

15 Submit Data

OpenClinica's Submit Data module allows OpenClinica users to track Subjects in the current Study, add new Subjects to the Study, view and schedule Events, enter and change information about Subjects and Events, create Notes and Discrepancies, and import data.

To access features in the Submit Data module, from the navigation bar select Tasks and then select the feature you want. See the [Glossary](#) for a description of terms used in this chapter.

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15.1 Add Subject

When you add a Subject to a Study, you create a Study Subject record and schedule one or more Events for the Subject. If you create a Rule with an [EventAction](#), when you add a Subject and schedule the first event, all subsequent events will be scheduled automatically. This saves you the effort of manually scheduling all the events for all subjects.

There are different ways to add a Subject to a Study:

- [From the Subject Matrix](#): Use to add one Subject and schedule the first Event.
- [From the Tasks menu](#): Use to add more than one Subject or schedule multiple Events. Scheduling multiple events for subjects is also possible by creating a Rule with an [EventAction](#).

Before you can add a Subject to a Study or Site, the Study or Site must exist and the [Study Status must be Available](#).

A Subject is added to the current Study or Site, although you can later change the assignment: see [Assign or Reassign Subject to Site](#).

After adding a Subject, you can edit the information in their Subject record, which you access from the Subject Matrix: see [View and Edit Details for a Subject](#).

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15.1.1 Add New Subject from Subject Matrix

To add one Subject and schedule the first Event for the Subject:

1. In the Subject Matrix, click the Add New Subject link.
The Add New Subject page opens. Complete the information on the page as described in the following steps. Some of the information might be optional for your Study; an asterisk (*) indicates a required field. For a description of the terms, see the [Glossary](#).
2. Enter the Study Subject ID. **Note:** For your Study, OpenClinica might be configured to automatically generate the ID.
3. Enter the Enrollment Date in the specified format, or click the calendar icon to select it.
4. Select the Sex.
5. Enter the Date of Birth in the specified format, or click the calendar icon to select it.
6. Select the Group(s) from the drop-down list, if any Subject Group Classes were defined in the Study setup.
7. Select the first Study Event from the drop-down list.
8. Enter the Start Date for the Event, or click the calendar icon to select it.
9. Click Add to add the Subject to the Study, or click Cancel and no data about the Subject is saved.

Add New Subject

Study Subject ID: *

Person ID: *

Enrollment Date: *

Sex:

Date of Birth: *

Subject Group Class:

Study Event: *

Start Date: *

15.1.2 Add Subject from Tasks Menu

To add more than one Subject, schedule one or more Events for the added Subjects, or provide more than the most common information for the new Subjects:

1. Select Tasks > Add Subject.
The Add Subject page opens. Complete the information on the page as described in the following steps. Some of the information might be optional for your Study; an asterisk (*) indicates a required field. For a description of the terms, see the [Glossary](#).
2. Enter the Study Subject ID.
3. Enter the Person ID.
4. Enter the Secondary ID.
5. Enter the Date of Enrollment in the specified format, or click the calendar icon to select it.

6. Select the Sex.
7. Enter the Date of Birth in the specified format, or click the calendar icon to select it.
8. Select the Group(s) from the drop-down list, if any Subject Group Classes were defined in the Study setup, and enter any notes.
9. Click one of these buttons, depending on what you want to do next:
 - Save and Assign Study Event: Adds the Subject and opens the Schedule an Event form for the Subject.
 - Save and Add Next Subject: Adds the Subject and opens the Add Subject form again so you can add another Subject.
 - Save and Finish: Adds the Subject and displays the Subject Matrix.
 - Cancel: Does not save the Subject and displays the Subject Matrix.

Docetaxel in Patients With Completely Resected NSCLC : Add Subject ⓘ

* indicates required field.

Study Subject ID: *

Person ID: *

Secondary ID

Date of Enrollment for Study: Docetaxel in Patients With Completely Resected NSCLC : * ⓘ

Sex: ⓘ

Date of Birth: ⓘ

Subject Group Class: **Treatment Group**


Notes:

15.1.3 Assign or Reassign Subject to Site

When you add a Subject, the Subject is added to the current Study or Site. Typically, you set the current Site and add Subjects to it. However, you can add a Subject to the overall Study and later assign the Subject to a Site. You can also change the Site a Subject is assigned to.

The Site a Subject is assigned to is reported in the [Study Subject Record](#). You can also see the Site assignment in the Subject matrix. When the current Study or Site is set to the Site level, the Subject matrix shows only the Subjects assigned to that Site, so any Subject in the matrix is assigned to the current Site. When the current Study or Site is set to the Study level, view the Site assignments in the Subject Matrix by clicking the Show More link. The Site ID field reports the Site assignment, where the Site ID names were established when the Sites were created.

To assign a Subject to a Site, or to reassign a Subject to a different Site:

1. Change the current Study to the Study level.
 2. Locate the Subject in the Subject matrix.
 3. In the Actions column for the Subject, click the Reassign icon .
- The Reassign Study Subject page opens, with the Subject's current assignment selected.

Reassign Study Subject

You choose to reassign the following subject:

Study Subject ID	STU101
Person ID	12345
Sex	m
Date Created	02-Mar-2012

Please choose a study in the following list:

☒ Docetaxel in Patients With Completely Resected NSCLC (currently in)

☐ Cambridge Center for Surgical Oncology

☐ Center for Cancer Research at Cambridge

☐ Somerville Cancer Research Consortium

☐ Somerville Medical Center

4. Select the Site you want to assign the Subject to and click Reassign Subject.
The Confirm Reassign Subject page opens.
5. Click Submit.
The Subject is now assigned to the Site you specified.

15.1.4 Adding a Subject to More than One Study

After adding a Subject to a Study in OpenClinica, the Subject can participate in other OpenClinica Studies. Add the Subject to each Study, using the same Person ID. When you add a Subject to a second or subsequent Study, OpenClinica presents you with a confirmation screen, and ensures that the Sex and Date of Birth for that Subject match the values already in the database for the Subject.

15.2 Schedule an Event

About Study Events

In OpenClinica, a Study Event has a type, date(s), status, and a package of Case Report Forms (CRFs) associated with it. A Study Event is also referred to as an Event.

Each Event is assigned an Event Definition, for example, Registration Visit.

Events can be repeating (occur more than once) or non-repeating (occur once).

For repeating Events, an ordinal is assigned to each occurrence of the Event (for example,


FOLLOWUP[1], FOLLOWUP[2], FOLLOWUP[3], etc.).

There are different ways that Study Events can be configured:

- **Scheduled Study Event:** When CRFs are expected for each subject as part of the planned sequence for the Study.
- **Unscheduled Study Event:** When the CRFs are designed to collect data that might or might not occur for any Subject, such as for early termination due to a serious adverse event.
- **Common Study Event:** When the CRFs are used for more than one different event, such as a Concomitant Medications Log.

Events can be scheduled automatically using a Rule with an [EventAction](#), or can be scheduled manually as outlined below.

Schedule a Study Event

1. Access the Schedule Study Event page in one of these ways:
 - In the navigation bar, select Tasks > Schedule Event. You'll need to provide the Study Subject ID.
 - In the Subject Matrix, for the Subject you want to schedule, click the icon in the Event column you want to schedule. What you can do depends on the type of Event, the current status of the Event, and your user role:
 - For a non-repeating Event, after you click the Not Started icon , click the Schedule link in the pop-up window.
 - For a repeating Event, the cell shows the number of occurrences of the Event that have already been scheduled or completed. After you click the icon in the cell, click the Add Another Occurrence link in the pop-up window.
 - For a new Subject, see [Add Subject](#).The Schedule Study Event page opens.
2. Enter information in the Schedule Study Event page. When you enter the dates, either type them in the field in the correct format, or click the calendar icon to select them. The End Date is optional: keep it empty if it does not apply.
3. After you complete scheduling the information, you can schedule another event or select the option to enter data.
4. After entering information for all events you want to schedule, click Proceed to Enter Data.
5. If you do not want to enter data about the Event until later, click Cancel, or if you do want to, enter the data. For details, see [Enter Data for an Event](#).



Schedule an Event from Tasks in the Navigation Bar



Schedule Study Event for

* indicates required field.

Study Subject ID: *

Study Event Definition: *

Start Date/Time:  : (DD-MMM-YYYY HH:MM) * 

































End Date/Time:  : (DD-MMM-YYYY HH:MM) 

Leave this field blank if the end date/time is not applicable.

☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)

Schedule an Event from the Subject Matrix Page

Subject Matrix for Cambridge Center for Surgical Oncology

Study Subject ID	Registration Visit	Initial Treatment	Follow-up Treatment	Adverse Events	Actions
					<input type="button" value="Apply Filter"/> <input type="button" value="Clear Filter"/>
CAM101			 x2		
CAM102			 x2		
CAM103					
CAM104					
CAM105					
CAM106					
CAM107					
CAM108					

Results 1 - 8 of 8.

Subject: CAM102
 Event: Follow-up Treatment [Add Another Occurrence](#) 1 | 2
 Occurrence#1 of 2
 27-May-2011
 Status: scheduled

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15.3 View and Update Events

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15.3.1 View Events

You can view information about all Events, or show only the Events that match criteria you specify:

1. In the navigation bar, select Tasks > View Events.
The View All Events page opens for the current Study or Site, presenting a filter.
2. Complete the fields in the filter to specify criteria for the Events you want to view. For example, specify Follow-up Treatment Events that occurred between May 1, 2011 and May 31, 2011.
3. Click Apply Filter.
OpenClinica displays all Events that match your criteria in a series of tables, with one table of results for each Event Definition.

To print the results, click the Print icon at the top of the page.

The View All Events Page Before Applying the Filter:

View All Events in Cambridge Center for Surgical Oncology

Filter events by:

Study Event Definition: --All-- Status: --All--

Date Started: 01-Dec-2011 (DD-MMM-YYYY) Date Ended: 31-Dec-2011 (DD-MMM-YYYY)

Apply Filter

The View All Events Page After Applying the Filter:

View All Events in Cambridge Center for Surgical Oncology

Filter events by:

Study Event Definition: Follow-up Treatment Status: --All--

Date Started: 01-May-2011 (DD-MMM-YYYY) Date Ended: 31-May-2011 (DD-MMM-YYYY)

Apply Filter

Event Name: Follow-up Treatment
Event Type: Scheduled, Repeating , Category: Treatment
Subjects who scheduled: 3 (start date of first event: 25-May-2011), Completed: 0 (completion date of last event: N/A), discontinued: 0

Page 1 of 1 **Find**

Study Subject ID	Event Date Started	Subject Event Status	Actions
CAM103	30-May-2011	scheduled	
CAM102	27-May-2011	scheduled	
CAM101	25-May-2011	scheduled	
CAM103	16-May-2011	data entry started	

15.3.1.1 About the Events Table

The View All Events page contains a table for each Event Definition that matches the criteria. Above each table is summary information for the list of Events the table contains. If a table includes more results than can fit on the page, use the arrows to view the other pages in that table.

By default, Events in the table are sorted by date, with the most recent Event shown first. To change the sort order, click the header of the column you want to sort by. To reverse the sort order in the column, click the column header again. An arrow indicates the order as ascending (up) or descending (down).

To find an Event within a table, type a string of characters in the find box, then click Find. OpenClinica finds matching strings in the Study Subject IDs or in Subject Event Status data, then shows only those Events in the table. To show all Events in the table after using Find, click Clear Search Keywords, which appears next to the Find button.

You can view details for an Event or edit the Event by clicking the View or Edit icon in the Actions column.

Yellow highlighting of a row indicates the Event Scheduled date has passed and data entry has not been started.

15.3.2 Update Events

You can update information for an Event, such as the date or status:

1. In the Subject Matrix, click the View icon for the Subject.
The View Subject page opens.
2. For the Event you want to modify, click the Edit icon.
The Update Study Event page opens.
3. Change the date or other information. If you are changing the status, you are presented only with appropriate options, given your user Role, the Study status, and the status of CRFs for the Event. For more information, see [About the Event Status](#).
4. Click Submit Changes.
The View Subject page opens, showing the updated information for the Event.

15.3.3 About the Event Status









You can manually update the Event status as described in Update Events. For some conditions, OpenClinica automatically updates it.

There are different ways to view the status of Study Events, including these:

- Use [View Events](#) to see all Events that match criteria you specify.
- The Subject Matrix icons show the status for each Event for each Subject.

These are the different status values for Study Events and a description of how the status changes:

Event Status Icon Description

Not Scheduled		After you add a Subject to a Study but before you schedule the Event, the Event status is set to "not scheduled." For certain Events, like Adverse Events, the Status might remain "not scheduled" throughout the Study.
Scheduled		<p>When you schedule a Subject for an Event, the Event status is automatically set to "scheduled."</p> <p>After you schedule a Subject for an Event and you open any CRF for that Event, the Event status is automatically set to "data entry started." The "data entry started" status applies even if you did not enter data.</p>
Data Entry Started		<p>If you inadvertently open a CRF but do not want to save data, you cannot change the Status for the CRF to "scheduled" or "not scheduled," nor can you change the Event status. To change the status you can instead delete the Event CRF or the Event for that Subject, then restore it when you are ready to enter data.</p> <p>After the status for all CRFs for an Event are marked complete, the OpenClinica system automatically sets the Event status to "completed."</p>
Completed		<p>If you make any changes to CRFs after an Event has a status of "completed," the status of the CRFs and the Event Status remain "completed;" you might need to complete a Reason for Change Discrepancy Note, depending on your system configuration. You can manually set the Event status back to "data entry started," and then again back to "completed," as needed.</p> <p>When all CRFs for an Event have a status of "completed" or "not scheduled," you can manually set the Event status to "signed." When you sign the casebook for a Subject, the OpenClinica system automatically sets the status for all Study Events for that Subject to "signed." After an Event status is "signed," any changes to the CRF automatically change the Event status to "completed." For more information, see Electronic Signatures in OpenClinica.</p>
Signed		
Skipped		When a Subject does not complete an Event, manually set the Event status to "skipped."
Stopped		When a Subject has temporarily stopped participating in a Study, manually set the Event status to "stopped."
Locked		When you no longer want users to be able to enter or change data for an Event, manually set the Event status to "locked." Note that you can set the status for a Study to "frozen" or "locked," and while that does not change the status of any Events in the Study, it does prevent users from changing data.

15.3.4 Electronic Signatures in OpenClinica

In OpenClinica, if your [user Role has appropriate permission](#), you can sign a Study Event or an entire casebook for a Subject.

The OpenClinica electronic signature process complies with the FDA Code of Federal Regulations (CFR) Title 21 Part 11.

15.3.4.1 Sign an Event

When you sign an Event, you provide your approval of all CRF data for the Event for the Subject. To sign an Event:

1. Follow the instructions in [Manually Change Event Status](#), and set the status to "signed."

Update Study Event

Study Subject ID: CAM105

Event: Registration Visit

Start Date/Time: 06-Jul-2011 : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM)

Status:

Submit Changes **Cancel**

2. Click Submit Changes.

The Update Study Event page displays links to all information for the Subject for the Study; click a link to review the information. It also presents a statement about what signing the Subject record signifies.

Update Study Event

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Ivan Camsurgon
Date/Time:
(The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator

User Name :
Password

Submit **Cancel**

Study Event

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Verification of Informed Consent	v2.0		agoodwin	IvanCamsurgon	
Physical Exam	English		agoodwin	IvanCamsurgon	
Eligibility	v1.0		agoodwin	IvanCamsurgon	

[Show events and discrepancy notes](#)

3. Enter your user name and password in the appropriate fields.

4. Click Submit.

The View Subject page opens, showing the status for the Event as "signed."

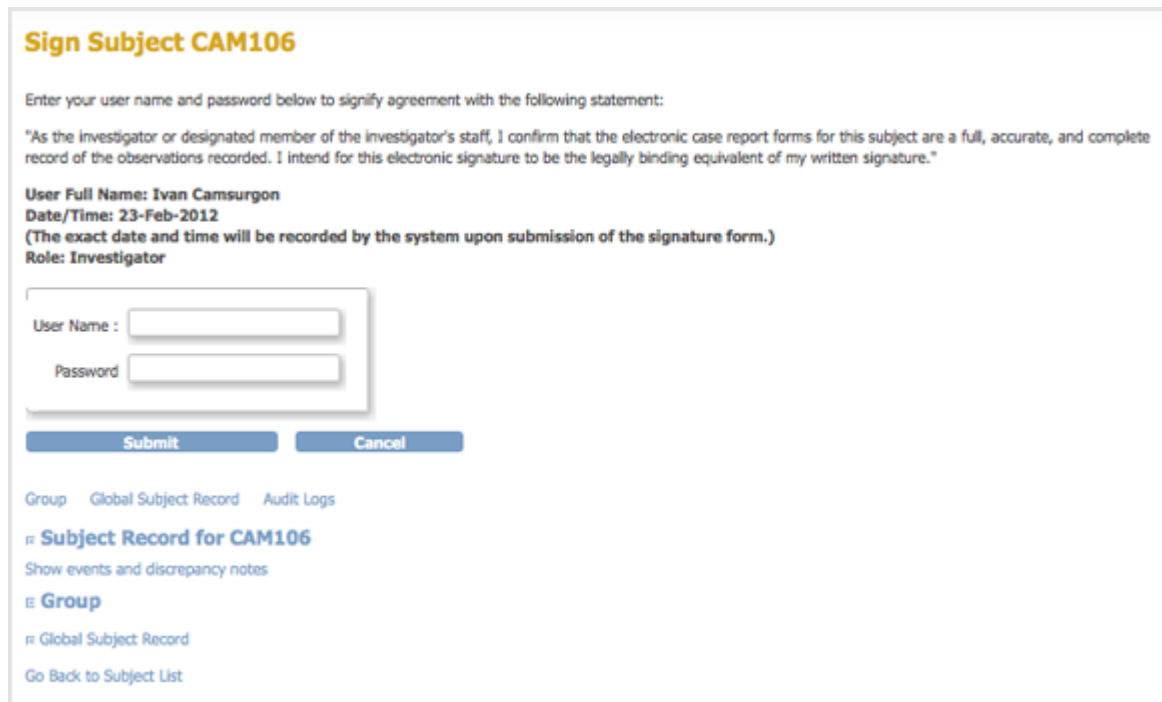
15.3.4.2 Sign a Casebook (Entire Subject Record)

When you sign a Subject casebook, which is also referred to as the complete Subject record, you provide your approval of all CRF data for all Study Events for the Subject.

1. To sign the casebook, no Events for that Subject can have a status of "scheduled" or "data

entry started." When that is true, the Sign icon is listed in the Actions column for that Subject. Click the Sign icon.

2. The Sign Subject page opens, showing links to all information for the Subject for the Study; click any link to review the information. The page also presents a statement about what signing the Subject record signifies.



3. Enter your user name and password in the appropriate fields.
4. Click Submit.

The Subject Matrix opens, showing the status for all Events as signed.

15.4 Entering Data for an Event Into CRFs

In OpenClinica, users provide information about an Event for a Subject using Case Report Forms (CRFs). There are different ways to fill in CRFs in OpenClinica:

- You [enter the CRF data](#) during or after an Event using the OpenClinica web-based interface. OpenClinica prevents users from inadvertently entering data for the same CRF at the same time by making the [CRF unavailable](#). There is also an option for [double data entry](#) that helps ensure the integrity of the data in the data entry process.
- You import CRF data for one or more Events from a file into OpenClinica. The import can occur once, or can be scheduled as a recurring job. For more details, see [Import Data](#).
- Use SOAP Web Services: see the [import Data Web Service](#) API in the *OpenClinica Technical Documentation*.

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15.4.1 Enter Data Into a CRF

When a CRF is created as part of [Study Setup](#), many aspects of the CRF and data entry for it are configurable. These instructions provide general guidelines; when you enter data for a CRF, the process might differ.

1. Open the CRF. There are different ways to open the CRF to enter data, including the following:
 - In the [Subject Matrix](#), find the Subject and Event you want to complete the CRF for, then click the icon in the cell for that Event, and click View/Enter Data.
 - When you Schedule an Event, after completing the Schedule Study Event page, click Proceed to Enter Data.

The Enter or Validate Data for CRFs page opens. The page reports the Event information followed by a table of all CRFs in that Study Event, with one CRF per row.

Enter or Validate Data for CRFs in Registration Visit

[Edit Study Event](#)

Study Subject ID	CAM107
Study Event	Registration Visit
Location	N/A
Study Subject OID	SS_CAM107
Start Date	06-Jul-2011
End Date/Time	
Subject Event Status	scheduled
Last Updated by	()

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Verification of Informed Consent	v2.0				
Eligibility	v1.0				
Physical Exam	English				

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

2. If there is more than one version of the CRF available for the current Site or Study, select the one you want from the drop-down list in the Version column.
3. If you want to print the CRF, click the Print icon for that CRF. The printout will include any data already entered in the CRF. To view a read-only version of the CRF, click the View icon. Note that when the CRF is viewed or printed in this manner all hidden fields in the CRF are displayed.
4. To enter data for a CRF, click the Enter Data icon in the Actions column for that CRF. The CRF opens, showing the first Section. Details about the CRF and entering the data depend on how the Study was configured during [Study Setup](#).

Example CRF -- Eligibility for Study Subject CAM107:

Eligibility v1.0

CAM107

- CRF Header Info

Event: Registration Visit (06-Jul-2011)

Study: Docetaxel in Patients With Completely Resected NSCLC

Site: Cambridge Center for Surgical Oncology

Sex: M

Age At Enrollment: 32 Years - 7 Months - 20 Days

Date of Birth: 14-Nov-1978

Discrepancy Notes on this CRF:

New	Updated	Resolution Proposed	Closed	Not Applicable
0	0	0	0	0

Inclusi...(0/9)

Exclusi...(0/5)

-- Select to Jump --

Title: Inclusion

Page: 1

Save

Exit

INCLUSION CRITERIA: All answers to questions 1-8 must be answered YES for subject to be eligible for participation.

1

Is the subject 18 years of age or older?

YES *

NO

2

Does the subject have an ECOG status of 0-2?

YES *

NO

3

Is the subject's WBC count 3,500/L?

YES *

NO

4

Is the subject's platelet count WBC count 100,000/L?

YES *

NO

5

Is the subject's serum creatinine <1.6 mg/dl?

YES *

NO

6

Is the subject's serum bilirubin 1.6 mg/dl?

YES *

NO

7

If the subject is of child-bearing potential, does the subject have a negative pregnancy test and agree to use adequate contraception during and two months after the duration of this study?

YES *

NO

8

Has the patient been properly informed of the study and signed the Informed Consent?

YES *




NO

Date Informed Consent was signed:

Return to top

Save

Exit

- To view information about the Subject, Event, and Discrepancy Notes, click the plus sign (+) next to CRF Header Info, which is at the top of the page. To hide the Header Info, click the minus sign (-).
- Select the Section you want to enter data for. The title of the current Section is listed in a tab below the CRF Header Info. To select a different Section, click the tab for that Section (tabs are below the CRF Header Info) or select the Section from the drop-down list next to the tabs.
- Enter the information for the current Section. The icon changes from  to , indicating the page now contains unsaved data. Items are numbered if the CRF was defined that way, with the total number of Items completed for that Section and total number of Items in the Section shown in the tab. For example, (0/5) indicates 5 Items in the Section, with no data entered in any of the Items. Instructions for completing Items in the Section are shown at the top of the page or with each Item, if the CRF was defined that way. If you enter a value that differs from what is required for the CRF, have a question, or want to make a note, add a Discrepancy Note by clicking the Add Discrepancy Note icon  for the Item and then completing the Note. For details, see [Notes and Discrepancies](#).
- After completing a Section (page):
 - If you don't want to save the information you entered for a Section, click Exit to end data

entry.

- If you want to keep the information you entered for that Section, click Save. If there are any problems with the data you entered, OpenClinica does not save the data, but displays messages about the information that is incorrect. Specifically, it checks that all required values are provided and that values entered comply with validation checks and [Rules](#) that are defined for the CRF. Correct any mistakes in the data or provide a Discrepancy Note for them, then click Save.

Upon saving the Section, OpenClinica performs any calculations that were set up for the Section of the CRF. After saving the Section, OpenClinica displays the next Section of the CRF.

9. Complete all Sections in the CRF, saving each Section as you complete it.

10. In the last Section:

- If all information has been entered for the CRF, select the Mark CRF Complete checkbox, then click OK in the confirmation dialog box. If a password is required, supply your password in the dialog box that opens. You can later edit the data in the CRF, even after marking it complete.
- If all information has not been completed, do not select Mark CRF complete. you can edit the CRF later to complete the information and mark the CRF complete at that time.
- If [double data entry](#) is required for the CRF, select the Mark CRF Complete checkbox. You or another user will need to enter the data for the CRF again before it can be verified as complete.

11. Click Save in the last Section.

If the CRF has been marked complete, the Enter or Validate Data for CRFs page opens, and the status for the CRF shows Data Entry Complete, or Data Entry Started if you did not mark it complete. The Study Events sidebar panel also shows the updated status for the Event.

12. If you want to print the completed CRF, click the Print icon for the CRF in the Enter or Validate Data for CRFs page.

15.4.2 CRF Unavailable

OpenClinica prevents two users from entering data for or editing a CRF at the same time. If you try to enter data for or edit a CRF that another user is already entering data for, OpenClinica does not show you the CRF but instead displays a message that the CRF is unavailable for data entry. The message also indicates who is currently editing the CRF. Click OK in the message. When the other user exits the CRF, you can edit it.

Note: When double data entry is specified, OpenClinica allows two users to enter data for the same CRF at the same time.

15.4.3 Double Data Entry

Double data entry is when the data for a CRF is entered twice to ensure the integrity of the captured data. It is typically used when CRF data is first captured on paper forms, then entered into the OpenClinica system. Double data entry can be optional or required, as specified for each CRF in the Study Event Definition.

During double data entry, OpenClinica flags any differences between the values in the initial data entry and the second data entry, and provides options for resolving the differences.

There are options for who performs the double data entry and when:






- After a user completes entering the initial CRF data, a different user can perform the double entry.
- The user who initially enters the data can also perform the double entry but must wait at least twelve hours after the initial data entry to perform the double entry.
- [Certain user roles](#) have permission to complete initial data entry and move directly to double data entry without waiting.

This is the process for completing data entry when double data entry is configured for a CRF:

1. Perform initial data entry for the CRF, mark it complete, and click Save.
2. Perform double data entry for the CRF, mark it complete, and click Save. If the value for any Items in the double data entry are different than for the initial data entry, an error message displays. Address the difference in one of these ways:
 - If the value in the double data entry is correct, keep that value by clicking Save again. The Audit Log stores the user name, date, time, and value for both the value entered in initial data entry and in double data entry.
 - If the value in the initial data entry is correct, change the value to the correct one in the CRF field for the double data entry, and click Save. The Audit Log stores only the initial value.
 - If you want to maintain the value from initial data entry and from double data entry for later followup, add a Discrepancy Note, then click Save.

15.4.4 CRF Status

This is how the CRF status progresses through the data entry process:

CRF Status	Icon	Description
Not Started		The CRF has not been opened for data entry.
Initial Data Entry		The CRF has been opened for data entry. The user might have entered some or all data into the CRF.
Data Entry Complete or Initial Data Entry Complete		The CRF has been marked complete. All required data has been entered and saved, and the OpenClinica edit checks have been performed. The completed icon is displayed when the CRF is not configured for double data entry; in the CRFs table, the Double Data Entry column in the Enter or Validate Data page, shows n/a (not applicable). If you make changes to a CRF when the status is complete, the status remains complete; if the system is set up to create a Reason for Change Discrepancy Note, you will be required to fill it out.
Double Data Entry Started		A user has opened the CRF for double entry. The status of double data entry for a CRF is shown in the Enter or Validate Data page, in the CRFs table.
Double Data Entry Complete		When the CRF has been marked complete after the double data entry.

Locked



The OpenClinica system automatically sets the status of all CRFs for an Event to "locked," when you set the status of the Event to "stopped," "skipped," or "locked." When the CRF status is "locked," you cannot enter or make changes to data in it. To enter data or change data in the CRF, you must change the CRF status by [changing the Event Status](#).

15.4.5 Editing and Adding Data to Previously Saved CRF Sections

When you return to edit a section of an event CRF that you (or somebody else) has previously saved, you will notice some differences in the display and behavior of the form versus entering data on a new event CRF.

Deletion of Previously Saved Repeating Group Rows Not Allowed

If your form uses repeating groups, the most noticeable difference is that you will no longer be able to delete previously saved rows from the grid using the 'X' icon at the end of the row. OpenClinica 3.1 has eliminated the ability to delete repeating group rows for records that have already been saved to the database. If a row needs to be removed, you must change all the item values to blank for that row. Newly added rows can still be deleted, provided they have not yet been saved.

This behavior, introduced for repeating groups in version 3.1, helps OpenClinica maintain an audit trail that allows users to trace back all changes that have occurred in the data. While it has some usability drawbacks, it provides a much needed improvement in the integrity and traceability of data values. The purpose of the audit trail is to be able to reconstruct the data as it looked at any point in time. The audit trail is one of the cornerstones of compliance to 21 CFR Part 11, and ensuring a complete and robust audit trail is necessary to make it possible the adoption of OpenClinica for regulated applications. The row will always display, and the audit records and discrepancy notes associated with the items in that row will be traceable in manner that is compliant with regulations and good clinical data management practices.

Consider the case of an Investigator that reviews and signs a CRF after confirming the CRF's values in a repeating group. After a certain time he goes back to the same CRF and finds that the CRF has been further edited, which may require review and re-signing. In OpenClinica 3.0, the method of deleting rows from the CRF so they are no longer viewable or traceable to entries in the audit log means he will have no means to understand what changes later occurred to the data, when they occurred and under whose responsibility. Addition of records to the repeating group have no trace (and thus they are not attributable to someone), removals were traced as change of state from Available to Removed, but no evidence of the formerly existing values was provided. This is critical because he has signed the CRF as a "whole record" and the addition or removal of sets of data in this whole record really is a change of that record. Providing detailed information on what has changed since the signing event is now possible based on the audit trail, and provides the investigator with a means to identify what has changed since the signing as part of his review.

User Required to Provide a Reason for Change

The other major difference in behavior applies only after the CRF has been marked complete and only if the study is set up to require 'Reason for Change'.

In this scenario, if you make any changes to CRF data (including adding new rows to a repeating

group) after it has been marked complete, you will be required to enter a discrepancy note indicating the reason for change.

As of OpenClinica 3.1.3, changes in the values of calculated fields do not require a reason for change. Note that if the calculation cannot be computed (such as division by zero) the reason for change message will be displayed, however the form can be safely submitted without a discrepancy note.

15.5 Import Data

OpenClinica allows you to import Event CRF data from a file as an alternative to performing [data entry using the OpenClinica web interface](#). The import data feature is useful when the data you want for a Study in OpenClinica is captured using a system other than OpenClinica. When data is imported, the Audit Log records the userid of the person performing the import as the data entry person.

Before importing data into OpenClinica, the following tasks must be completed:

- Create the Study in OpenClinica
Tasks>Create Study and then Tasks>Build Study>Create Study
- Create the CRFs for the data being imported
Tasks>Build Study>Create CRF
- Add the Event Definitions for the data being imported, and associate CRFs for the data being imported with the Event(s)
Tasks>Build Study>Create Event Definitions
- Enroll the Study Subjects for the data being imported
Subject Matrix>Add New Subject
- For each of the Subjects, schedule the Events for which data is being imported
Subject Matrix>Click on an Event for a Subject, then click Schedule and schedule the Event.

In addition, the following data characteristics are enforced when data is imported:

- Data cannot be imported into a CRF that has a status of DoubleDataEntryStarted or DoubleDataEntryComplete.
- Dates must be imported in the format YYYY-MM-DD
- Data types in the import file must match the item data type in OpenClinica (i.e., you cannot import a character string into an item that was defined as integer).
- Data values must match the response values specified in the eCRF. For example you cannot import "3" if the only response options provided were Yes (1) and No (2).
- Required fields cannot be empty.

The information in the import file can be for:

- one or more Subjects
- one or more Events for each Subject
- one or more CRFs for each Event

The type or amount of information for each Subject does not have to be the same. For example, the file can include one Subject with two Events - each with one CRF, and another Subject with one Event that contains three CRFs.

Sample eCRF and Import File

This section presents a sample eCRF and the related XML file that would import data into that CRF. Prior to performing the import, all of the steps listed above were performed.

Sample eCRF:

The image shows a sample eCRF form titled "Basic Demographic Information". The form contains the following fields and options:

- Height: Text input field with a small icon and an asterisk.
- Weight: Text input field with an asterisk.
- Age: Text input field with an asterisk.
- Marital Status: Dropdown menu with the text "Please select one..." and an asterisk.
- Sex: Radio button options for Male, Female, and Not Provided, with an asterisk.
- Are you pregnant?: Dropdown menu with the text "Please select one...".
- Do you have prostate cancer?: Dropdown menu with the text "Please select one...".
- How many months pregnant?: Text input field with "(Weeks)" to its right.
- How long have you had prostate cancer?: Text input field with "(Months)" to its right.

Sample XML File:

The following XML file was used to import data into the above eCRF. In the sample below, all highlighted values are values that must be specified for each import as follows:

- Values in red are where your various OIDs must be provided
- Values in **bold** are where you specify the description and status conditions for the import
- Values highlighted in blue should be replaced with the actual data values that you want to import into the associated Item OID.


```

<?xml version="1.0" encoding="UTF-8"?><ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 ODM1-3.xsd" ODMVersion="1.3" FileOID="1D20080412202420"
FileType="Snapshot" Description="Demographics Import" CreationDateTime="2008-04-12T20:24:20">
<ClinicalData StudyOID="S_THEJUN01" MetaDataVersionOID="v1.0.0">
  <UpsertOn NotStarted="true" DataEntryStarted="false" DataEntryComplete="false"/>
  <SubjectData SubjectKey="SS_0001">
    <StudyEventData StudyEventOID="SE_FIRSTVISIT" StudyEventRepeatKey="1">
      <FormData FormOID="F_DEMOG_1" OpenClinica:Status="initial data entry">
        <ItemGroupData ItemGroupOID="IG_DEMOG_BASICS" ItemGroupRepeatKey="1" TransactionType="Insert">
          <ItemData ItemOID="DEMOG_PGDEMOG1" Value="58"/>
          <ItemData ItemOID="DEMOG_PGDEMOG2" Value="116"/>
          <ItemData ItemOID="DEMOG_PGDEMOG3" Value="53"/>
          <ItemData ItemOID="DEMOG_PGDEMOG4" Value="2"/>
          <ItemData ItemOID="DEMOG_PGDEMOG5" Value="2"/>
          <ItemData ItemOID="DEMOG_PGDEMOG6" Value="2"/>
          <ItemData ItemOID="DEMOG_PGDEMOG7" Value="2"/>
          <ItemData ItemOID="DEMOG_PGDEMOG8" Value="0"/>
          <ItemData ItemOID="DEMOG_PGDEMOG9" Value="1"/>
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
</ClinicalData>
</ODM>

```

For each Item OID, specify the value that should be imported.

Import Status and Form Status

Beginning with version 3.6 of OpenClinica, the UpsertOn tag in the XML code for importing data allows you to specify whether to perform the import or not based on the current CRF status. This provides the option to update data that has already been imported or entered. For example, the following specification would only import the data if the current status of the form is "not started":

```
<UpsertOn NotStarted="true" DataEntryStarted="false" DataEntryComplete="false"/>
```

If you want to use the import to update data that is already in the database, but has not yet been marked complete, then use the following settings:

```
<UpsertOn NotStarted="false" DataEntryStarted="true" DataEntryComplete="false"/>
```

If all three statuses were set to true, then the import would occur regardless of the CRF status. If all three statuses were set to false, data would not be imported.

If you choose to remove the UpsertOn option from the XML file, then OpenClinica performs the import as if all UpsertOn statuses were set to "true."

Note:

- For any data that is being imported and does not match the criteria for the UpsertOn settings, a list of "skipped" records is displayed for your review. Based on the data that is displayed, you may need to modify the UpsertOn settings, or you may want to continue with the import if the data was skipped appropriately.
- You cannot import data into a CRF that has a status of DoubleDataEntryStarted or DoubleDataEntryComplete. OpenClinica does not include that data in the import, but does provide information about the skipped data in the Summary Statistics and Import CRF Data details window.

Assign a Status

By default, when an import is complete, OpenClinica sets the CRF status to "complete." OpenClinica version 3.6 provides the option to instead set the status of the CRF to "data entry started" after the import is complete. To do this, set the "OpenClinica:Status=" to "initial data entry" (case sensitive). The following tag includes the Form OID (in this example F_DEMOG_1) as well as the status setting for that Form once the import is complete:

```
<FormData FormOID="F_DEMOG_1" OpenClinica:Status="initial data entry">
```

In this example, once the data is imported, the form will have a status of initial data entry.

If you remove the OpenClinica:Status clause from the XML file, or provide any value other than "initial data entry", OpenClinica implements the default behavior and sets the status of the form to "complete". Although you may omit the OpenClinica:Status="initial data entry" clause, the rest of the FormData statement must remain in place in order for the import to function.

The data import file must be a properly-formatted XML file. For details, see [Data File for Import](#).

Automatic Edit Checks

For Rules to run automatically upon import, the **Run** parameter **ImportDataEntry** must be set to **"true"**. For more information, see [Creating Rules](#).

Edit checks are processed as follows:

- If Rules are set to run during import, failed Rules automatically create Failed Validation Discrepancy Notes.
- If there are errors with the import definition (for example you tried to import text into an item defined as a date), then an error message displays in the Alerts and Messages section of the screen.
- If there are no errors, the CRF is automatically marked with the status provided in the "OpenClinica:Status=" clause.
- Any subsequent changes can be done by editing the data via the Subject Matrix or by re-importing using the appropriate UpsertOn value. If you had set the OpenClinica:Status to "complete" on the initial import, the data can only be edited using Administrative Editing.
- If there are any calculated value fields in the CRF, you must either supply the correct data in the import file or open and save the CRFs manually to generate the calculations.

You can automate the importing of data, which is useful when you import the data files on a recurring basis: see [Scheduled Import Jobs](#). Another alternative for getting data into OpenClinica is with SOAP Web Services: see the [import Data Web Service](#) API in the *OpenClinica Technical Documentation*.

Functional approval by Laura Keita. Signed on 2016-06-06 11:56AM

Approved for publication by Ben Baumann. Signed on 2016-06-07 11:14AM

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

15.5.1 Import the Data File

Users whose role has appropriate permission can import data from the OpenClinica web interface. The Study or Site in the import file must be the same as the current Study or Site.

To import the data:

1. From the navigation bar, select **Tasks > Import Data**.
The Import CRF Data page opens.
2. Browse for the XML file that contains the import data, select the file, and click **Open**.
The filename you selected is listed on the Import CRF Data page.
3. On the Import CRF Data page, click **Continue**.
OpenClinica [validates the XML file](#). If there are any validation errors, the Alerts and Messages sidebar panel reports the problems. Correct the errors in the file, then in the Import CRF Data page, browse to select the filename, and click Continue.

If there are no validation errors, OpenClinica displays a page summarizing the CRF data being imported, and presents the results of the Hard Validation Error Checks, including any errors. For example, it reports an error if a date format is invalid.

Correct any problems in the file, then, in the Import CRF Data page, browse to select the filename, and click Continue.
4. If there are no Hard Validation Errors, to continue to import the data, click **Continue**.
5. In the confirmation dialog box, to complete the data import, click **OK**. To cancel the import, click **Cancel**.
If you completed the import, the CRF(s) for the Subject(s) specified in the import file now contain the imported data, and the status of the CRF(s) are set to the status specified in the import file.
6. If the CRF contains empty fields for any calculated values, manually open the CRF and save each page that contains the calculated values.
OpenClinica only calculates the values when you save the page manually. For details, see [Complete a CRF](#).
7. If there are [Rules](#) associated with the CRFs where the data was imported, check to see if you need to manually run the Rules. As of OpenClinica 3.1.3, the Rule option **<Run ImportDataEntry="true">** ensures that Rules are run when importing data. If this option was set to "false" in the Rule, go to **Tasks>Monitor and Manage Data>CRFs**. Then, on the top row for the CRF (original), click the view icon. Scroll to the bottom of the page and click **Run All Rules for this CRF**.

15.5.2 Data File for Import

To import Event CRF data, generate a properly-formatted XML file that contains the data to import. The XML file includes the [Object Identifiers \(OIDs\)](#) that OpenClinica uses to uniquely identify the

entities in the Study. The XML file is compliant with the Clinical Data Interchange Standards Consortium Object Data Module ([CDISC ODM](#)), version 1.2 or 1.3.

To generate the XML file for importing data:

1. Determine OIDs for the Subjects, Study, Event Definitions, Forms, Item Groups, and Items that you want to import data for. See details at [Determine OIDs](#).
2. Generate the import file using the OIDs and the data. For details, see [Generate Data Import File](#).

15.5.3 Determine OIDs

Use the following methods to determine [Object Identifiers \(OIDs\)](#). Record the OIDs for use in the data import file. The OIDs for Study, Study Event Definitions, Forms (CRFs), Item Groups, and Items were created as part of Study Setup. The OIDs for Study Subjects were created when the Subject was added to the Study.

To determine OIDs for Study Subjects, view the Subject Matrix, then click Show More. The Subject OIDs are in the OID column. For the example Subject Matrix shown here, the OID for Subject CAM107 is SS_CAM107:

Subject Matrix for Docetaxel in Patients With Com

14

15

16

17

15

Hide

Select An Event

Add New Subject

Study Subject ID	Subject Status	Site ID	OID	Sex	Second
CAM101	available	R01-123456-CCSO	SS_CAM101	f	
CAM102	available	R01-123456-CCSO	SS_CAM102	m	
CAM103	available	R01-123456-CCSO	SS_CAM103	m	
CAM104	available	R01-123456-CCSO	SS_CAM104	m	
CAM105	available	R01-123456-CCSO	SS_CAM105	m	
CAM106	available	R01-123456-CCSO	SS_CAM106	m	
CAM107	available	R01-123456-CCSO	SS_CAM107	m	
CAM108	available	R01-123456-CCSO	SS_CAM108	f	

To determine OIDs for the Study, Study Event Definitions, CRF, Item Groups, and Items, use one of these methods:

- [View study details](#) in the OpenClinica web interface.
- [View the Study Metadata file](#). You should be familiar with XML file structure to use this method.

15.5.3.1 View Study Details to Determine OIDs

1. Select Tasks > View Study.
A page with details about the current study opens.

2. From the Overview section, record the Study OID.

Docetaxel in Patients With Completely Resected NSCLC ?

Download the study metadata [here](#). Click to open in your browser, or right click (option click for Mac users) and save to your computer. (Please note, you will still need to get the Study Subject OIDs from the Subject Matrix by selection the 'Show Subject Matrix' table.)

Overview




Name:	Docetaxel in Patients With Completely Resected NSCLC
Unique Protocol ID:	R01-123456
OID:	S_R0112345
Principal Investigator:	Thomas Katz MD, PhD
Brief Summary:	Administering chemotherapy drugs such as Docetaxel after surgery, may kill any tumor cells that remain post surgery.
Owner:	agoodwin
Date Created:	02-Jul-2011


3. From the Sites section, record the Site OID.
4. From the Event Definitions section, record the Event OIDs.
5. For the Event Definition whose CRF OIDs you want, click the View icon.
The View Event Definition page opens, displaying a table of CRFs for that Event.
6. In the CRFs table, click the View icon for the CRF whose OIDs you want.
The View CRF Details page opens and displays a table of Versions.
7. From the Versions table, record the OID for the version of the CRF you want to use.

View CRF Details

Name:	Eligibility
Description:	Eligibility criteria
OID:	F_ELIGIBILITY

Versions

Version Name	oid	Description	Status	Revision Notes	Action
v1.0	F_ELIGIBILITY_V10	Eligibility criteria	available	agoodwin 2011-04-27	  

8. For the CRF version you want, click the Metadata icon .
9. From the View CRF Version Details page, record the OIDs for the Item Groups and Items.

View CRF Version Details: Eligibility v1.0

SECTION

Section Name	Title	Subtitle	Instructions	Page Number Label
Inclusion Criteria	Inclusion			

Groups

Group Name	OID	Header	Repeat Number	Repeat Max	Is shown?	Group I
Ungrouped	IG_ELIGI_UNGROUPED		1	1	Yes	non-rep

Items

Name	Item_OID	GROUP_OID	Description	Group Name	Unit
OVER_18	I_ELIGI_OVER_18	IG_ELIGI_UNGROUPED	18 or older		
ECOG_STATUS	I_ELIGI_ECOG_STATUS	IG_ELIGI_UNGROUPED	ECOG status of 0-2		
WBC_CT	I_ELIGI_WBC_CT	IG_ELIGI_UNGROUPED	WBC count 3,500/L?		

15.5.3.2 View the Study Metadata File to Determine OIDs

If you are familiar with XML file structure, you can determine OIDs using the Study metadata file:

1. Download the Study metadata file: Select Tasks > View Study, then follow the instructions at the top of the page.
2. Open the Study metadata file in a browser or text editor.

Following is an excerpt of a Study metadata file that provides an example of the structure, showing only the tags that are relevant to finding and determining OIDs needed for the data import file. Comments `<!-- ... -->` indicate where the OID values are. You can download and view the complete Study metadata file for the example Study.

Starting with the `<Protocol>` tag, the general structure is that the OID for an element is defined in a `<...Ref>` tag. After that, a `<...Def>` tag for the element contains tags that define the OIDs for the subelements, and so on, through the hierarchy. The heirarchy is: Study Event Definition > Form (CRF) > Item Group > Item.

```
<?xml version="1.0"?>
```

```
<ODM ... >
```

```
<Study OID="YourStudyOID"> <!-- Get the Study OID here. -->
```


<GlobalVariables>

...

</GlobalVariables>

<BasicDefinitions>

...

</BasicDefinitions>

<MetaDataVersion OID="*YourMetaDataVersionOID*" ... > <!-- Get the MetaDataVersion OID here. -
-->

<Protocol>

<StudyEventRef StudyEventOID="*YourFirstStudyEventOID*" .../> <!-- Get the OID for your first
Study Event here -->

<StudyEventRef StudyEventOID="*YourSecondStudyEventOID*" .../> <!-- Get the OID for your
second Study Event here -->

...

</Protocol>

<StudyEventDef OID="*YourFirstStudyEventOID*" ... > <!-- This section contains the OIDs for the
Forms (CRFs) in the Study Event whose OID is *YourFirstStudyEventOID* -->

<FormRef FormOID="*YourFirstFormOID*" ... /> <!-- Get the OID for the first CRF used in this Study
Event here -->

<FormRef FormOID="*YourSecondFormOID*" ... /> <!-- Get the OID for the second CRF used in this
Study Event here -->

...

</StudyEventDef>

<StudyEventDef OID="*YourSecondStudyEventOID*" ... > <!-- This section contains the OIDs for the
Forms (CRFs) in the Study Event whose OID is *YourSecondStudyEventOID* -->

</StudyEventDef>

...

<FormDef OID="*YourFirstFormOID*" ...> <!-- This section contains the OIDs for the Item Groups in
the CRF whose OID is *YourFirstFormOID* -->

<ItemGroupRef ItemGroupOID="*YourFirstItemGroupOID*" ... /> <!-- Get the OID for the first Item
Group in this CRF here -->

<ItemGroupRef ItemGroupOID="*YourSecondItemGroupOID*" .../> <!-- Get the OID for the second
Item Group in this CRF here -->

...

<OpenClinica:FormDetails ... >

...

</OpenClinica:FormDetails>

</FormDef>


```

<FormDef OID="YourSecondFormOID" ...> <!-- This section contains the OIDs for the Item Groups
in the CRF whose OID is YourSecondFormOID -->
...
</FormDef>

<ItemGroupDef OID="YourFirstItemGroupOID" ... > <!-- This section contains the OIDs for the
Items in the Item Group whose OID is YourFirstItemGroupOID -->
<ItemRef ItemOID="YourFirstItemOIDInYourFirstItemGroup" /> <!-- Get the OID for the first Item
in this Item Group here -->
<ItemRef ItemOID="YourSecondItemOIDInYourFirstItemGroup" /> <!-- Get the OID for the second
Item in this Item Group here -->
...
<OpenClinica:ItemGroupDetails ... >
...
</OpenClinica:ItemGroupDetails ...>
</ItemGroupDef>

<ItemGroupDef OID="YourSecondItemGroupOID" ... > <!-- This section contains the OIDs for the
Items in the Item Group whose OID is YourSecondItemGroupOID -->
...
</ItemGroupDef>
...

<ItemDef OID="YourFirstItemOIDInYourFirstItemGroup" ... > <!-- This section contains details for
the Item whose OID is YourFirstItemOIDInYourFirstItemGroup -->
...
</ItemDef>
<ItemDef OID="YourSecondItemOIDInYourFirstItemGroup" ... > <!-- This section contains details
for the Item whose OID is YourSecondItemOIDInYourFirstItemGroup -->
...
</ItemDef>
...

```

15.5.4 Create the Data Import File

Create the data import XML file using the [OIDs for your Study](#), and the data for each Item. Use the example in this section as a template for the structure of your data import file. You can also [download example files](#).

Starting with the <SubjectData> tag, the general structure is that the tag for an element contains the tags for its subelements, and so on, through the hierarchy. The hierarchy is: Study Subject > Study Event Definition > Form (CRF) > Item Group > Item. So within a <SubjectData> tag are the <EventData> tags for that Subject, and so on.

For Repeating Events and Repeating Item Groups, specify the value 1 for the first Repeat Key, 2 for the second Repeat Key, and so on.

Following is an XML import file that imports data into a demographics form in the sample Juno study:


```

1  <?xml version="1.0" encoding="UTF-8"?>
2  <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="
   http://www.cdisc.org/ns/odm/v1.3 ODM1-3.xsd" ODMVersion="1.3" FileOID="1D20080412202420" FileType="Snapshot" Description="
   OpenClinica Data Import" CreationDateTime="2015-04-12T20:24:20" >
3
4  <!-- Replace the S_OID with the Study OID of the Study to which you are importing data. -->
5  <ClinicalData StudyOID="S_OID" MetaDataVersionOID="v1.0.0">
6
7      <!-- Specify whether or not to update existing data based on the current status of the data. May be set to "true"
8       (update) or "false" (do not update) for each of the listed statuses.-->
9      <UpsertOn NotStarted="true" DataEntryStarted="true" DataEntryComplete="true"/>
10
11     <!-- Replace the SS_OID with the Study Subject OID for whom you're importing data. This Subject must already be
12      enrolled and scheduled for the Event to which you are importing. -->
13     <SubjectData SubjectKey="SS_OID">
14
15         <!-- Replace the SE_OID with the OID of the Study Event. For non-repeating Events, the StudyEventRepeatKey
16          should be set to 1. For repeating Events, specify the ordinal for the occurrence of the Event to which you are
17          importing. For example, specify 2 to import the data into the second repeat occurrence of an Event. -->
18         <StudyEventData StudyEventOID="SE_OID" StudyEventRepeatKey="1">
19
20             <!-- Replace the F_OID with the OID of the Form that will be populated with the imported data. Also specify
21              the status the Form should have after the import is complete. Options are initial data entry or complete.-->
22             <FormData FormOID="F_OID" OpenClinica:Status="initial data entry">
23
24                 <!-- Replace the IG_OID with the Item Group OID. If the Group is a Grid, specify the row number for the
25                  insert in ItemGroupRepeatKey. TransactionType for an import should always be Insert.-->
26                 <ItemGroupData ItemGroupOID="IG_OID" ItemGroupRepeatKey="1" TransactionType="Insert" >
27
28                     <!-- For each Item in the Form, replace the I_OID with the Item OID and specify the value that should
29                      be imported into that Item. Add or remove lines below as needed to match the number of Items in your
30                      Form.-->
31                     <ItemData ItemOID="I_OID" Value="68"/>
32                     <ItemData ItemOID="I_OID2" Value="116"/>
33                     <ItemData ItemOID="I_OID3" Value="53"/>
34                     <ItemData ItemOID="I_OID4" Value="2"/>
35
36                 </ItemGroupData>
37             </FormData>
38         </StudyEventData>
39     </SubjectData>
40     <!-- To import data for more than one Subject, copy the opening and closing SubjectData tags, and everything between
41      those tags. Then update OIDs and values as needed.-->
42 </ClinicalData>
43 </ODM>

```

To create an XML data import file:

1. Download the [import template](#)
2. Open the import template in an XML editor
3. Save the template as an XML file.
4. Modify the template as needed to meet the requirements of the data you are importing.
Instructions are provided throughout the template for guidance.

15.5.5 Validate and Check the Data Import File

When you import a data file, OpenClinica validates the file format and performs validity checking for the data, then displays any error messages in the Alerts and Messages sidebar panel. Correct any errors in the file and import it again.

OpenClinica also displays Summary Statistics of imported and skipped records and displays detailed information about the import. Details on the validation and rules applied during import are listed below the screen shot.

Alerts & Messages

Passed XML Validation...
Passed Study Check...
Passed OID Metadata Check...
Passed Event CRF Status Check...
Passing CRF Edit Checks...

Instructions

Batch upload CRF data to OpenClinica using an XML file. Upon successful validation of the data provided in the xml file, Openclinica will save this information.

Other Info

Study: JUNO
Start Date: 05-Jan-2015
End Date: N/A
PI: Martin Van Buren
Protocol Verification/IRB Approval Date:

Import CRF Data

Upload an xml file that contains CRF data. If your CRF has calculated value fields, you will have to go in and save each section. OpenClinica only calculates values on a manual save.

Summary Statistics:

Subjects Affected: 2
Total Event CRFs: 2
Event CRFs Available for Import: 1
Event CRFs Skipped: 1
Validation Rules Generated: 0

Skipped CRFs (due to import rules)

Study OID	Study Subject OID	Event CRF OID	CRF Version OID	Event CRF Status
S_THEJUNOD	SS_0520	SE_FIRSTVISIT	F_DEMOG_1	Invalid

Valid Data Import

Study Subject: SS_0001	
Event CRF OID	
SE_FIRSTVISIT (Repeat Key 1)	
	CRF Version OID
	F_DEMOG_1
IG_DEMOG_BASICS (Repeat Key 1)	
I_DEMOG_PGDEMOG1	68
I_DEMOG_PGDEMOG2	116
I_DEMOG_PGDEMOG3	53
I_DEMOG_PGDEMOG4	2

Continue
Cancel

Validation that OpenClinica Performs on the Data Import File

- XML is well-formed against the ODM.
- The Study OID in the import file matches the current Study in the OpenClinica session you are performing the import from.
- Study Subject OIDs exist for the current Study.
- Study Event Definition OIDs exist for the current Study.
- OIDs for the CRF versions exist for the Study Event Definition OID.
- Study Subject OIDs are scheduled for the Study Events.
- Data values for the Items comply with the metadata. For example, if the metadata for an Item calls for a value of 1 or 2, the data value for that Item in your import file must be 1 or 2.
- Data values are in the correct format. For example, when an integer is required, a decimal value generates an error.

Edit Checks that OpenClinica Performs on the Data Import File

If your study is configured to flag errors in Edit Checks, OpenClinica checks the following:

- The status of the CRF (prior to import) is not "double data entry started" or "double data entry complete."
- Data is in the correct format. For example, a date that is not in the required YYYY-MM-DD format generates an error.
- Data values are within limits specified for CRF Items. For example, when the CRF accepts 90 to 110 degrees for temperature, a value of 200 is not accepted.
- Data values match acceptable criteria for CRF Items. For example, if a Yes answer is required

- for an Item and the value in the import file for that Item is No, a discrepancy note is required.
- Required fields are not empty.

15.5.6 Example Data Import File

This sample file is provided as an example only - your OIDs and item values will vary.

Click the file to open or download it, using the standard features in your browser for accessing linked files.

For best results, copy the content of the file to an XML editor and save as an XML file type. XML editors Notepad++ (for Windows) and TextWrangler (for Mac) are available for free download on the internet.

- [Simple Data Import File with One Item Group](#): One Subject, one Event, one CRF, one Item Group, multiple Items.

15.6 Notes and Discrepancies

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:07AM

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

15.6.1 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.

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.

15.6.3 Status of a Discrepancy Note

The status for a Discrepancy Note provides an indication of who is responsible for the next step. The Discrepancy Note Type determines what status values are allowed. These are the possible values:

- **New** 🆕: The initial status for a Query or Failed Validation Check Note Type.
- **Updated** 🔄: Used when responding to a Note, but the response requires further follow up or additional information.
- **Resolution Proposed** 📝: When a user addresses a Note by fixing a data problem or by explaining why the existing data is correct, the user provides an explanation in a child Note, and sets the status to Resolution Proposed. A Monitor, Data Manager or Study Director then reviews the proposed resolution and updates the status.
- **Closed** 🏁: The final action for a Failed Validation Check or Query Note Type. When a Note

has a status of Closed, it cannot be changed in any way. Child Notes cannot be added and the status must remain Closed. Only users with certain Roles can mark a Discrepancy Note as Closed.

- **Not Applicable** : This status is for Reason for Change and Annotation Note Types because no further action is required. The Not Applicable status cannot be used for Failed Validation Check and Query Note Types.

When there is more than one Discrepancy Note associated with a CRF Item, the most urgent status is shown in summary presentations that include Discrepancy Note status. When you view the Discrepancy Notes for the Item, you see the status for each Discrepancy Note.

15.6.4 Working with Individual Discrepancy Notes

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:

Con_Med_Name: Add Discrepancy Note

"Con_Med_Name" Properties:

Subject:	CAM107	Event:	Initial Treatment
Event Date:	13-Jul-2011	CRF:	Concomitant Medications
Current Value:	aspirin	More:	Data Dictionary

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.

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
--------	------------------	--------------------------------	---------------

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
--------	--------------------	--------------------------------	---------------

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 **ekely**

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?

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

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

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.)

15.6.5 Manage Discrepancy Notes

15.6.5.1 Notes and Discrepancies Table

Use the OpenClinica Notes and Discrepancies table to view a summary of Notes and Discrepancies for the current Study or Site.


A quick way to see the table with only the Notes and Discrepancies assigned to you is from the OpenClinica home page. The home page opens when you first log in to OpenClinica, or you can access it at any time by clicking Home in the navigation bar. The home page reports how many Notes and Discrepancies are assigned to you in the current Study or Site. Click the link to see those Notes in the Notes and Discrepancies table.

To view the table of all Notes and Discrepancies for the current Study or Site, click Notes & Discrepancies in the navigation bar. From the table, you can also find Notes and Discrepancies that match criteria you specify, and take action on individual Notes. The features you can access depend on your user Role in OpenClinica.






At the top is a table of summary statistics, which you can show or hide.



















Below the summary statistic is the main table, which contains one row for each Discrepancy Note. In this table:

- Entity Name refers to the CRF Item that the Note is associated with.
- Entity Value is the value recorded in the CRF for the Item.
- Description is the description provided in the Discrepancy Note.
- Assigned User is who the Discrepancy Note is assigned to, if anyone.

Notes and Discrepancies 

[Hide summary statistics](#)


	Query	Failed Validation Check	Reason for Change	Annotation	Total
New		1	3	...	4
Updated	
Resolution Proposed	
Closed	
Not Applicable		...	1	1	2
Total		1	3	1	6

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
SCRC010	Failed Validation Check	 New	R01-12345-SCRC	0	274	Registration Visit	Eligibility	FASTING_CHOLESTEROL_TRGGLY		Paper source was missing value	()	 
CAM105	Failed Validation Check	 New	R01-123456-CCSD	0	273	Initial Treatment	Physical Exam	PULSE	59	Pulse was taken twice and was 59 BPM	()	 
SCRC005	Failed Validation Check	 New	R01-12345-SCRC	0	274	Registration Visit	Physical Exam	PULSE	55	Pulse rate is lower than expected	()	 
SMC102	Reason for Change	 Not Applicable	R01-12345-SMC			Registration Visit	Physical Exam	PEDAT	01-Jul-2011	Date was entered as Jul instead of Jun where actually exam was Jun	()	 
SCRC011	Annotation	 Not Applicable	R01-12345-SCRC			Registration Visit	Physical Exam	APPEARANCE	1	Appears distracted	()	 
CAM105	Query	 New	R01-123456-CCSD	0	273	Registration Visit	Verification of Informed Consent	IPC_PDF		Please attach signed informed consent	Alicia Goodwin (agoodwin)	 

Results 1 - 6 of 6.

15.6.5.2 Actions to Take for Discrepancy Notes

Following are actions you can take for Notes and Discrepancies, from the Notes and Discrepancies table.

- **Print:** To print the table in its current view, click the Print icon, which is above the column headers.
- **View More Information for Notes:** To see the detailed description and other information for all Discrepancy Notes, click the Show More link, which is above the column headers.
- **View Details for a Note:** To view all details for a single Discrepancy Note, click the View icon in the Actions column for that row. The Discrepancy Note opens in a window. To close the Discrepancy Note, click Exit Window.
- **View CRF and Note Details:** In the Actions column, click the View within Record icon . OpenClinica opens the Discrepancy Note as well as the CRF page the Note is associated with. If the CRF Status is Completed, you may also edit data in the opened CRF page. Otherwise, you may only view the data on the page, but can modify the Discrepancy Note. After you close the Note and the CRF, OpenClinica displays the Notes and Discrepancies table.
- **Update a Note:** For instructions to update a Discrepancy Note when you view it, see [Update a Discrepancy Note](#).
- [Find and Organize Notes](#)
- [Download Notes](#)

15.6.5.3 Organize and Find Discrepancy Notes

These features help you organize and find Notes and Discrepancies using the table. They are similar to the features you use to find and organize data in the Subject Matrix.

Number of Discrepancy Notes Per Page

The bottom left corner shows the total number of Discrepancy Notes relevant to you as well as the number currently in view. When there are more Notes than can be listed on the page, use the green arrows above the table to scroll through the pages of Notes. When there is only one page of Notes, the arrows are gray.

To change the number of Notes shown on a page, click the drop-down list next to the arrows and select a value: 15, 25, or 50 per page.

Sort Notes By Column

To sort the table by Study Subject ID, Days Open, or Days Since Updated, click that column header. To reverse the sort order, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

For example, click Study Subject ID to show Notes in that order, with the lowest Study Subject ID value first. Click the column header again to show the highest Study Subject ID value first. The arrow in the column header then points down.

Filter Notes to Show Only Matches for Specified Criteria

You can filter the information shown in the Notes and Discrepancies table to show only Notes and Discrepancies whose data matches criteria you specify:


1. For the column whose data you want to filter, click the gray field below the column header.
2. What you enter in a field depends on the type of field:
 - If a drop-down list displays, select the value you want from it; a value representing your selection appears in the gray field.
 - If no drop-down list displays, type the string of characters you want to include, and press Enter or click Apply Filter (which is to the right of the gray fields).
3. Repeat the above steps to filter by additional columns.
4. To remove filtering for a column, either clear the text you typed, or from a drop-down list, select the empty (top) item. Then press Enter or click Apply Filter.
When filtering is applied, only those Notes and Discrepancies that contain the data you specified are shown.

To clear the filter and show all data, click Clear Filter (which is to the right of the gray fields).






Example of Sort and Filter in Notes and Discrepancies

1. For Type, select the Failed Validation Check option.
The field displays the option (or a numerical code representing the option).
2. Press Enter or click Apply Filter.
The table shows only Notes of the Failed Validation Check Type.
3. For Resolution Status, from the drop-down list in the gray field, select New.
The field displays that option (or a numerical code representing that option).
4. Press Enter or click Apply Filter.
The table shows only Notes whose Status is New and whose Type is Failed Validation Check.
5. For Event Name, in the gray field, type Reg, and press Enter or click Apply Filter.
The table shows only Notes whose Event includes Reg in the name, whose Status is New, and whose Type is Validation Check.
6. Click the Study Subject ID column to sort by that column.
The rows in the table are in Study Subject ID order, with the lowest value first.

Example of Notes and Discrepancies Table After Filtering and Sorting:



Notes and Discrepancies 







[in Hide summary statistics](#)

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

15

Show More




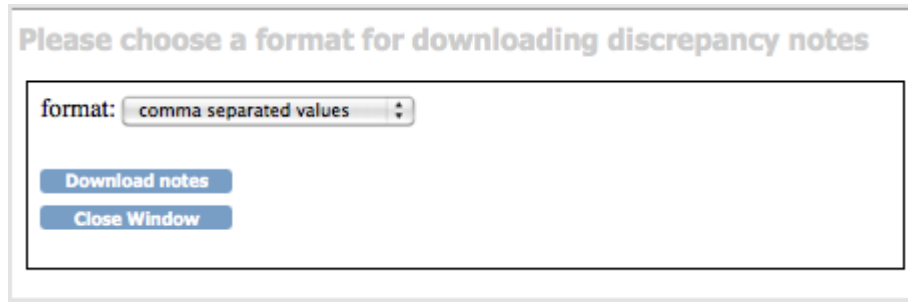
Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
	Failed Validation Check	New				reg						Apply Filter Clear Filter
SCRC005	Failed Validation Check	 New	R01-12345-SCRC	0	274	Registration Visit	Physical Exam	PULSE	55	Pulse rate is lower than expected	()	 
SCRC010	Failed Validation Check	 New	R01-12345-SCRC	0	274	Registration Visit	Eligibility	FASTING_CHOLESTEROL_TRIGLY		Paper source was missing value	()	 

Results 1 - 2 of 2.

15.6.5.4 Download Discrepancy Notes

You can download Discrepancy Notes to a file:

1. [Use the Notes and Discrepancies Filter](#) so the table shows only the Notes you want to download. All data for those Notes will be downloaded, that is all the data that appears when you click Show More, even if you did not click Show More.
2. Click the Download button , which is located above the column headers.
The Download Notes window opens.



Please choose a format for downloading discrepancy notes

format: comma separated values

Download notes

Close Window

3. Select the format for the downloaded file from the drop-down list:
 - Comma separated values (CSV), which is best for use with other software, such as a spreadsheet or database.
 - Portable document format (PDF), which creates a file that is easy-to-read and to print.
4. Click Download notes.

Depending on your browser settings, you might be prompted to open or save the downloaded file.
5. In the downloaded file:
 - The CSV file contains one row for each Note, whether it is a child or parent Note.
 - The PDF file shows a parent Note in bold, followed by the child Notes associated with the parent Note, in the normal font style.
6. In the Download Notes window, click Close Window.

Example of Page from Downloaded Discrepancy Notes, PDF File:

Study Identifier: R01-123456	
Item field name/value: IFC_PDF	
Study Subject: CAM105	Study Event: Registration Visit
Study Event Date: 2011-07-06 12:00:00.0	CRF: Verification of Informed Consent Status: Complete
Type: Query	Resolution Status: New
Number of notes: 2	Discrepancy Note ID: 9
Days Open: 167	Days Since Updated: 167
Discrepancy note id: 10	
Subject name: CAM105	CRF name: Verification of Informed Consent
Description: Please attach signed informed consent	Discrepancy note type: Query
Event name: Registration Visit	Parent note ID: 9
Resolution status: New	Detailed notes: This subject has a signed paper form on record. Please attach
Entity name: IFC_PDF	Entity value:
Date updated: 06-Jul-2011	Study ID: 3

Example of Records from Downloaded Discrepancy Notes, Comma Separated Values File:


	A	B	C	D	E	F	G	H	I	J	K	L
1	Study Subject	Subject Status	Study/Site OID	Thread ID	Note ID	Parent Note ID	Date Created	Date Updated	Days Open	Days Since Updated	Discrepancy Type	Resolution Status
2	CAM105	available	S_R0112345	1	9		6-Jul-11	6-Jul-11	167	167	Query	New
3	CAM105	available	S_R0112345	1	10	9	6-Jul-11	6-Jul-11			Query	New
4	SCRC010	available	S_R0112345_7	2	3		5-Jul-11	5-Jul-11	168	168	Failed Validation	New
5	SCRC010	available	S_R0112345_7	2	4	3	5-Jul-11	5-Jul-11			Failed Validation	New
6	SCRC005	available	S_R0112345_7	3	1		5-Jul-11	5-Jul-11	168	168	Failed Validation	New
7	SCRC005	available	S_R0112345_7	3	2	1	5-Jul-11	5-Jul-11			Failed Validation	New
8	CAM105	available	S_R0112345	4	7		6-Jul-11	6-Jul-11	167	167	Failed Validation	New
9	CAM105	available	S_R0112345	4	8	7	6-Jul-11	6-Jul-11			Failed Validation	New
10												

15.7 Remove, Restore, and Delete Study Events and CRFs for a Subject


If your [User Type and Role have appropriate permissions](#), you can remove and restore Study Event CRFs and Events, as well as delete Study Event CRFs and Events.

15.7.1 Remove and Restore Study Event CRFs for a Subject


You can remove a Study Event CRF if you want to prevent the information in it from being changed, but still want to access the information and potentially restore it for future use. You cannot remove a Study Event CRF when the Study Event status is "scheduled" or "not scheduled." To remove a Study Event CRF for a Subject:

1. In the Subject matrix, click the View icon in the Actions column.
The View Subject page opens.
2. Click the Remove icon  for the Study Event CRF you want to remove.
The Remove CRF from Event page opens.
3. Click Remove Event CRF.
4. Click OK in the confirmation dialog box.
The View Subject page opens, reflecting the removal of the Study Event CRF for that Subject.

After you remove a Study Event CRF:

- You cannot change data in the Study Event CRF.
- You can create Discrepancy Notes for Items in the Study Event CRF.
- The Study Event CRF status is "invalid" .

After a Study Event CRF has been removed, you can restore it so that you can enter data in it:

1. In the Subject matrix, click the View icon in the Actions column.
The View Subject page opens.
2. Click the Restore icon  for the Study Event CRF you want to restore.
The Restore CRF to Event page opens.
3. Click Restore Event CRF.
4. Click OK in the confirmation dialog box.
The View Subject page opens. The Study Event CRF status is no longer "invalid."


15.7.2 Delete Study Event CRFs for a Subject

If you no longer need the data in an Event CRF, you can delete that Event CRF. This is most often used when one Subject's data has been entered into another Subject's form. Unlike the Remove action, once a Study Event CRF has been deleted, that data cannot be restored.

You cannot delete a Study Event CRF if the Event status is "scheduled" or "not scheduled."

To delete a Study Event CRF for a Subject:

1. In the **Subject Matrix Actions** column, click .
- The View Subject page opens.*


2. For the Study Event CRF you want to delete, in the Actions column, click .
The Delete CRF from Event page opens.
3. Click **Delete Event CRF**.
A confirmation box displays.
4. To confirm the deletion, click **OK**.
The View Subject page opens, reflecting the deletion of the Study Event CRF for that Subject.

After you delete a Study Event CRF:


- The CRF is cleared of all data and is available for re-entry.
 - All Notes and Discrepancies associated with the Event CRF are set to auto-closed and attributed to the username of the person who deleted the Event CRF.
 - All Rules that had executed based on the deleted data are reset.
 - All fields that have show/hide functionality are reset to their original state, whether show/hide is done in a Rule or using Simple Conditional Display.
- The Study Event CRF status is "data entry started."
The status is set to "data entry started" because data entry was started on this form, and there is province data associated with that Event CRF (e.g., the audit log and any auto-closed Notes and Discrepancies).

15.7.3 Remove and Restore Study Events for a Subject


You can remove a Study Event if you want to prevent the information in it from being changed, but still want to access the information and potentially restore it for use in the future. You cannot remove a Study Event when its Event status is "not scheduled." To remove a Study Event for a Subject:

1. In the Subject matrix, click the View icon in the Actions column.
The View Subject page opens.
2. Click the Remove icon  for the Study Event.
The Remove Event from Study page opens.
3. Click Remove Event from Study.
4. Press OK in the confirmation dialog box that displays.
The View Subject page opens, reflecting the Study Event's removal for that Subject.

After you remove a Study Event for a Subject:

- Data in CRFs for the Study Event cannot be changed.
- Discrepancy Notes can be created for Items in CRFs for the Study Event.
- The status for all CRFs in the Study Event is "invalid" .

You can restore a Study Event that has been removed for a Subject:

1. In the Subject matrix, click the View icon in the Actions column.
The View Subject page opens.
2. Click the Restore icon  for the Study Event you want to restore.
The Restore Event from Study page opens.
3. Click Restore Event to Study.

4. Press OK in the confirmation dialog box.


The View Subject page opens, reflecting that the Study Event was restored for that Subject.

After restoring a Study Event, the status of the CRFs for that Study Event for the Subject are no longer "invalid."

15.7.4 Delete Study Events

Delete a Study Event to reset the Study Event Status from "scheduled" to "unscheduled." You can delete a Study Event only when the Study Event status is "scheduled."

To delete a Study Event:

1. In the Subject matrix, click the View icon in the Actions column.
The View Subject page opens.
2. Click the Delete icon  in the Actions column for the Study Event CRF.
The Delete Event from Study page opens.
3. Click Delete Event from Study.
4. Click OK in the confirmation dialog box.
The View Subject page opens, showing the Study Event Status as "unscheduled."

15.8 Subject Matrix

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:05AM

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

15.8.1 Overview of Subject Matrix

To access the Subject Matrix, click Subject Matrix in the navigation bar.

The Subject Matrix is a table with Event information for all Subjects in a Study. You can view, enter, and change information for Subjects and their Events in the Study, starting either with the Event or from the collection of all information for the Subject. There is one Subject per row, with the Study Subject ID in the first column. The other columns are for each Event Definition in the Study.

Each cell in the matrix contains an icon that identifies the status of the Event for the Study Subject. Move the cursor over an icon in the matrix to view and access a Subject's data and to access actions you can perform for that Event. Refer to the Icon Key in the sidebar for icon descriptions, and see [About the Event Status](#) for more details.

When the current Study/Site is set to the overall Study level, the matrix shows all Subjects in the Study. When the current Study/Site is set to a Site, the matrix shows only Subjects at the Site.

To add a Subject to the Study, click the Add New Subject link, which is just above the column

headers in the matrix. For more details, see [Add Subject](#).

To work with a Subject across multiple Studies in your OpenClinica system, or to change information about a Subject that cannot be changed using the Submit Data module, instead use the [Administer Subjects](#) features in the Administration Module.

15.8.2 View and Enter Event Data in Subject Matrix

To view or enter data for an Event for a Subject, move the cursor over the icon in the cell.

Subject Matrix After Hovering Over the Icon in the Registration Visit Column for Subject ID CAM102:

The screenshot displays the OpenClinica Enterprise interface. The top navigation bar includes the OpenClinica logo, the study name 'Docetaxel in Patients With ... (R01-123456)', and user information 'StuartDirk (Study Director)'. The main navigation menu has options like Home, Subject Matrix, Notes & Discrepancies, Study Audit Log, Tasks, Report Issue, Support, and a search bar for 'Study Subject ID'. The left sidebar contains sections for Alerts & Messages, Instructions, Info, and an Icon Key. The main content area is titled 'Subject Matrix for Docetaxel in Patients With Completely Resected NSCLC'. It features a table with columns: Study Subject ID, Registration Visit, Initial Treatment, Follow-up Treatment, Adverse Events, and Actions. A tooltip is shown over the Registration Visit icon for Subject CAM102, indicating the event status. The Actions column contains icons for various actions: View, Edit, Remove, Restore, Reassign, and Sign. The bottom of the table shows 'Results 1 - 15 of 26'.

Study Subject ID	Registration Visit	Initial Treatment	Follow-up Treatment	Adverse Events	Actions
CAM101			x2		
CAM102			x2		
CAM103			x3		
CAM104					
CAM105			x2		
CAM106					
CAM107					
CAM108					
CCRC001					
CCRC002					
CCRC003					
SCRC001					
SCRC002					
SCRC003					
SCRC004					

To see the actions you can perform for that Event, click the icon.

You can then select the action you want to perform, or click X to close the list of actions. Depending on your Role and the status of the Event, the actions include: Schedule, View, Enter Data, Edit, Remove, or Add Another Occurrence.

Subject Matrix After Clicking the Icon in the Registration Visit Column for Subject ID CAM102:

Subject Matrix for Docetaxel in Patients With Completely Resected NSCLC

<div> <div>15</div> <div>Show More</div> <div>Select An Event</div> <div>Add New Subject</div> </div>					
Study Subject ID	Registration Visit	Initial Treatment	Follow-up Treatment	Adverse Events	Actions
<div>Apply Filter</div> <div>Clear Filter</div>					
CAM101			x2		
CAM102			x2		
CAM103			x3		
CAM104					
CAM105			x2		
CAM106					
CAM107					
CAM108					
CCRC001					

Subject: CAM102
Event: Registration Visit
Status: data entry started

View/Enter Data

Edit

Remove

15.8.3 Show More Information About Subjects in Subject Matrix

To see more information about Subjects in the Subject Matrix, click the Show More link, which is just above the column headers in the matrix. The matrix widens to add the Subject Status, Site ID, OID (see Object Identifiers in the [Glossary](#)), Sex, Secondary ID, and Group information.

When the matrix is expanded, you can stop showing the additional columns by clicking the Hide link, which is just above the column headers in the matrix.

Subject Matrix After Clicking Show More Provides Additional Information About Subjects:

Subject Matrix for Docetaxel in Patients With Completely Resected NSCLC

<div> <div>15</div> <div>Hide</div> <div>Select An Event</div> <div>Add New Subject</div> </div>											
Study Subject ID	Subject Status	Site ID	OID	Sex	Secondary ID	Treatment Group	Registration Visit	Initial Treatment	Follow-up Treatment	Adverse Events	Actions
<div>Apply Filter</div> <div>Clear Filter</div>											
CAM101	available	R01-123456-CCSO	SS_CAM101	f		Regimen III			x2		
CAM102	available	R01-123456-CCSO	SS_CAM102	m		Regimen II			x2		
CAM103	available	R01-123456-CCSO	SS_CAM103	m		Regimen III			x3		
CAM104	available	R01-123456-CCSO	SS_CAM104	m		Regimen I					
CAM105	available	R01-123456-CCSO	SS_CAM105	m		Regimen I			x2		
CAM106	available	R01-123456-CCSO	SS_CAM106	m		Regimen II					
CAM107	available	R01-123456-CCSO	SS_CAM107	m		Regimen III					
CAM108	available	R01-123456-CCSO	SS_CAM108	f		Regimen I					
CCRC001	available	R01-123456-CCRC	SS_CCRC001	m							
CCRC002	available	R01-123456-CCRC	SS_CCRC002	m		Regimen I					
CCRC003	available	R01-123456-CCRC	SS_CCRC003	m		Regimen I					
SCRC001	available	R01-12345-SCRC	SS_SCRC001	m		Regimen I					
SCRC002	available	R01-12345-SCRC	SS_SCRC002	f		Regimen III					
SCRC003	available	R01-12345-SCRC	SS_SCRC003	m		Regimen I					
SCRC004	available	R01-12345-SCRC	SS_SCRC004	m		Regimen I					

Results 1 - 15 of 26.

15.8.4 Find and Organize Data in Subject Matrix

These features in the Subject Matrix help you find and organize data for the Study Subjects.

Number of Subjects Per Page

The bottom left corner shows the total number of subjects as well as the number currently in view. When there are more Subjects in the Study than can be listed on the page, use the green arrows above the table to scroll through the pages of Subjects. When there is only one page of Subjects, the arrows are gray.

To change the number of Subjects shown on a page, click the drop-down list next to the arrows and select a value: 15, 25, or 50 per page.

Sort Data By Column

By default, the Subject Matrix is sorted by Study Subject ID, with the lowest ID value first. To sort the data by a column, click the column header. Some columns cannot be sorted on; when a column cannot be sorted on, the cursor does not change shape when you hover over the column header. To reverse the sort order, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

For example, click Study Subject ID to show data with the highest ID value first, and the lowest value last. The arrow in the column header then points down. Click again to show the lowest value first.

Filter Data to Show Only Matches for Specified Criteria

You can filter the information shown in the Subject Matrix to show only Subjects whose data matches criteria you specify. You can specify criteria for one Event column and any of the other columns:

1. For the column whose data you want to filter, click the gray field below the column header.
2. If a drop-down list displays, select the value you want from it. If no list displays, type in the string of characters you want to include, and press Enter or click Apply Filter (which is to the right of the gray fields).
3. Repeat the above steps to filter by additional columns.
4. To remove filtering for a column, either clear the text you typed, or from a drop-down list, select the blank (top) item.

When filtering is applied, the Subject Matrix shows only those Subjects that contain the data you specified.

To clear all filtering and show all data, click Clear Filter (which is to the right of the gray fields).

Example of Sort and Filter in Subject Matrix

When Show More in Subject Matrix is selected, as shown in the previous example image, the following filtering and sorting were performed:






1. For Study Subject ID, type CAM in the gray field and press Enter.
The matrix shows only Study Subject IDs that contain CAM.
2. For Treatment Group, from the drop-down list in the gray field, select Regimen I. A 1 displays in the field to indicate that value was selected.
The matrix shows only the Subjects whose ID includes CAM and who are assigned to Regimen I.
3. For the Initial Treatment Event, from the drop-down list in the gray field, select scheduled.
The matrix shows only the Subjects whose ID includes CAM, who are following Regimen I, and whose Initial Treatment is scheduled.
4. Click the Study Subject ID column header to show the highest value first.
The order of the rows changes and a down arrow appears in the column header.

Example of Subject Matrix After Filtering and Sorting:

Subject Matrix for Docetaxel in Patients With Completely Resected NSCLC									
SO Hide Select An Event Add New Subject									
Study Subject ID	Subject Status	Site ID	OID	Sex	Secondary ID	Treatment Group	Registration Visit	Initial Treatment	Follow-up
CAM						1		scheduled	
CAM108	available	R01-123456-CCSO	SS_CAM108	f		Regimen I			
CAM104	available	R01-123456-CCSO	SS_CAM104	m		Regimen I			
Results 1 - 2 of 2.									

15.8.5 Actions for a Subject in Subject Matrix

In the Actions column for a Subject in the Subject Matrix, click the icon for the action you want. The icons that appear depend on the status of the Subject and your user Role.

-  View icon displays a page of detailed information for the Study Subject. From there, you can enter and change Event information for the Subject. For details, see [Enter Data for an Event: Completing CRFs](#).
-  Signed icon indicates all the Events for a Subject are marked complete, and you can [sign the Subject Case Book](#). After you click the icon, you apply your electronic signature, which requires your user name and password.
-  Remove icon removes a Subject from the Study or Site. You can restore the Subject to the Study or Site later.
-  Restore icon appears in the display after the Subject was removed. Restore adds the Subject back into the Study.
-  Reassign Study Subject icon reassigns a [Study Subject to a different Site](#) in the Study.

15.8.6 View Event Details in Subject Matrix

To view the details for a Study Event from within the Subject Matrix, select the Event from the

Select an Event drop-down list, located above the column headers.

This page is similar to the default Subject Matrix, displaying the table with one row per Subject, but the columns are for the Case Report Forms (CRFs) for the Study Event you selected. The first column, Event Status, contains an icon that indicates the overall status of the specified Event for that Subject.

Each cell in the CRF columns contains an icon showing the status of the CRF for that Subject. Hover the cursor over an icon to see more information in a pop-up window. To see the actions you can perform for that Event, click the icon. You can then select the action you want to perform for that particular CRF, including View, Edit, Remove, and Print. Removing an Event marks any CRFs that contain data as Invalid; if needed, you can later restore a CRF you removed. For details about Editing, see [Enter Data for an Event: Completing CRFs](#). Click X in the corner of the pop-up window to close it.

Event Details in Subject Matrix for the Registration Event, After Clicking an Icon for a CRF

Subject Matrix for Docetaxel in Patients With Completely Resected NSCLC

14 15 Show More Events: Registration Visit Add New Subject

Study Subject ID	Event Status	Event Date	Verification of Informed Consent	Eligibility	Physical Exam	Actions
						Apply Filter Clear Filter
SMC103		07-Jul-2011				
SCRC005		05-Jul-2011				
SCRC008		05-Jul-2011				
SCRC002		28-Jun-2011				
SMC102		07-Jul-2011				
SCRC003		07-Jun-2011				
SMC101		06-Jul-2011				
SCRC011		05-Jul-2011				
SCRC007		07-Jun-2011				
SCRC010		05-Jul-2011				
CAM101		17-May-2011				
CAM107		06-Jul-2011				
CCRC002		21-Sep-2011				
SCRC004		20-Jun-2011				
CCRC003		01-Sep-2011				

Subject: SCRC005
CRF: Verification of Informed Consent
Status: data entry complete
View
Print
Edit
Remove

Results 1 - 15 of 26.

To restore the default Subject Matrix view after viewing Event details, select All Events from the drop-down list.





15.8.7 View and Edit Details for a Subject in Subject Matrix

To view detailed information for a Subject, click the View icon in the Actions column. This is a way to see the Subject casebook, that is, all Study information for the Subject. The View Subject page for that Subject opens, with the following sections: Study Subject Record, Events, Group, and Global Subject Record.

To show or hide the information for a section, click the plus or minus sign next to that section. The Events section is shown by default.

Study Subject Record Section

The Study Subject Record section provides overall information about the Subject including the OID (Object Identifier) and other fields such as Date of Birth that are shown if your Study was configured to do so. To view all captured transactions for the Subject, click the Audit Log link. To make changes for the Study Subject, click the Edit Record link, which opens the Update Study Subject Details page.

Study Subject Record			
		Audit Logs Edit Record	
Study Subject ID	CAM101	Person ID 	OC001
Secondary ID		Date of Birth 	07-Jul-1970
OID	SS_CAM101	Sex 	Female
Status	available	Enrollment Date 	10-May-2011
Study Name	Docetaxel in Patients With Completely Resected NSCLC		Site Name Cambridge Center for Surgical Oncology

Events Section

The Events section shows a table of all the events assigned to a Study Subject.

To find Events by name or location, enter the value you are looking for in the text box and click Find.

To add an event for a Subject, click Schedule New Event, which opens the Schedule Study Event page.

Each row in the Events table shows details for an Event for that Subject, reported in the first column.

The other columns of the Events table show details for that Event occurrence:

- Start Date
- Location
- Status
- Actions, represented by icons, that you can perform for the Event
- CRFs for the Event

For each CRF in the Event, the table shows:

- CRF Name
- Version
- Status, represented by icons
- Updated, which reports when the CRF was last updated and who updated it
- Actions, represented by icons, that you can perform for the CRF

You can remove a CRF for a Subject; after being removed, the CRF is marked as Invalid. You can restore a CRF that has been removed.

For more details about editing a CRF, see [Enter Data for an Event: Completing CRFs](#).

By default, Events are ordered by Start Date, with the most recent Start Date first. Click a column header to order by that information. Click again in that column to reverse the sort order.

View Subject: CAM101

Study Subject Record

Events

Page 1 of 1

Find

Schedule New Event

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		 	
Initial Treatment	18-May-2011		data entry started	 	Concomitant Medications	v1.0		06-Jul-2011 (agoodwin)	
					Physical Exam	English		06-Jul-2011 (agoodwin)	
					Agent Administration	v1.0		06-Jul-2011 (jsmith_crc)	
Registration Visit	17-May-2011		completed	 	Verification of Informed Consent	v2.0		06-Jul-2011 (agoodwin)	
					Physical Exam	English		06-Jul-2011 (agoodwin)	
					Eligibility	v1.0		06-Jul-2011 (agoodwin)	

Group

Global Subject Record

Go Back to Subject List

Group Section

The Group section shows the Groups the Subject is assigned to. To add a Subject to a Group, click Assign Subject to Group, which opens the Update Study Subject Details page.

Group

Assign Subject to Group

Subject Group Class	Study Group	Notes
Treatment Group	Regimen III	

Global Subject Record Section

The Global Subject Record section shows the Subject Record.

[Global Subject Record](#)

Person ID	OC001
Date Record Created	06-Jul-2011
Created By	jsmith_crc
Date Record Last Updated	
Updated by	
Status	available
Date of Birth	07-Jul-1970
Sex	Female