status Description SDV Verified This icon indicates that the form has been **Source Data Verified** (SDV). This icon indicates that **verification is required** but has not yet been SDV Required, Not completed. Data Managers and Monitors can perform verification once Verified data entry is complete. For more information, refer to Source Data **Verification** (Monitors) or **Source Data Verification** (Data Managers). **SDV Status** This icon indicates that the data in the form was updated after verification Changed Since was completed, so **re-verification is required**. For more information, Verified refer to **Source Data Verification**.

This icon appears when a guery has been raised within a form. For more information, refer to **Queries (CRC)**, **Queries (CRC)**, or **Queries (Data** Manager), depending on your role.



The **Consent** form has not been signed by the participant yet.



Consent Signed

The participant has signed the **Consent** form.



Consent Countersigned The participant has signed this **Consent** form and it has been countersigned by a site user (CRC or Investigator). For more information, refer to Consent in Study Runner.



The previously added **Consent** signature has been invalidated or the Requires Reconsent Consent form has been reassigned to a new form version. The participant must sign again.



Participate-Enabled The form is accessible to the participant via the **Participate** module. This is configured during form creation in Study Designer. Form

1.4.12 Events

An **Event** is a group of Forms used in your Study. An Event may or may not correspond to a realworld visit. There are two main types of Events:

- Visit-Based Events
- Common Events

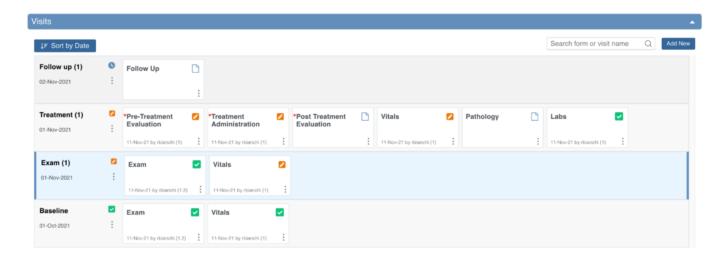
Visit-Based Events

Most Events in a clinical trial are **Visit-Based Events**, such as *Week 2*, *Week 6*, or *Monthly Follow*up.

- These visits are scheduled relative to the baseline (for example, Week 2 occurs two weeks after baseline, Week 6 occurs six weeks after baseline).
- The visit schedule is defined in the Study protocol.
- Each visit includes a specific set of Forms to be collected.

When you review the **Visits** section, the system automatically opens the earliest visit that is not complete. Incomplete visits display with a blue background.

A visit is considered complete when it has one of the following statuses: Complete, Skipped, Stopped, Removed, or Archived.



Common Events

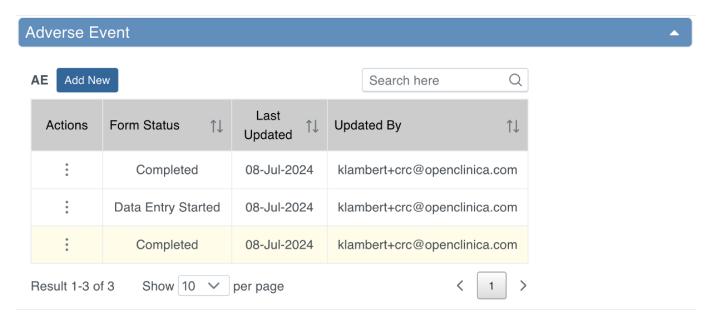
Some Events are not tied to a visit date and occur outside of the regular schedule. Examples include:

- Adverse Events (AEs)
- Concomitant Medications (ConMeds)
- Early Termination

Common Events are used to collect information independent of visit timing.

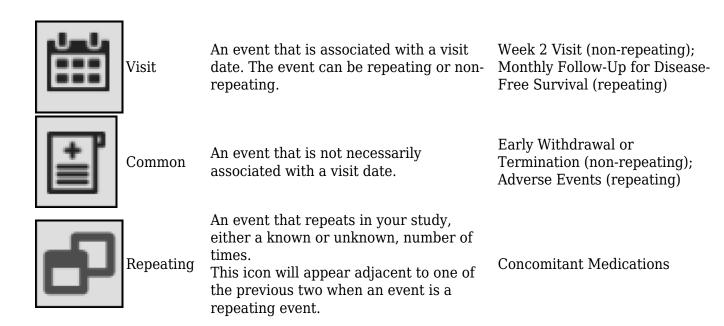
They can be configured as:

- **Repeating Events** for data that may occur multiple times per Participant (e.g., AEs, ConMeds).
- **Non-Repeating Events** for data that can occur only once per Participant (e.g., Early Termination).



Event Types and Icons

Icon Event Type Description Example(s)



Scheduling an Event

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

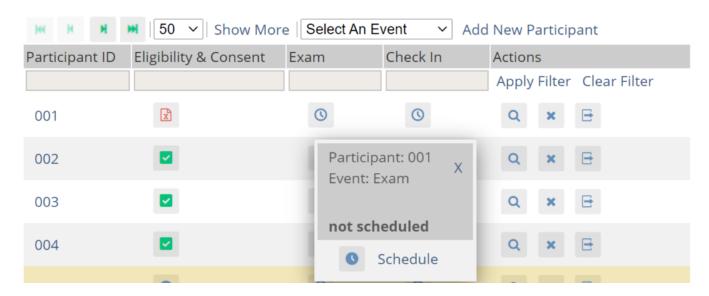
You can schedule Events from:

- The **Participant Matrix**
- The **Participant Details** screen
- The **Tasks** menu

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.

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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.

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**.

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.
0	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	At least one Form in the Event has been completed. Note: The Event status changes to Completed automatically when all Forms are complete. You can also manually set the Event to Completed if at least one Form is complete.
C	Skipped	The Event will not be completed. You can select this status from the Update Event screen when the Event is <i>Scheduled</i> . Events cannot be skipped if data entry has started.
0	Stopped	The Participant has temporarily stopped participating in the Study. Entered data remains viewable and exportable. You can select this status from the Update Event screen when the Event is <i>Scheduled</i> or <i>Data Entry Started</i> .
X	Removed	The Event has been removed. Users can still view Forms. This will supersede any of the other statuses.

Event Attributes

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



Form Actions

Some actions can be performed on Forms within Events. Permissions vary by role and/or form.

Icon	Action	Description
	Enter/Edit	Enter or edit data in the Form.
Q	View	View data in the Form.

×	Remove	Remove the Form from the Event. This is not permanent.
C	Restore	Restore a Form that was previously removed. All data is restored.
Û	Clear Form	Clear all Form data. The Form is reset to Not Started and all queries are closed. Audit history is retained.
\Rightarrow	Reassign CRF Version	Change the version of the Form if data has already been entered.

Form Statuses and Icons

The table below displays Form statuses and icons:

Icon	Status	Module	Description
v	SDV Verified	N/A	The Form has been Source Data Verified.
\mathbb{V}	SDV Required, Not Verified	N/A	The Form has at least one item requiring SDV that has not yet been verified.
V	SDV Status Changed Since Verified	N/A	The Form was verified, but a change was made that requires re-verification.
•	Query	N/A	There is at least one open query on the Form. Note: Users with review or edit permission to the form may add or update queries but cannot close them; Monitors and Data Managers with review or edit permission can also close queries; read-only users cannot create or update queries.
∓ !	Consent Not Signed	eConsen	The eConsent Form has not yet been signed by the t Participant. The Form icon appears once the Event containing the eConsent Form is scheduled.
₽	Consent Signed	eConsen	The Participant has signed the eConsent Form. The Form is t marked <i>Completed</i> . It must still be countersigned by a CRC or Investigator.
≟ *	Consent Countersigned	eConsen	The Participant has signed the eConsent Form, and it has tbeen countersigned by a CRC or Investigator. The Form is marked <i>Completed</i> .
	Requires Reconsent	eConsen	The eConsent Form was signed, but an OpenClinica user (CRC or Investigator) clicked Unconsent . The Form is marked <i>Data Entry Started</i> and reappears on the Participant's dashboard for re-signing.