

15.4.3 Double Data Entry

Double data entry is when the data for a CRF is entered twice to ensure the integrity of the captured data. It is typically used when CRF data is first captured on paper forms, then entered into the OpenClinica system. Double data entry can be optional or required, as specified for each CRF in the Study Event Definition.

During double data entry, OpenClinica flags any differences between the values in the initial data entry and the second data entry, and provides options for resolving the differences.

There are options for who performs the double data entry and when:

- After a user completes entering the initial CRF data, a different user can perform the double entry.
- The user who initially enters the data can also perform the double entry but must wait at least twelve hours after the initial data entry to perform the double entry.
- <u>Certain user roles</u> have permission to complete initial data entry and move directly to double data entry without waiting.

This is the process for completing data entry when double data entry is configured for a CRF:

- 1. Perform initial data entry for the CRF, mark it complete, and click Save.
- 2. Perform double data entry for the CRF, mark it complete, and click Save. If the value for any Items in the double data entry are different than for the initial data entry, an error message displays. Address the difference in one of these ways:
 - If the value in the double data entry is correct, keep that value by clicking Save again.
 The Audit Log stores the user name, date, time, and value for both the value entered in initial data entry and in double data entry.
 - If the value in the initial data entry is correct, change the value to the correct one in the CRF field for the double data entry, and click Save. The Audit Log stores only the initial value.
 - If you want to maintain the value from initial data entry and from double data entry for later followup, add a Discrepancy Note, then click Save.

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