

1.4.5 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.

[table id=1 /]

Scheduling an Event

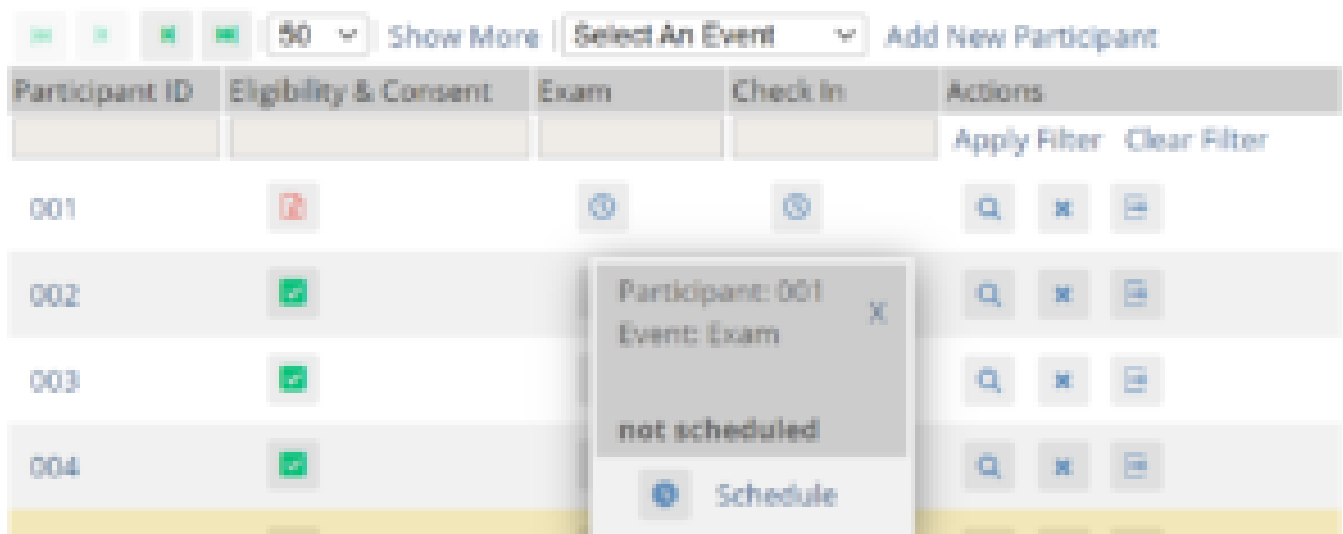
Once a Participant has been added, you can schedule Events.

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



The screenshot displays the Participant Matrix interface. At the top, there are navigation elements including a search bar with '50' and a 'Show More' button, a dropdown menu for 'Select An Event', and an 'Add New Participant' button. The table has columns for Participant ID, Eligibility & Consent, Exam, Check In, and Actions. A modal window is open over the 'Exam' column for Participant 001, showing 'Participant: 001', 'Event: Exam', and a 'Schedule' 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.

Visit Name	Date	Forms
Follow up (1)	02-Nov-2021	Follow Up
Treatment (1)	01-Nov-2021	Pre-Treatment Evaluation, Treatment Administration, Post Treatment Evaluation, Vitals, Pathology, Labs
Exam (1)	01-Nov-2021	Exam, Vitals
Baseline	31-Oct-2021	Exam, Vitals

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

AE [Add New](#)

Actions	Form Status ↑↓	Last Update ↑↓	Updated By ↑↓
Edit Search Delete Lock	completed	16-Nov-2021	rbianchi

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Casebook ?

Event Statuses

The table below displays Event statuses:

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Event Attributes

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

[table id=21 /]

Event Actions

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

[table id=22 /]

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Approved for publication by Paul Bowen. Signed on 2021-12-21 1:21AM

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