

15.6.4 Working with Individual Discrepancy Notes

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15.6.4.1 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:

The screenshot shows a web form titled "Con_Med_Name: Add Discrepancy Note". At the top, there is a section labeled "Con_Med_Name" Properties: containing a table with the following data: Subject: CAM107, Event: Initial Treatment, Event Date: 13-Jul-2011, CRF: Concomitant Medications, Current Value: aspirin, and More: Data Dictionary. Below this is the "Add Note" section. It includes a "Description:" label followed by a text input field, a "Detailed Note:" label followed by a larger text area, a "Type:" label with a dropdown menu set to "Annotation", and a "Set to Status:" label with a dropdown menu set to "Not Applicable". A blue "Submit" button is at the bottom of the form.

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.

15.6.4.2 View a Discrepancy Note

To see a list of Discrepancy Notes or to find a Discrepancy Note, see [Manage Discrepancy Notes](#).

To view a Discrepancy Note in OpenClinica:

1. Go to the CRF page that contains the Discrepancy Note.
2. Hover over the flag icon for the Item that has the Discrepancy Note.
OpenClinica displays a pop-up window with summary information about the Discrepancy Note.
3. Click the flag icon to view details about the Discrepancy Note.

OpenClinica displays details for the Discrepancy Note in a Notes and Discrepancies window. If there are multiple Discrepancy Notes associated with the Item, each Note is presented in a separate table, and has a unique Note ID.

4. When you finish viewing the Note details, close the Notes and Discrepancies window by clicking Exit Window in the top right corner.

Example of an Annotation Discrepancy Note:

Con_Med_Name: Notes and Discrepancies
Exit Window

"Con_Med_Name" Properties:

Subject: **CAM107** Event: **Initial Treatment**
Event Date: **13-Jul-2011** CRF: **Concomitant Medications**
Current Value: **aspirin** More: [Data Dictionary](#)
 [Audit History](#)

Note Details

☒ **Aspirin Usage**

Last updated: **19-Dec-2011** by **ChrisRCole**
Assigned to: **()**

ID: 33	Type: Annotation	Current Status: Not Applicable	# of Notes: 1
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Aspirin Usage

Status: **Not Applicable** 19-Dec-2011 by **ChrisRCole**

Takes aspirin regularly to treat headaches.

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	19-Dec-2011 10:49:08	ChrisRCole	Con_Med_Name	asprin	aspirin

(This item was initially entered on 09-Dec-2011.)

15.6.4.3 Update a Discrepancy Note

You can update any Discrepancy Note, even if it is assigned to someone else.

To update a Discrepancy Note:

1. View the Discrepancy Note in one of these ways:
 - Go to the CRF page that contains the Discrepancy Note and click the flag icon for that Item.
 - From the [Notes and Discrepancies table](#), click the View icon for the Discrepancy Note.
2. In the Discrepancy Note window, click the button that represents the status you are setting the Note to. For example:
 - If you will add more information that needs to be reviewed, click Update Note.
 - If the information you plan to provide should be enough to allow the Note to be Closed, click Propose Resolution.
 - If your [User Role allows it](#) and you have enough information, you can close the Discrepancy Note by clicking Close Note.

The window expands, showing fields that allow you to add a thread to the Note.

3. Complete the fields: Description, Detailed Note, Status, and if appropriate given the Status value, Assign to User and Email Assigned User. Note that you can specify a user to assign the Discrepancy Note to if the Type is Query or Failed Validation Check.
4. Click Submit to save the updated information but keep the window open, or click Submit and Exit to save the updated information and close the window. If you do not want to save any of the information you provided in updating the Note, click the Exit Window link (in the upper right corner).

The Discrepancy Note includes the information you provided as a new child note in the thread. In the CRF and in the Notes and Discrepancies table, the color of the flag icon for that Note changes to reflect the new status.

Example of an Updated Discrepancy Note:

Con_Med_Name: Notes and Discrepancies [Exit Window](#)

"Con_Med_Name" Properties:
Subject: **CAM107** Event: **Initial Treatment**
Event Date: **13-Jul-2011** CRF: **Concomitant Medications**
Current Value: **aspirin** More: [Data Dictionary](#)
[Audit History](#)

Note Details

☐ **What is the frequency of aspirin usage?** Last updated: **19-Dec-2011** by **StuartDirk**
Assigned to: **Stuart Dirk (StuartDirk)**

ID: 42	Type: Query	Current Status: Updated	# of Notes: 2
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What is the frequency of aspirin usage?

Status: New

19-Dec-2011 by StuartDirk
Assigned to: Chris Cole (ChrisRCole)

Please clarify how often the Subject has headaches and how often the Subject takes aspirin as treatment.

Frequency of headaches is **eeekly**

Status: Updated

19-Dec-2011 by ChrisRCole
Assigned to: Stuart Dirk (StuartDirk)

Subject indicated that headaches occurred on at least a weekly basis, but aspirin not always needed. Should I get more details on how often?

[Update Note](#) [Propose Resolution](#) [Close Note](#)

☐ **Aspirin Usage** Last updated: **19-Dec-2011** by **ChrisRCole**
Assigned to: **()**

ID: 33	Type: Annotation	Current Status: Not Applicable	# of Notes: 1
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Aspirin Usage

Status: Not Applicable

19-Dec-2011 by ChrisRCole

Takes aspirin regularly to treat headaches.

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	19-Dec-2011 10:49:08	ChrisRCole	Con_Med_Name	asprin	aspirin

(This item was initially entered on 09-Dec-2011.)