

1.2 Study Audit Log

Use the Study Audit Log to view a history of actions on Subjects in the current Study. <u>Only certain</u> <u>user Roles</u> 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 <u>Find and Organize Data in the Subject Matrix</u>.

The View Study Log Page, Sorted by Subject ID:



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.

1.2.1 Audit Logs Page for a Subject

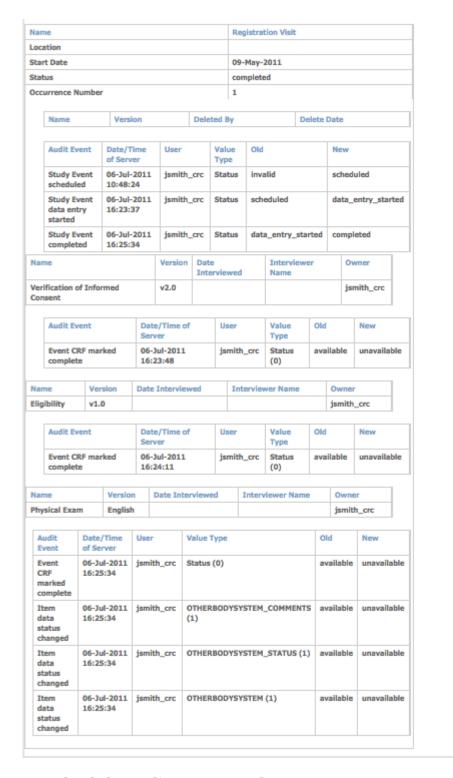
To view the Audit Logs of Events for a Subject, click the View icon in the Actions column of the View Study Log page. The Audit Logs page opens for the Subject, providing a detailed history for all Events for the Subject.

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):

Study Subject ID	Secondary Subject I			ID Date of Birth		Person ID OC003		Cı	Created By jsmith_crc	Status
CAM103			13-Jun-1959					js		
Audit Event	Date/Time of Server		User		Value Type		Old	d 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		js	mith_crc St				Regi III	imen	
Study Events		Location	Date		(Occurrence Nu		Numb	per	
Registration Visit			09-May-2011		1	1				
Initial Treatment			16-May-2011		1	1				
Follow-up Treatment			16-May-2011		1	1				
Follow-up Treatment			30-May-2011		2	2				
Follow-up Treatment			06-Jun-2011		3	3				



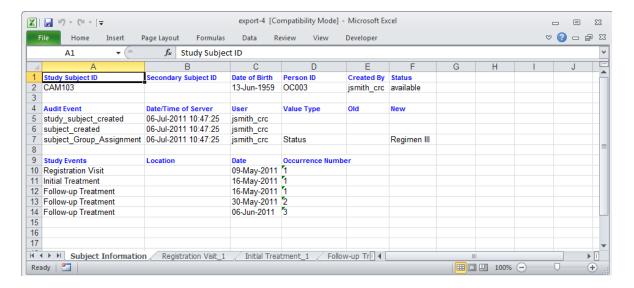
Download the Audit Log to Excel

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.



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.

1.2.2 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.