

OpenClinica Data Entry User's Guide



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Overview and Purpose

The following OpenClinica user guide explains the roles configured for Data Entry personnel. This guide also details the data entry screens, workflows, monitoring, auditing and the functions associated with locking a Study Event after all Case Report Forms (CRFs) have been completed.

Case Report Forms and Study Event Status

(**Figure 1**) displays the Status and Action icon keys that help identify the study event's progression within the Study Management System.

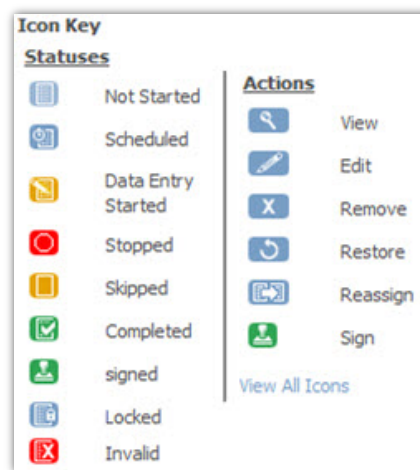


Figure 1

OpenClinica Data Entry Roles

After successfully logging into OpenClinica (with one of the following roles), the Subject Matrix page will display (see **Figure 2**).

Note: The Subject Matrix page contains a list of the subject records that designated roles can access.

Study Data Entry Role

- The Study Data Entry role can create subjects at the study level for any site.
- This role also has access to all subject data for the study.

Site Clinical Research Coordinator Role

- The Clinical Research Coordinator role can only create subjects for the assigned site.
- This role only has access to subject data for that site.

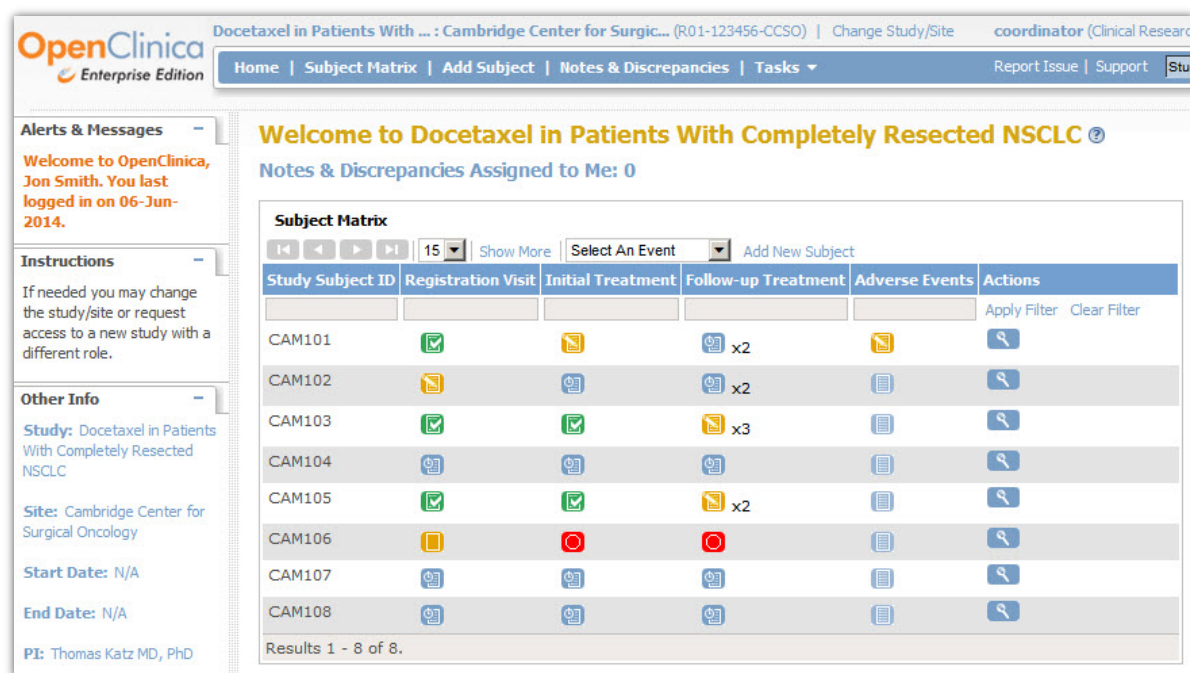
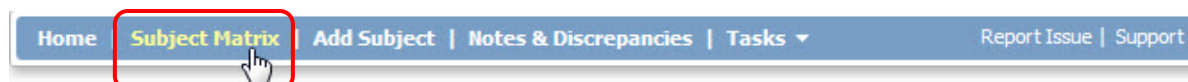


Figure 2

Viewing Study Subjects

The Subject Matrix page displays a grid listing all participating subjects and their study event status.

1. To view all subjects enrolled in the study, click on the Subject Matrix link located on the menu bar.



2. The Matrix can be filtered by the Study Subject ID and Study Event names.
3. Study Events are configured and contain the CRFs that are relevant for the event.

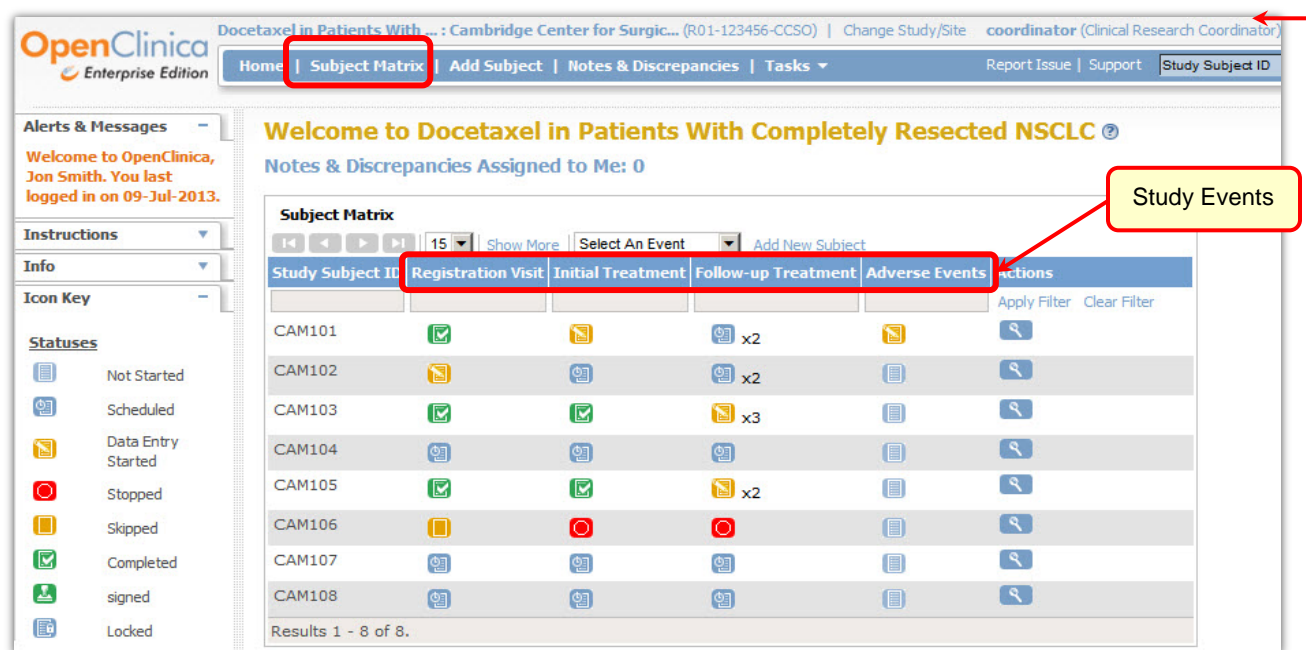


Figure 3

Creating New Study Subjects

1. There are various ways to create a new subject:
 - a. Use the **Add Subject** link on the menu bar, or
 - b. Click on the **Add New Subject** link, or
 - c. Click the Tasks menu, and select the **Add Subject** option under the Submit Data section.

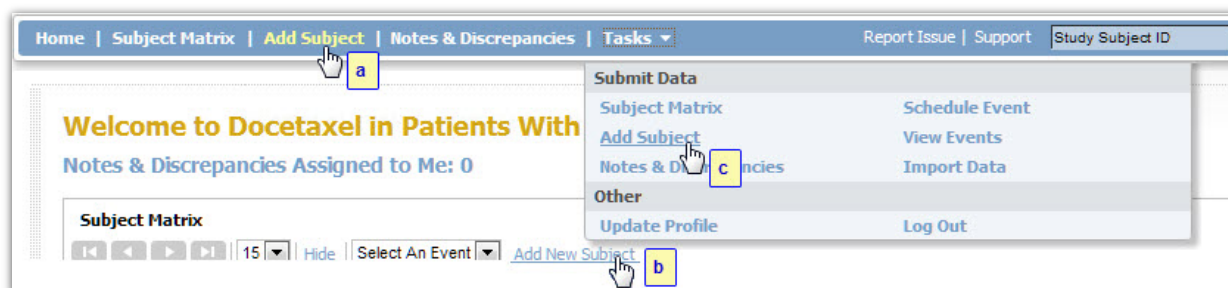


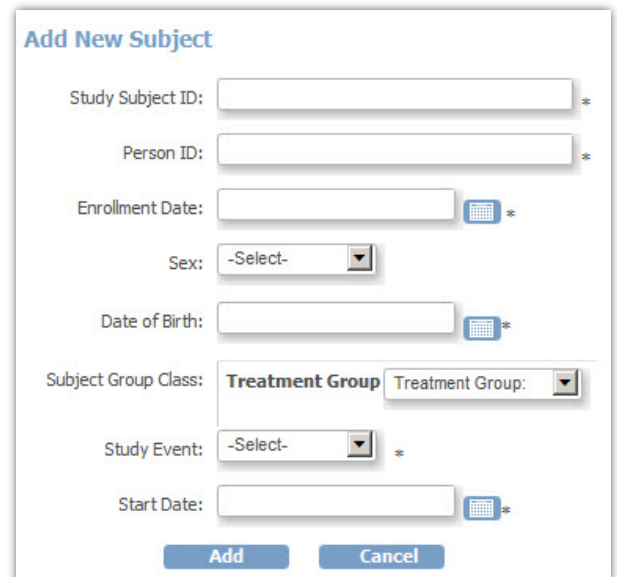
Figure 4

Note: Use any of these links to correctly add a new subject to the system.

2. At the Add New Subject window:
 - a. The Study Subject ID can be configured for manual entry or automatically system generated.
 - b. The Person ID is an *optional* manual entry field.

This field can be used to track an individual across studies (e.g., for MWPNC-related studies, it will be MWPNC - ##) or MRN if there is a need to maintain a link between a subject's Study ID and the patient's Clinical ID.

Note: All entries with an asterisk (*) require a response.






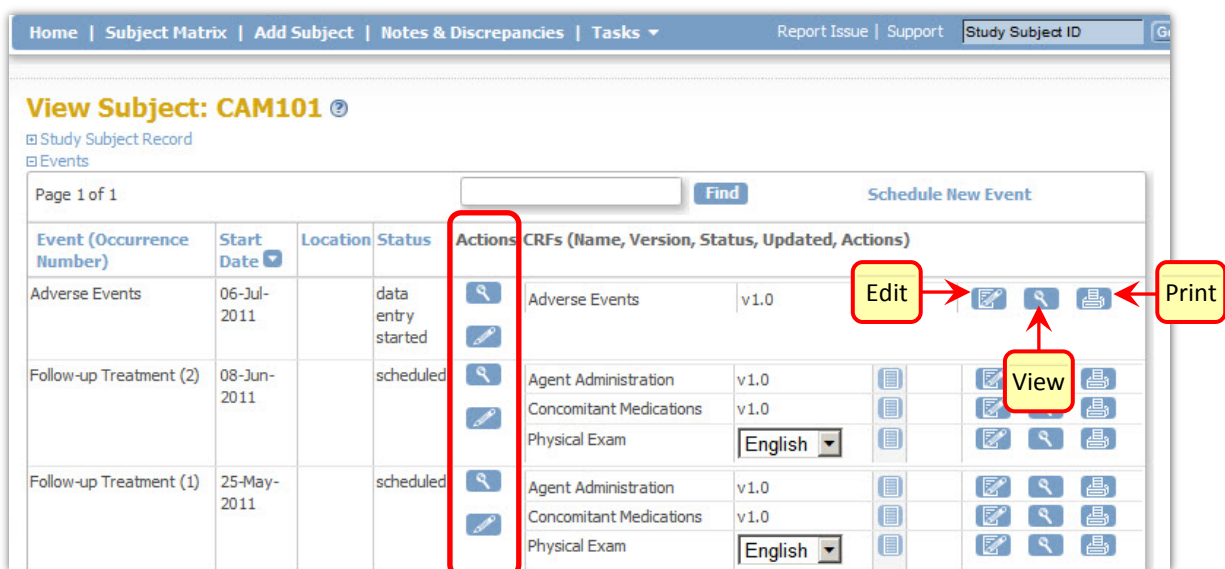
The 'Add New Subject' window contains the following fields and controls:

- Study Subject ID: Text input field with an asterisk (*)
- Person ID: Text input field with an asterisk (*)
- Enrollment Date: Date picker with an asterisk (*)
- Sex: Dropdown menu with '-Select-' selected
- Date of Birth: Date picker with an asterisk (*)
- Subject Group Class: Dropdown menu with 'Treatment Group' selected; a secondary 'Treatment Group' dropdown is also present.
- Study Event: Dropdown menu with '-Select-' selected and an asterisk (*)
- Start Date: Date picker with an asterisk (*)
- 'Add' and 'Cancel' buttons at the bottom.

Figure 5

Viewing and Entering Individual Subject Records

1. An individual's record displays after the subject and study event is created. Click on the Action icons in the "Actions" column to perform data actions:
 - Use the magnifying glass  to view all records for an individual. Figure 6 is an example of an individual subject's record.
 - Use the paper/pencil icon  to open/edit the CRF to enter data into the form.
 - Use the print icon  to print the CRF.



The 'View Subject: CAM101' interface shows a table of events with columns: Event (Occurrence Number), Start Date, Location, Status, and Actions. The 'Actions' column contains icons for viewing, editing, and printing. A red box highlights the 'Actions' column. A yellow box labeled 'Edit' points to the pencil icon. A yellow box labeled 'View' points to the magnifying glass icon. A yellow box labeled 'Print' points to the print icon.








Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Adverse Events	06-Jul-2011		data entry started	 	Adverse Events v1.0
Follow-up Treatment (2)	08-Jun-2011		scheduled	 	Agent Administration v1.0 Concomitant Medications v1.0 Physical Exam English
Follow-up Treatment (1)	25-May-2011		scheduled	 	Agent Administration v1.0 Concomitant Medications v1.0 Physical Exam English

Figure 6

- Data can also be entered into the CRFs for a specific event by clicking on the  Data Entry Started icon for a subject, and then clicking on the View/Enter Data link.

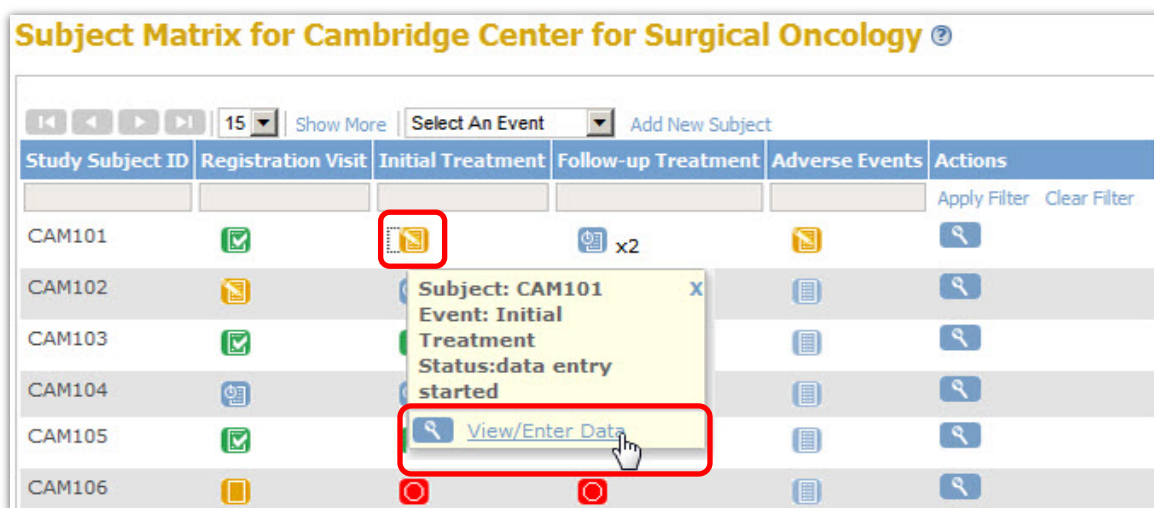


Figure 7

- The View/Enter Data option will open a screen that has a table with the list of CRFs that are part of the event.



Figure 8

4. If the CRF has multiple sections, use the tabs or drop-down arrow to move between the **tabbed sections**.
 5. After entering and saving data in a tab, users are automatically taken to the next tabbed section.
- Note:** Alert notifications and information will display to help guide data entry.
 Example: The **orange** text shows a message that data has been saved, but can be edited.


The screenshot shows the 'Physical Exam English' CRF form for 'CAM101'. A red box highlights a message at the top: 'Your data has been saved. You can continue entering/editing data now or return at a later time.' Below this, there are tabs for 'I Basic (9/9)', 'II Body...(18/35)', and 'III Oth...(0/3)'. A red arrow points from the message box to the 'II Body...' tab. The form content includes a 'Title: Body System/Site' section with a 'Page:' indicator, 'Save' and 'Exit' buttons, and a 'Body Mass Index' field with the value '18.49'. Below this is a section titled 'Body System / Site' with instructions: 'If 'Abnormal' is selected, comments are required.' It contains three rows of data entry: '9 Appearance Normal', '10 Skin Normal', and '11 H/E/E/N/T Normal', each with a dropdown menu and a flag icon.

Figure 9

6. Data entry is complete for a study event after all CRFs assigned to that study event have been marked complete. To mark a CRF complete, place a check in the checkbox next to "Mark CRF Complete."
- a. At the message asking for a confirmation to complete the CRF, click OK to confirm the completion.

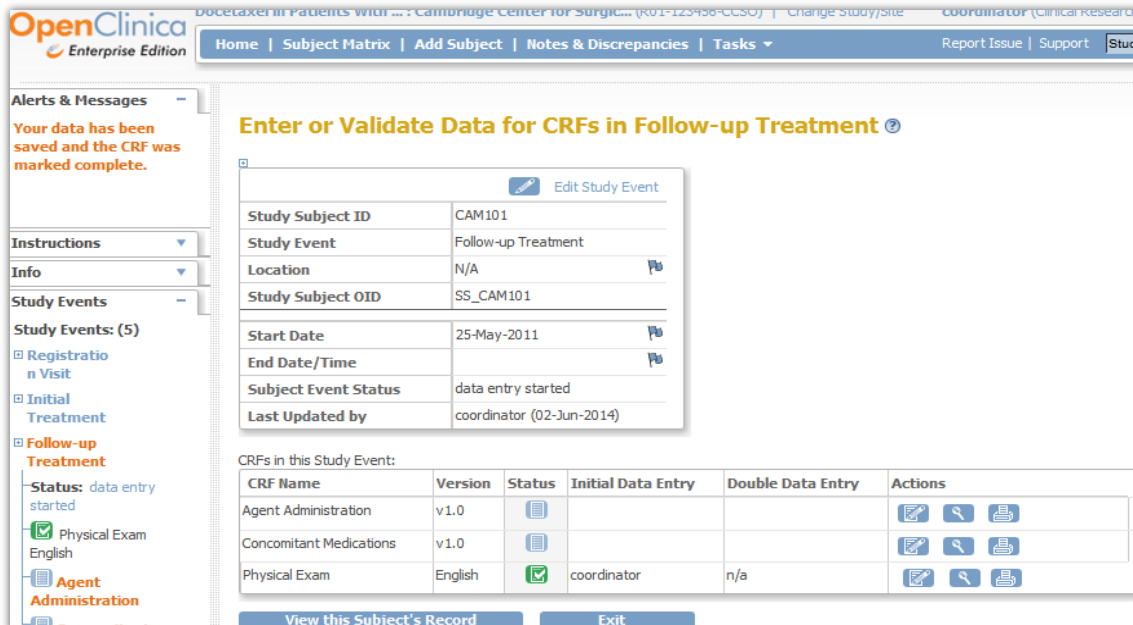
The screenshot shows the 'Physical Exam English' CRF form for 'CAM101'. The 'III Oth...(0/3)' tab is selected. A red box highlights the 'Mark CRF Complete' checkbox, which is checked. Below the form, a 'Message from webpage' dialog box is displayed. The message reads: 'Marking this CRF complete will finalize data entry. You will be allowed to edit the data later but this data entry stage is completed. If Double Data Entry is required and has not started, you or another user may need to complete this CRF again before it is verified as complete. Are you sure you want to mark this CRF complete?' The dialog box has 'OK' and 'Cancel' buttons. The background form shows the 'Title: Specify Other Body System/Site' section with a 'Page:' indicator, 'Save' and 'Exit' buttons, and a table for 'Other Body System / Site' with columns for 'Other Body System/Site:' and 'Sta'. There is an 'Add' button and a 'Return to top' link.

Figure 10

7. When all study event CRFs are completed, the study event's status changes to complete and a green  checkmark icon will display.

Notes:

- Once the CRF has a complete status any changes made to the CRFs data will be tracked in an audit trail.
- The completed data can be altered (Administrative Editing); however, OpenClinica automatically creates a “Reason for Change” discrepancy note (See **Adding Discrepancy Notes**) that will be completed by the person entering the data.



OpenClinica Enterprise Edition

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study

Alerts & Messages
Your data has been saved and the CRF was marked complete.











Instructions
Info
Study Events
Study Events: (5)
Registration Visit
Initial Treatment
Follow-up Treatment
Status: data entry started
Physical Exam English
Agent Administration
Concomitant

Enter or Validate Data for CRFs in Follow-up Treatment

[Edit Study Event](#)

Study Subject ID	CAM101
Study Event	Follow-up Treatment
Location	N/A
Study Subject OID	SS_CAM101
Start Date	25-May-2011
End Date/Time	
Subject Event Status	data entry started
Last Updated by	coordinator (02-Jun-2014)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Agent Administration	v1.0				  
Concomitant Medications	v1.0				  
Physical Exam	English		coordinator	n/a	  

[View this Subject's Record](#) [Exit](#)

Figure 11

Discrepancy Note Color Statuses

The status of a discrepancy note is denoted by the color of the flag next to the data entry box.



Default:

This is the default status, no note has been created.



Initial:

This is a “Query” note for the initial status of a “Failed Validation Check.”



Resolution Proposed:

This is the “Resolution Proposed” status, which occurs when a user (typically the data entry person) resolves a data problem, or gives an explanation that the data entered is correct. This occurs in a child Note, and sets the note’s status to “Resolution Proposed.” Applies only to notes with the “Query” or “Failed Validation Check” type.



Closed:

When a note has a Closed status, it cannot be changed nor can a child Note be created. This happens when a monitor has reviewed and accepted proposed resolution or data update. Only an individual with a monitor or study Data Manager or Study Director can close a note.




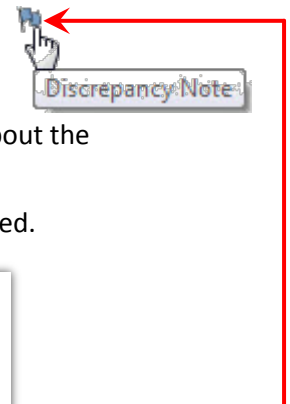
Not Applicable:

This status applies only to a note regarding the “Reason for Change” or “Annotation.” Because no further action is required for these types of notes.

Adding Discrepancy Notes

Note: If issues are encountered while entering data, create a Discrepancy Note to track the issue.

1. To create a Discrepancy Note, click on the  flag icon to the right of the data fields that have an issue.
2. The flag provides a visual indicator that a Discrepancy Note has been created for the CRF. It acts as a validation check failure, and provides information and a description about the reason the note is being entered.



Note: The Discrepancy note can only be saved, if the CRF data entry has already started.

Figure 12

3. There are three different Discrepancy Note types that a Data Entry and Clinical Research Coordinator role can select:

Figure 13

- Failed Validation Check** – select this type of discrepancy note, if the data does not comply with expected values. OpenClinica can also create this note, if a response failed validation and the data entry person does not change the response value after receiving a warning.

Note: The “Failed Validation Check” note will have a status of “New” when first created, and then it can be changed to “Updated,” “Resolution Proposed,” or “Closed.”

- Annotation** – select this discrepancy note to include a comment, or provide information about data that cannot be adequately represented in the CRF.
- Reason for Change** – select this discrepancy note, if the data needs to be changed after the CRF is marked Completed.

Note: An “Annotation” or “Reason for Change” note will always have a “Not Applicable” status.

Viewing and Updating Discrepancy Notes

1. To view all discrepancy notes, click on the "Notes & Discrepancies" link on the menu bar, or click on the "Tasks" menu, and select the Notes & Discrepancies option.

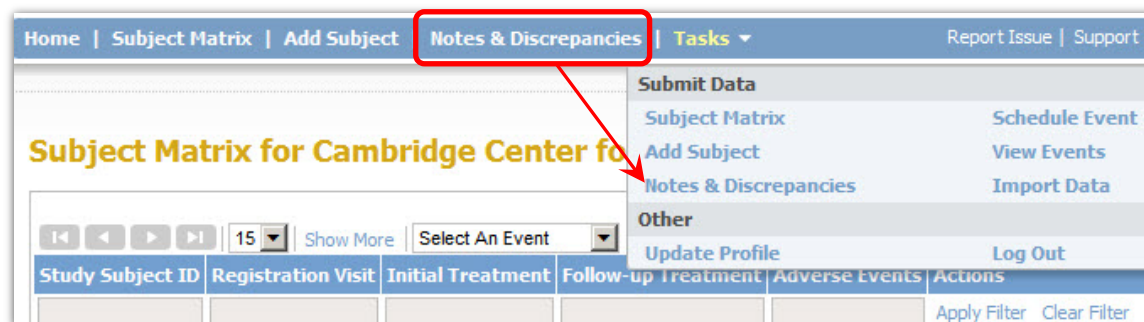





Figure 14





2. To view or update the Discrepancy Note details, click the magnifying glass  or the arrow  next to the note to view the note within the associated CRF. Also, clicking on the flag  next to the data entry field in the CRF can also be used to view the discrepancy note details.

Note: New notes will be sorted to the top and all columns in grid can be filtered.

The screenshot shows the 'Notes and Discrepancies' page. At the top, there is a navigation bar with links: Home, Subject Matrix, Add Subject, Notes & Discrepancies (highlighted), and Tasks. Below the navigation bar, there is a search bar for 'Study Subject ID' and a 'Go' button. The main content area is titled 'Notes and Discrepancies' and includes a 'Hide summary statistics' link. Below this, there is a summary table with columns: Query, Failed Validation Check, Reason for Change, Annotation, and Total. The summary table shows the following data:

Query	Failed Validation Check	Reason for Change	Annotation	Total
New	1	1	--	2
Updated	--	--	--	--
Resolution Proposed	--	--	--	--
Closed	--	--	--	--
Not Applicable	--	--	1	1
Total	1	1	--	1

Below the summary table, there is a grid of notes with columns: Study Subject ID, Type, Resolution Status, Site ID, Days Open, Days Since Updated, Event Name, CRF, Entity Name, Entity Value, Description, Assigned User, and Actions. The grid shows two rows of notes:

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
CAM105	Query	New	R01-123456-CCSO	1062	1062	Registration Visit	Verification of Informed Consent	IFC_PDF		Please attach signed informed consent	Alicia Goodwin (agoodwin)	 
CAM105	Failed Validation Check	New	R01-123456-CCSO	1062	1062	Initial Treatment	Physical Exam	PULSE	59	Pulse was taken twice and	()	 

The 'Actions' column in the grid has icons for magnifying glass, arrow, and flag, which are highlighted with a red box.

Figure 15

- Discrepancy Notes with the “Failed Validation Check” or “Query” type can be updated, resolved or closed. However, an individual with the Data Entry or Research Clinical Coordinator role only has the “Update Note” or “Proposed Resolution” button to choose from to change the status of the note.

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

"PULSE" Properties:

Subject: **CAM105** Event: **Initial Treatment**
 Event Date: **01-Aug-2011** CRF: **Physical Exam**
 Current Value: **59** More: [Data Dictionary](#)
[Audit History](#)

Note Details

☐ **Pulse was taken twice and was 59 BPM** Last Updated: **06-Jul-2011** by **agoodwin**
 Assigned to: **()**

ID: 7	Type: Failed Validation Check	Current Status: New	# of Notes: 1
--------------	--------------------------------------	----------------------------	----------------------

Pulse was taken twice and was 59 BPM Status: **New** 06-Jul-2011 by **agoodwin**
 [Pulse rate out of expected range of 60-100(must be an integer)]

Update Note **Propose Resolution**

[Begin New Thread](#)

Audit History

(No changes have been made to this data point since it was initially entered on 06-Jul-2011.)

Select the either Update Note or Propose Resolution button to change the Note's status

Figure 16

- Clicking either Update Note or Propose Resolution button will display the following window.

Update Note **Propose Resolution**

Respond below to Update/Resolve/Close this Discrepancy Note: [?](#) [X](#)

Description: *

Detailed Note: *

Set to Status: *

Submit **Submit & Exit**

Figure 17

- Enter a Description and a Detailed Note (optional), and click the “Submit & Exit” button to Save the entry and Exit, or click the “Submit button” to just Save the entry.
- Click on the “Exit Window” link at the top right corner of the window to exit without saving the entry.

- This creates a child thread from the information entered. The color of the flag inside the CRF will change to reflect the status change.

PULSE: Notes and Discrepancies

"PULSE" Properties:

Subject: **CAM105** Event: **Initial Treatment**
 Event Date: **01-Aug-2011** CRF: **Physical Exam**
 Current Value: **59** More: [Data Dictionary](#)
[Audit History](#)

Note Details

☐ **Pulse was taken twice and was 59 BPM** Last Updated: **06-Jun-2014** by **agoodwin**
 Assigned to: **()**

ID: 7	Type: Failed Validation Check	Current Status: Updated	# of Notes: 2
--------------	--------------------------------------	--------------------------------	----------------------

Pulse was taken twice and was 59 BPM	Status: New	06-Jul-2011 by agoodwin
[Pulse rate out of expected range of 60-100(must be an integer)]		
testing only	Status: Updated	06-Jun-2014 by coordinator

Update Note **Propose Resolution**

A new child note has been added successfully.

[Begin New Thread](#)

Audit History

Figure 18

- If the Discrepancy Note is for a "Query" type, then the note can be assigned to an individual and an email will be sent to the individual listed.

Respond below to Update/Resolve/Close this Discrepancy Note:

Description: *

Detailed Note:

Set to Status: * **Updated**

Assign to User: **Monitor, Alicia (ag_monitor)**

Email Assigned User: ☐

Submit **Submit & Exit**

Figure 19

9. Click the “Begin New Thread” link to begin a new discrepancy note in the same field.

PULSE: Notes and Discrepancies

"PULSE" Properties:
Subject: **CAM105** Event: **Initial Treatment**
Event Date: **01-Aug-2011** CRF: **Physical Exam**
Current Value: **59** More: [Data Dictionary](#)
 [Audit History](#)

Note Details

☐ **Pulse was taken twice and was 59 BPM** Last Updated: **06-Jun-2014 by agoodwin**
Assigned to: **()**

ID: 7	Type: Failed Validation Check	Current Status: Updated	# of Notes: 2
--------------	--------------------------------------	--------------------------------	----------------------

Pulse was taken twice and was 59 BPM	Status: New	06-Jul-2011 by agoodwin
[Pulse rate out of expected range of 60-100(must be an integer)]		
testing only	Status: Updated	06-Jun-2014 by coordinator

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

[Begin New Thread](#)

Audit History
(No changes have been made to this data point since it was initially entered on 06-Jul-2011.)

Figure 20