



8.5 Participant Audit Log

The **Participant Audit Log** tracks all changes made to a participant's data. Each row in the log records an audited event, detailing what changed and which user made the change.

You can access the **Participant Audit Log** in two ways:

1. From the Study Audit Log:

- Click **Study Audit Log** from the navigation menu or the Tasks menu.
- Click the icon in the Actions column for the desired participant.

2. From the Participant Details Page (PDP):

- Navigate to the PDP for the participant you wish to review.

Study Audit Log

The **Study Audit Log** page provides high-level information about each participant, offering a central point of access for all participants' audit logs. The table includes the following elements:

• Participant Data

- **Participant ID:** Unique identifier for each participant. Each row represents a participant in the study.
- **Created By:** Username of the user who added the participant.
- **Status:** Current status of the participant (e.g. Available, Removed and Signed).
- **Actions:** Click the **View** icon to access the detailed audit history for the selected participant.

• Table Controls

- **Pagination Controls:** Located at the top of the table, these allow you to navigate through the list of participants. Use the buttons for first/previous/next/last page, and the page-size selector to adjust the number of rows shown per page.
- **Filters:** Text boxes or filter links appear in the header row, allowing you to enter criteria and click **Apply Filter** to narrow the list by Participant ID or other values. The **Clear Filter** link resets the filtering.

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Participant ID	Created By	Status	Actions
			Apply Filter Clear Filter
12001	aflathers	Available	Q
12001**	aflathers	Available	Q
01-004	nkausar+crc@openclinica.com	Removed	Q
01-001	nkausar+crc@openclinica.com	Available	Q
01-003	nkausar+crc@openclinica.com	Removed	Q
01-008	nkausar+crc@openclinica.com	Available	Q
01-009	nkausar+crc@openclinica.com	Available	Q
01-011	nkausar+crc@openclinica.com	Available	Q
01-012	nkausar@openclinica.com	Available	Q
01-0002	nkausar@openclinica.com	Available	Q
01-0001	nkausar@openclinica.com	Available	Q

Participant Audit Log

The **Participant Audit Log** details what data was added, modified, or removed at the participant, event, and form levels, when it was changed, and who made each change. The combination of timestamp, event type, and old/new values provides a complete history of the participant record, including changes made to participant-level data, event data, and form data.

Participant-Level Data

Participant-level data includes updates to status and contact information. The first two tables within the **Participant Audit Log** show this information.

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Participant ID	Created By	Status
01-001	nkausar+crc@openclinica.com	Available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Participant status changed	20-May-2025 12:52:01	nkausar@openclinica.com	Status	Removed	Available
Participant status changed	20-May-2025 09:36:42	nkausar@openclinica.com	Status	Available	Removed
Participant first name changed	20-May-2025 09:34:23	nkausar+crc@openclinica.com	Participant First Name	<Masked>	<Masked>
Participant access code reset	20-May-2025 09:34:23	nkausar+crc@openclinica.com	Participant access code		
Participant value changed	20-May-2025 07:17:07	S_HEADACHE.TEST.SS_01001	Secondary Subject ID		
Participant first name changed	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant First Name	<Masked>	<Masked>
Participant email address changed	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant Email Address	<Masked>	<Masked>
Participant access code reset	20-May-2025 06:08:34	nkausar+crc@openclinica.com	Participant access code		
Participant Created	20-May-2025 06:07:03	nkausar+crc@openclinica.com			

- **Participant ID:** Unique identifier for each participant in the study.
- **Created By:** Username of the person who created the participant record.
- **Status:** Current status of the participant (e.g., Available, Removed).
- **Audit Event:** Type of action recorded (e.g., Participant Created, Participant [contact data type] changed).
- **Date/Time of Server:** Server timestamp when the audit event occurred.
- **User:** Username of the person who performed the logged action.
- **Value Type:** Field that was modified (e.g., Participant First Name, Status).
- **Old:** The value before the change was made (blank if newly created).
- **New:** The updated value after the change (blank if the value was removed).

□ **Note: Protected data, such as a participant's name, email, or other contact information, is masked in the audit logs for all roles except CRC and Investigator, even if the user has access to view the form containing that data. For more information about contact data, refer to [Understanding Contact Data](#).**

Event-Level Data

Event-level data includes updates to a participant's events. This section contains a **Table of Contents** with links to the various events and the associated event-specific audit log.

- **Event Table of Contents**
 - **Study Events:** The defined visits or common events for a study participant (e.g., Consent, Follow-up).
 - **Start Date:** The start date of a specific study event.
 - **Occurrence Number:** Displays the sequence number for a repeating study event (e.g.,

"1" indicates the first occurrence). The highest number indicates how many times the event has occurred.

Study Events	Location	Start Date	Occurrence Number
Consent		20-May-2025	1
Eligibility		20-May-2025	1
Participant Baseline		20-May-2025	1
Clinical Exam		20-May-2025	1
Followup Visit		20-May-2025	1
End of Study		20-May-2025	1

• **Event Audit Log**

- **Audit Event:** The type of action recorded (e.g., Study Event workflow status changed, Study Event start date changed, etc.)
- **Date/Time of Server:** The server timestamp when the audit event occurred.
- **User:** The username of the person who performed the logged action, or **System** for actions triggered automatically, such as Calendaring or Randomization.
- **Value Type:** The field that was modified (e.g., Status, Start Date).
- **Old:** The value before the change was made. Blank if newly created.
- **New:** The updated value after the change. Blank if the value was removed.
- **Details:** Populated with the signature attestation when an Investigator or Data Specialist signs the participant’s event.

Audit Event	Date/Time of Server	User	Value Type	Old	New	Details
Study Event signed status changed	19-Sep-2025 07:47:28	nkausar+investigator@openclinica.com	Signed		Yes	This event was signed by Neha Kausar (nkausar+investigator@openclinica.com) on Fri Sep 19 07:47:28 UTC 2025 under the following attestation: "I confirm that the data for this participant 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." This signature applies to the following forms in this event: Eligibility, Screening Criteria.
Study Event workflow status changed	19-Sep-2025 07:45:24	nkausar@openclinica.com	Status	Data Entry Started	Completed	
Study Event workflow status changed	19-Sep-2025 07:45:03	nkausar@openclinica.com	Status	Scheduled	Data Entry Started	
Study Event start date changed	19-Sep-2025 07:38:15	system	Start Date		19-Sep-2025	
Study Event workflow status changed	19-Sep-2025 07:38:15	system	Status		Scheduled	

Form-Level Data

Form-level data includes information about form status as well as all data entry / updates made to form data.

- **High Level Form Information**

- **Name:** The name of the form.
- **Version:** The current version of the form.
- **Owner:** These are the options for the owner:
 - Form entered or modified by the study user in Study Runner: The owner is shown as the user's email address.

Name	Version	Date Interviewed	Interviewer Name	Owner
Screening Criteria	1			nkausar@openclinica.com

- Form entered or completed by the Participant in Participate: The owner is shown as the participant's unique ID.

Name	Version	Date Interviewed	Interviewer Name	Owner
eConsent	1e			S_HEADACHE.TEST.SS_01001

- **PublicURL:** Displays “PublicURL” when the form is submitted through the PublicURL feature (no authenticated participant is associated with the submission).

- **Form Data Changes**

- **Audit Event:** The type of action recorded (e.g., Event CRF workflow status changed, Item data value updated, etc.)
 - For data pulled via Unite from an Electronic Health Record (EHR), this column also includes:
 1. **Source:** The system type where the data originated (e.g., Electronic Health Record).
 2. **Data Originator:** The site or healthcare organization from which the data was retrieved (e.g., hospital or clinic).
 3. **Data Element Identifier:** The unique identifier of the specific data element imported from that site’s EHR system.
- **Date/Time of Server:** The server timestamp when the audit event occurred.
- **User:** The username of the person who performed the logged action.
- **Value Type:** The field that was modified (e.g., Status, [form item OID], etc.).
- **Old:** The value before the change was made. Blank if newly created.
- **New:** The updated value after the change. Blank if the value was removed.
- **Details:** Populated with the signature attestation when an eConsent form is signed.

□ **Note:** Form data for which the user lacks access permissions is masked in the Participant Audit Log. For more information about form data access, refer to [Managing Form Access and Permissions](#).

Audit Event	Date/Time of Server	User	Value Type	Old	New	Details
Event CRF workflow status changed	20-May-2025 09:26:38	S_HEADACHE.TEST.SS_01009	Status	Initial Data Entry	Completed	
Consent status changed	20-May-2025 09:26:38	S_HEADACHE.TEST.SS_01009	Consent		Consent Signed	This form was signed by <Masked> (01-009) (SS_01009) on Tue May 20 09:26:38 UTC 2025 under the following attestation: "I freely and voluntarily consent to participate in this study. I intend for this electronic signature to be the legally binding equivalent of my written signature."
Item data value updated	20-May-2025 09:26:27	S_HEADACHE.TEST.SS_01009	CONSENT_YN (1)		Yes	
Item data value updated	20-May-2025 09:26:26	S_HEADACHE.TEST.SS_01009	AGREE (1)		I am willing to participate in this study. (1)	
Item data value updated	20-May-2025 09:26:20	S_HEADACHE.TEST.SS_01009	CODE (1)		CAR-T	
Event CRF workflow status changed	20-May-2025 09:26:20	S_HEADACHE.TEST.SS_01009	Status		Initial Data Entry	

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