



## 1.4.9 Events

An **Event** is a group of Forms used in your Study. An Event may or may not correspond to a real-world 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*.

Visit	Form	Status
Follow up (1) 02-Nov-2021	Follow Up	Not completed
Treatment (1) 01-Nov-2021	*Pre-Treatment Evaluation	Not completed
	*Treatment Administration	Not completed
	*Post Treatment Evaluation	Not completed
	Vitals	Not completed
	Pathology	Not completed
	Labs	Completed
	Exam (1) 01-Nov-2021	Exam
Vitals		Not completed
Baseline 31-Oct-2021	Exam	Completed
	Vitals	Completed

### 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).




## Adverse Event

AE [Add New](#)

Actions	Form Status	Last Updated	Updated By
⋮	Completed	08-Jul-2024	klambert+crc@openclinica.com
⋮	Data Entry Started	08-Jul-2024	klambert+crc@openclinica.com
⋮	Completed	08-Jul-2024	klambert+crc@openclinica.com

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## Event Types and Icons

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.

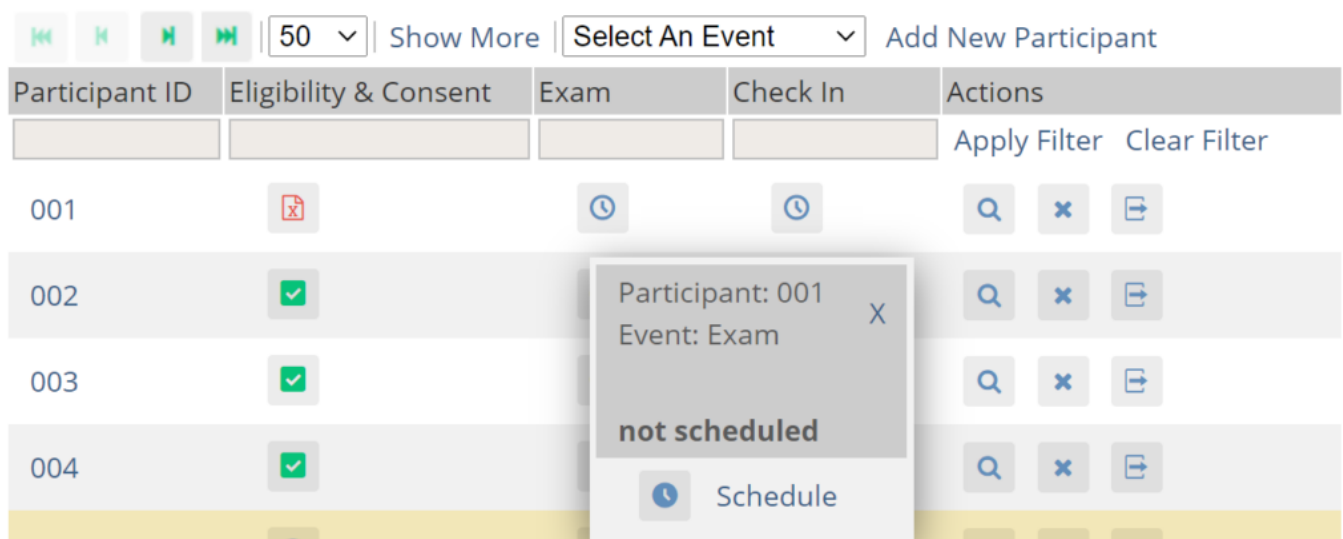
You can schedule Events from:

- The **Participant Matrix**
- 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.

## Participant Matrix for Severe Headache Study



Participant Matrix for Severe Headache Study

Navigation: 50 | Show More | Select An Event | Add New Participant

Participant ID	Eligibility & Consent	Exam	Check In	Actions
001				
002				
003				
004				

Modal Window:

Participant: 001  
Event: Exam  
not scheduled  
 Schedule

## 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**.






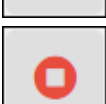

- (Optional) To schedule additional Events, click **Schedule Another Event**, and enter information for that Event. Repeat as needed.
- To go to the **Participant Details** screen to enter data, click the Proceed to **Enter Data** button.

## To Schedule a Common Event from the Participant Details screen:

- Click the Participant ID or **View** button next to a Participant.
- 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.
	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. <input type="checkbox"/> <b>Note:</b> 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.
	Skipped	The Event will not be completed. You can select this status from the <b>Update Event</b> screen when the Event is <i>Scheduled</i> . Events cannot be skipped if data entry has started.
	Stopped	The Participant has temporarily stopped participating in the Study. Entered data remains viewable and exportable. You can select this status from the <b>Update Event</b> screen when the Event is <i>Scheduled</i> or <i>Data Entry Started</i> .
	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.

Icon	Status	Description
	Signed	The Event has been signed. This icon appears in addition to the status. <input type="checkbox"/> <b>Note:</b> If a signed Event changes in any of these ways, the signature is removed: <ul style="list-style-type: none"> <li>An Item in a Form is changed.</li> <li>The Event status changes from <i>Completed</i>, <i>Stopped</i>, <i>Skipped</i>, or <i>Not Scheduled</i>.</li> <li>A Form is archived/unarchived (unless the Form status is <i>Not Started</i>).</li> <li>A Form is removed.</li> </ul> Multiple users can sign an Event. The most recent signature appears on the Form; previous signatures are recorded 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

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.
	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 Form data. The Form is reset to Not Started and all queries are closed. Audit history is retained.
	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
	SDV Verified	N/A	The Form has been Source Data Verified.
	SDV Required, Not Verified	N/A	The Form has at least one item requiring SDV that has not yet been verified.
	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. <input type="checkbox"/> <b>Note:</b> 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	eConsent	The eConsent Form has not yet been signed by the Participant. The Form icon appears once the Event containing the eConsent Form is scheduled.
	Consent Signed	eConsent	The Participant has signed the eConsent Form. The Form is marked <i>Completed</i> . It must still be countersigned by a CRC or Investigator.



Consent  
Countersigned

The Participant has signed the eConsent Form, and it has been countersigned by a CRC or Investigator. The Form is marked *Completed*.



Requires  
Reconsent

The eConsent Form was signed, but an OpenClinica user (CRC or Investigator) clicked **Unconsent**. The Form is marked *Data Entry Started* and reappears on the Participant's dashboard for re-signing.

Approved for publication by Kate Lambert. Signed on 2025-10-16 3:13PM

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