

15.3.3 About the Event Status

You can manually update the Event status as described in Update Events. For some conditions, OpenClinica automatically updates it.

There are different ways to view the status of Study Events, including these:

- Use <u>View Events</u> to see all Events that match criteria you specify.
- The Subject Matrix icons show the status for each Event for each Subject.

These are the different status values for Study Events and a description of how the status changes:

Event Status Icon Description		
Not Scheduled		After you add a Subject to a Study but but before you schedule the Event, the Event status is set to "not scheduled." For certain Events, like Adverse Events, the Status might remain "not scheduled" throughout the Study.
Scheduled	(dil	When you schedule a Subject for an Event, the Event status is automatically set to "scheduled."
		After you schedule a Subject for an Event and you open any CRF for that Event, the Event status is automatically set to "data entry started." The "data entry started" status applies even if you did not enter data.

Data Entry Started

If you inadvertently open a CRF but do not want to save data, you cannot change the Status for the CRF to "scheduled" or "not scheduled," nor can you change the Event status. To change the status you can instead delete the Event CRF or the Event for that Subject, then restore it when you are ready to enter data.

After the status for all CRFs for an Event are marked complete, the OpenClinica system automatically sets the Event status to "completed."

Completed

If you make any changes to CRFs after an Event has a status of "completed," the status of the CRFs and the Event Status remain "completed;" you might need to complete a Reason for Change Discrepancy Note, depending on your system configuration. You can manually set the Event status back to "data entry started," and then again back to "completed," as needed.

When all CRFs for an Event have a status of "completed" or "not scheduled," you can manually set the Event status to "signed." When you sign the casebook for a Subject, the OpenClinica system automatically sets the status for all Study Events for that Subject to "signed." After an Event status is "signed," any changes to the CRF automatically change the Event status to "completed." For more information, see Electronic Signatures in OpenClinica.

Signed

When a Subject does not complete an Event, manually set the Event status to "skipped."

Stopped

Skipped

When a Subject has temporarily stopped participating in a Study, manually set the Event status to "stopped."

Locked

When you no longer want users to be able to enter or change data for an Event, manually set the Event status to "locked." Note that you can set the status for a Study to "frozen" or "locked," and while that does not change the status of any Events in the Study, it does prevent users from changing data.

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