



## 2.6.4.1 Create a Discrepancy Note

Discrepancy Notes can be created automatically by OpenClinica, or by users.

### Automatically-Created Discrepancy Notes

OpenClinica can automatically generate a Discrepancy Note as part of an Edit Check or data validation:

- When a CRF is marked complete and you make a change to an Item in it, OpenClinica automatically creates a Reason for Change Discrepancy Note for you to fill out, if the [Study Parameters Configuration](#) setting for Forced Reason for Change in Administrative Editing is marked "Yes."
- When you enter data into a CRF, if you do not provide a value for a required field and click Save, OpenClinica prompts you to provide a value. You must either provide the missed value or click the flag next to the item to create a "[Missing data in a required field.]" Discrepancy Note.
- When you import data into OpenClinica, if there are errors, OpenClinica automatically generates a Failed Validation Check Type of Discrepancy Note.

### User-Created Discrepancy Notes

A user can generate a Note in OpenClinica during data entry or when reviewing a CRF, as follows:

1. When viewing or entering data for a CRF Item, click the Add Discrepancy Note icon  next to the Item.  
The Add Discrepancy Note window opens for that Item.
2. In the Add Discrepancy Note window, complete the fields. Some of the options are available only for appropriate User Roles or based on the circumstances under which you are creating the Discrepancy Note. Some of the options available are different after you've created the Note and can be assigned when you [Update the Discrepancy Note](#):
  1. Complete the Description and Detailed Note fields.
  2. Select the Type from the drop-down list. The list includes only the appropriate options. If you accessed the Discrepancy Note by viewing rather than editing, you can only select the Query Type.
  3. Select the Status for the Discrepancy Note from the drop-down list. The list includes only the appropriate options.
  4. For a Query Note Type, select from the Assign to User drop-down list the user you recommend to take the next step for the Note; note that OpenClinica will not prevent other users from taking the next action for the Note. To send an email to the assigned user, select the Email Assigned User checkbox. You cannot assign other Types of Discrepancy Notes when creating the Note.
3. Click Submit.  
A message replaces the contents of the window, indicating the Note was created. The window then closes automatically.
4. In the CRF page, the flag icon for the Item is no longer blue, but instead is a color that reflects the status of the Discrepancy Note.

### The Add Discrepancy Note Window:

**Con\_Med\_Name: Add Discrepancy Note**

"Con\_Med\_Name" Properties:

Subject:	<b>CAM107</b>	Event:	<b>Initial Treatment</b>
Event Date:	<b>13-Jul-2011</b>	CRF:	<b>Concomitant Medications</b>
Current Value:	<b>asprin</b>	More:	<a href="#">Data Dictionary</a>

**Add Note**

Description:\*

Detailed Note:

Type:\*

Set to Status:\*

### Multiple Discrepancy Notes for a CRF Item

If a Discrepancy Note already exists for an Item, and you want to create a new, different Note for the Item:

1. In the CRF, click the flag icon for the existing Discrepancy Note for that Item.  
OpenClinica opens the Notes and Discrepancies window, which contains details for the Item.
2. In the Notes & Discrepancies window, click Begin New Thread.
3. Complete the process as if adding a new Discrepancy Note.

Functional approval by Laura Keita. Signed on 2015-05-27 3:43PM

Approved for publication by Ben Baumann. Signed on 2015-05-29 8:39AM

Not valid unless obtained from the OpenClinica document management system on the day of use.