2.6.1 About Discrepancy Notes

The OpenClinica Notes and Discrepancies module provides a means for users to document, communicate, and manage issues about data in a clinical trial, in order to facilitate verification of the accuracy and completeness of the data. In the clinical trial community, these issues are sometimes referred to as queries, and are sometimes managed with data clarification forms. When you set up a Study, as part of the Study Parameter Configuration details, you specify whether or not Notes and Discrepancies will be used in the Study.

A Discrepancy Note is also referred to as a Note.

There are various situations where you use Discrepancies Notes. For example:

- You can create a Discrepancy Note when capturing or validating data in order to flag an item as incomplete or as having a value that is not expected.
- You can leave a required field in a CRF empty if you provide a Discrepancy Note that provides an explanation.
- OpenClinica can automatically create a Discrepancy Note when you save a CRF that contains errors in the data, as determined by OpenClinica's edit checking.
- OpenClinica can also automatically generate Discrepancy Notes when Rules run.

After you create a Discrepancy Note, another user, such as a Clinical Research Coordinator, reviews the Discrepancy Note and replies with information to help resolve the issue.

The original Note is referred to as the parent note. Responses to the original note are referred to as child notes. The thread of a single parent Note with the child Notes under it is referred to as one Discrepancy Note.

A Discrepancy Note is associated with a single data element, usually a CRF Item, such as a diagnosis, medication, or weight, but it can also be associated with the Subject record, such as sex or date of birth, or the Study Event, such as the date.

Once a Discrepancy Note is created, it cannot be deleted. If a Discrepancy Note is created in error, a common practice is to add a new Child Note with a Status of Closed.

To use Notes and Discrepancies, your browser must have:

- JavaScript enabled
- Pop-up blockers disabled

A Discrepancy Note has four key properties, which the user assigns when creating the note:

- Note Type
- Status
- Description
- Detailed Note

After the Discrepancy Note has been created, you cannot change the Note Type. To update the other properties, you add new child Notes.

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