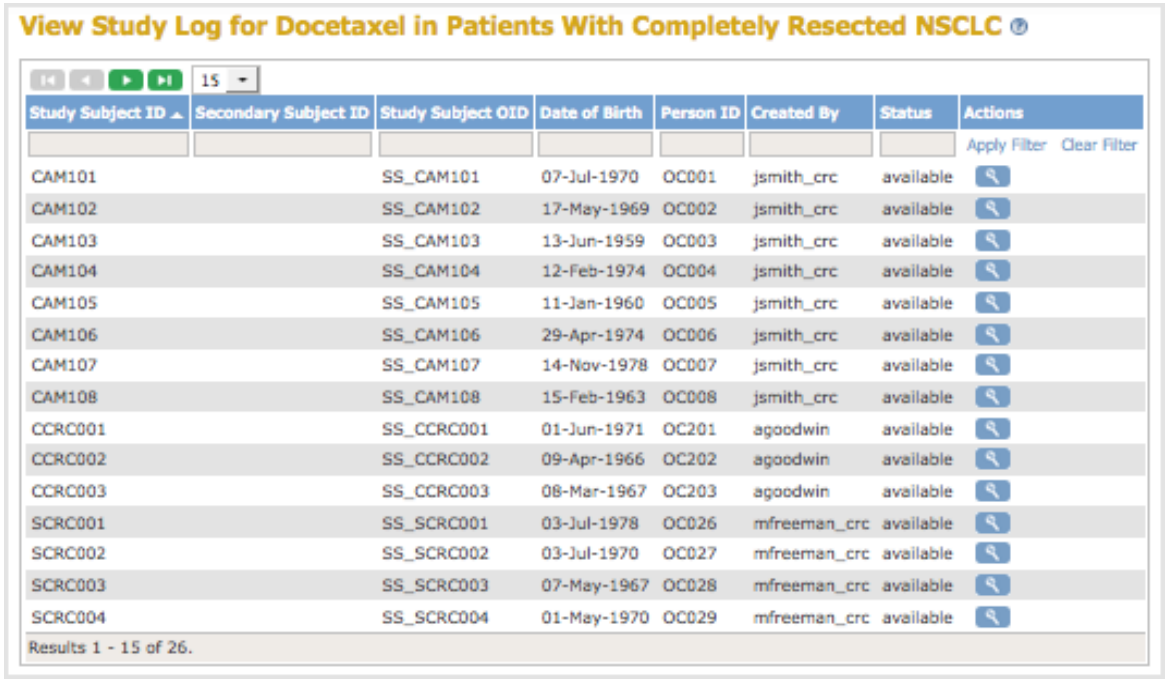
3.2 Study Audit Log

Use the Study Audit Log to view a history of actions on Subjects in the current Study. Only certain user Roles can access the log.

To access the Study Audit Log, click the Study Audit Log link in the navigation bar. The View Study Log page opens for the current Study, presenting a table with each Study Subject in its own row.

You can change the number of Subjects shown per page, change the sort order, and filter the table to show only the Subjects you want to see. These features work the same way as in the Subject Matrix: for more information, see Find and Organize Data in the Subject Matrix.

The View Study Log Page, Sorted by Subject ID:



View Study Log for Docetaxel in Patients With Completely Resected NSCLC

15

Study Subject ID	Secondary Subject ID	Study Subject OID	Date of Birth	Person ID	Created By	Status	Actions
							Apply Filter Clear Filter
CAM101		SS_CAM101	07-Jul-1970	OC001	jsmith_crc	available	
CAM102		SS_CAM102	17-May-1969	OC002	jsmith_crc	available	
CAM103		SS_CAM103	13-Jun-1959	OC003	jsmith_crc	available	
CAM104		SS_CAM104	12-Feb-1974	OC004	jsmith_crc	available	
CAM105		SS_CAM105	11-Jan-1960	OC005	jsmith_crc	available	
CAM106		SS_CAM106	29-Apr-1974	OC006	jsmith_crc	available	
CAM107		SS_CAM107	14-Nov-1978	OC007	jsmith_crc	available	
CAM108		SS_CAM108	15-Feb-1963	OC008	jsmith_crc	available	
CCRC001		SS_CCRC001	01-Jun-1971	OC201	agoodwin	available	
CCRC002		SS_CCRC002	09-Apr-1966	OC202	agoodwin	available	
CCRC003		SS_CCRC003	08-Mar-1967	OC203	agoodwin	available	
SCRC001		SS_SCRC001	03-Jul-1978	OC026	mfreeman_crc	available	
SCRC002		SS_SCRC002	03-Jul-1970	OC027	mfreeman_crc	available	
SCRC003		SS_SCRC003	07-May-1967	OC028	mfreeman_crc	available	
SCRC004		SS_SCRC004	01-May-1970	OC029	mfreeman_crc	available	

Results 1 - 15 of 26.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:21AM

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

3.2.1 Audit Logs Page for a Subject

To view the Audit Logs of Events for a Subject, click the View icon in the Actions column of the View Study Log page. The Audit Logs page opens for the Subject, providing a detailed history for all Events for the Subject.

You can also access the Audit Logs for a Subject from the Subject Matrix. Click the View icon in the Actions column of the Subject Matrix, and then on the View Subject page, expand the Study Subject Record section and select the Audit Logs link (located at the top of the section). The Subject's Audit

Logs page opens.

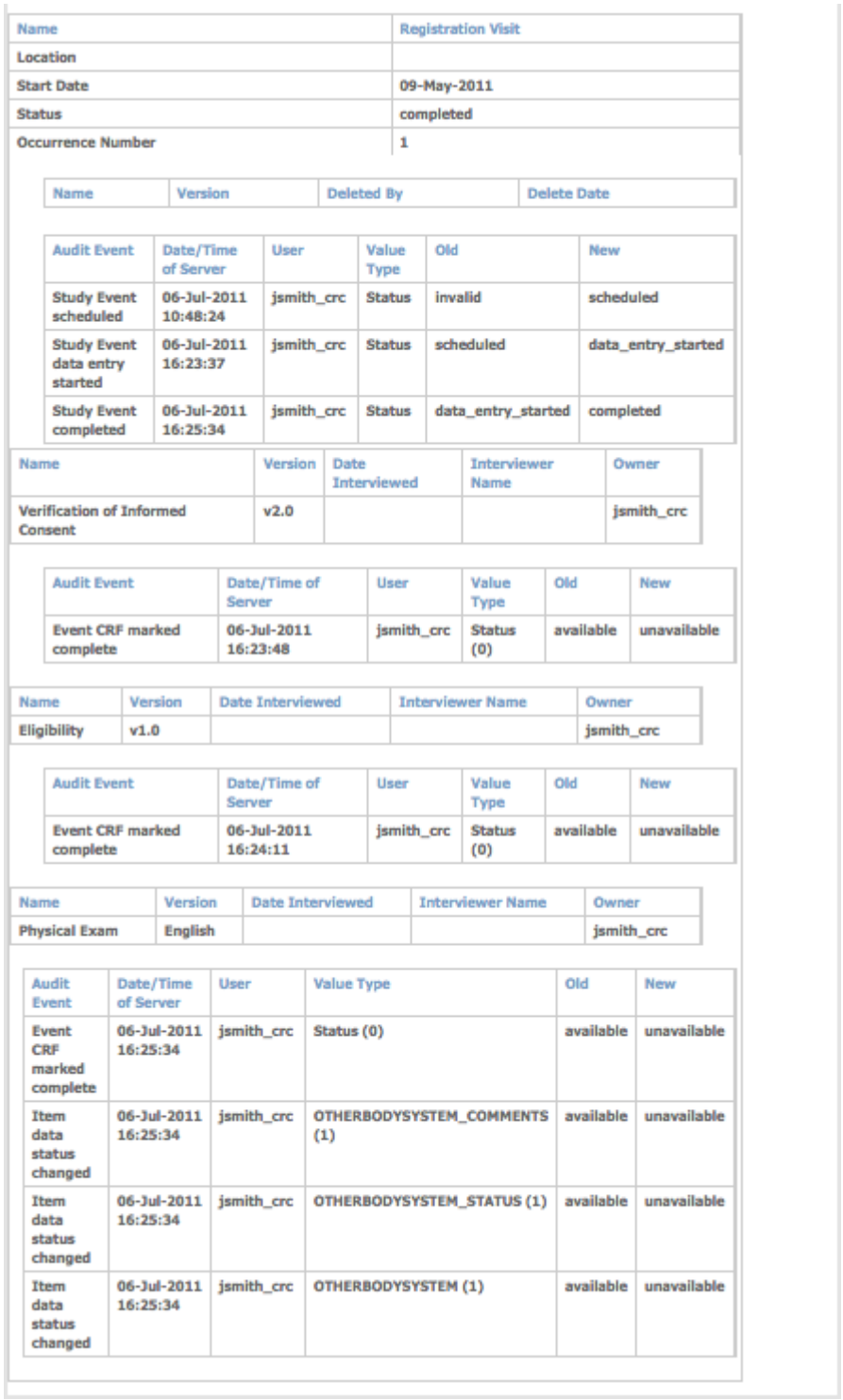
Excerpt from Audit Logs Page for a Subject (CAM103):

CAM103 Audit Logs

Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
CAM103		13-Jun-1959	OC003	jsmith_crc	available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study Subject Created	06-Jul-2011 10:47:25	jsmith_crc			
Subject Created	06-Jul-2011 10:47:25	jsmith_crc			
Subject Group Assignment	06-Jul-2011 10:47:25	jsmith_crc	Status		Regimen III

Study Events	Location	Date	Occurrence Number
Registration Visit		09-May-2011	1
Initial Treatment		16-May-2011	1
Follow-up Treatment		16-May-2011	1
Follow-up Treatment		30-May-2011	2
Follow-up Treatment		06-Jun-2011	3



Name	Registration Visit
Location	
Start Date	09-May-2011
Status	completed
Occurrence Number	1

Name	Version	Deleted By	Delete Date

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study Event scheduled	06-Jul-2011 10:48:24	jsmith_crc	Status	invalid	scheduled
Study Event data entry started	06-Jul-2011 16:23:37	jsmith_crc	Status	scheduled	data_entry_started
Study Event completed	06-Jul-2011 16:25:34	jsmith_crc	Status	data_entry_started	completed

Name	Version	Date Interviewed	Interviewer Name	Owner
Verification of Informed Consent	v2.0			jsmith_crc

Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:23:48	jsmith_crc	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Eligibility	v1.0			jsmith_crc

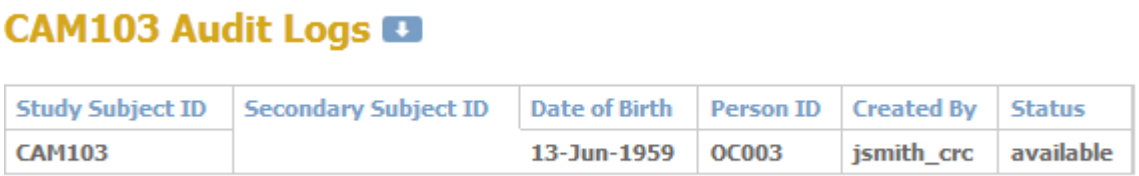
Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:24:11	jsmith_crc	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Physical Exam	English			jsmith_crc

Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:25:34	jsmith_crc	Status (0)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM_COMMENTS (1)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM_STATUS (1)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM (1)	available	unavailable

Download the Audit Log to Excel

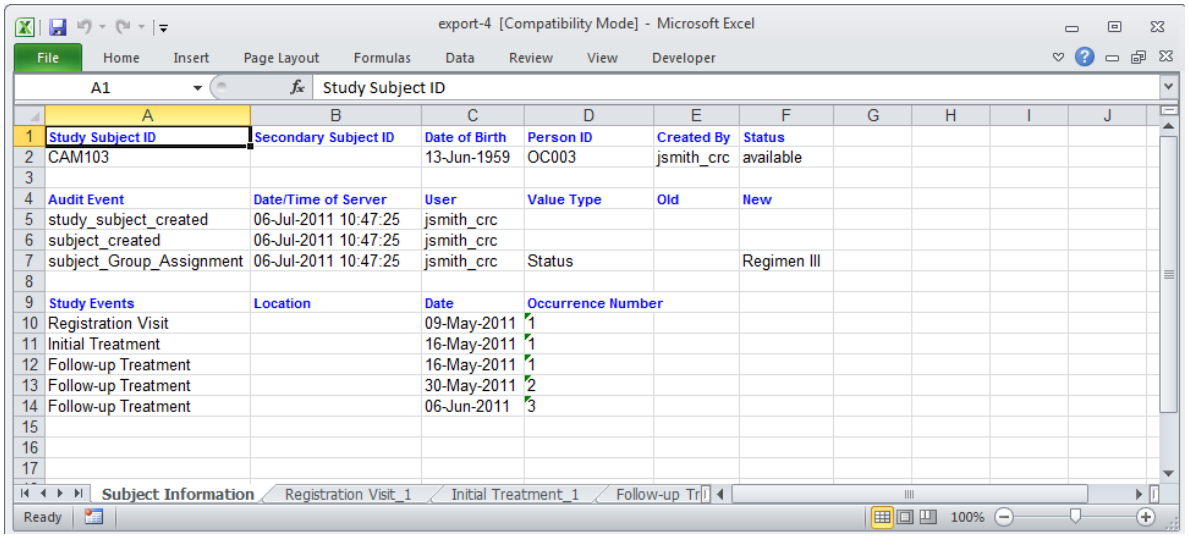
To download the Audit Log to Excel, click the blue download button to the right of the Audit Log header.



CAM103 Audit Logs

Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
CAM103		13-Jun-1959	OC003	jsmith_crc	available

Then, to open the Audit Log in Excel, click OK.



	A	B	C	D	E	F
1	Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
2	CAM103		13-Jun-1959	OC003	jsmith_crc	available
3						
4	Audit Event	Date/Time of Server	User	Value Type	Old	New
5	study_subject_created	06-Jul-2011 10:47:25	jsmith_crc			
6	subject_created	06-Jul-2011 10:47:25	jsmith_crc			
7	subject_Group_Assignment	06-Jul-2011 10:47:25	jsmith_crc	Status		Regimen III
8						
9	Study Events	Location	Date	Occurrence Number		
10	Registration Visit		09-May-2011	1		
11	Initial Treatment		16-May-2011	1		
12	Follow-up Treatment		16-May-2011	1		
13	Follow-up Treatment		30-May-2011	2		
14	Follow-up Treatment		06-Jun-2011	3		
15						
16						
17						

The Subject information is displayed on the first worksheet, and the audit information for each Event is displayed on a separate worksheet.

Note: Though the Audit Log may be easier to read in Excel, this cannot be considered a compliant Audit Log since it can be edited. This functionality is solely provided for ease of viewing the audit information. The Audit Log that is viewed in OpenClinica, however, is fully compliant and cannot be edited.

3.2.2 What the Study Audit Log Tracks

The Audit Log tracks the following for Events:

- Date and time
- Location
- Status
- Date started

This table lists the actions the Audit Log tracks:

What	Actions
CRF	Initial data entry complete
CRF	Initial data entry completed with password
CRF	Double data entry complete
CRF	Double data entry completed with password
CRF	Marked complete
CRF	Completed with password
CRF	Properties changed
CRF	Source data verification status changed
Item on CRF	Data value updated (see Note, below the table)
Item on CRF	Data status changed
Item on CRF	Data deleted
Item on CRF	Data inserted for repeating row
Event	Scheduled
Event	Data entry started

Event	Completed
Event	Stopped
Event	Skipped
Event	Locked
Event	Removed
Event	Start date changed
Event	End date changed
Event	Location changed
Event	Signed
Study Subject	Created
Study Subject	Status changed
Study Subject	Value changed
Subject	Created
Subject	Status changed
Subject	Value changed
Subject	Global value changed
Subject	Site assignment made
Subject	Group assignment made
Subject	Group changed

Note: Starting with the OpenClinica 3.1.2 release, initial values for CRF Items provided during data entry are tracked in the Audit Logs, and reported as "Item data value updated." This is only tracked when a value is provided; empty or non-existent values are not tracked. Prior to the OpenClinica 3.1.2 release, initial values for CRF items were not tracked.

The Audit Log does not track Discrepancy Notes, but you can view or download the full thread for any Discrepancy Notes you want to see. Discrepancy Notes cannot be removed, so they are all always available.