

15.6.2 Types of Discrepancy Notes

The purpose, behavior, and workflow are different for each Note Type. The Note Types that can be assigned to an element depend on when in the process the Note is created. OpenClinica has these Note Types:

- Failed Validation Check
- Query
- Reason for Change
- Annotation

Failed Validation Check

A Failed Validation Check Note Type is for data that does not comply with expected values. When initially created, the Status is New. The Note then requires further review to determine if the data is acceptable. A Failed Validation Check Discrepancy Note can be created in these ways:

- A user entering data can manually create this Note Type.
- OpenClinica can automatically generate this Note Type when validating a field or using Rules or when running an Edit Check. OpenClinica first displays a warning message. If the user does not change the value to one that conforms to the expected values for the Item, it creates a Failed Validation Check Discrepancy Note. OpenClinica also generates this Note Type when importing data if the data does not conform to expected values.

Query

A Query Note Type is used to ask a question about data provided for an Item. For example, a Data Manager might create a Query Discrepancy Note to ask a Clinical Research Coordinator about an Item that seems incomplete or incorrect, even though the item has met all automated edit checks. This is a typical workflow:

1. The originator creates the Query Note. The Status is New. The originator assigns the query to the user who can answer the question.
2. The user it is assigned to updates the Query by adding a new child Discrepancy Note to the parent thread. The user might or might not modify the data value in conjunction with the update. If the user believes the issue is resolved, the user sets the Status to Resolution Proposed and assigns it to the originator, or, if the user believes further consideration is required, the user sets the Status to Updated.
3. The originator reviews the response and if satisfied, marks it as Closed, or adds further comments, assigns it back to the user, and sets the Status to Updated.

Reason for Change

If a Study is configured to include Force Reason for Change, any change made to the CRF after the CRF data entry is marked complete requires a Discrepancy Note. Typically, use the Reason for Change Note Type to address the change, but the change can also be addressed with a Query or Failed Validation Check Note Type. A Reason for Change Discrepancy Note always has a Status of Not Applicable.

Annotation

Annotation Discrepancy Notes are to make comments or provide information about the data that cannot be adequately represented in the CRF. Refer to guidelines for your CRF and Study about appropriate use of Annotations. Annotation Notes always have a Status of Not Applicable.

This page is not approved for publication.