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.

Participant Matrix for Severe Headache Study

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).

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
V	SDV Verified	N/A	The form has been SDV Verified.
V	SDV Required, Not Verified	N/A	The form has not yet been SDV Verified, but has at least one SDV Required item.
V▲	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.