

Audit Trail

eTMF contains an audit trail that allows you to chronologically track system and user-initiated actions (i.e., events) throughout the system. In the audit trail, these events provide timestamped evidence of activities performed in the eTMF, particularly those that result in a change to the database. The audit trail can be used for a variety of purposes, but it primarily provides proof of compliance with Title 21 CFR Part 11 of the Code of Federal Regulations, which states the following requirement:

Use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying. (CFR – Code of Federal Regulations Title 21, 2018)

eTMF records numerous events in the audit trail, including, but not limited to:

- User creation
- Login attempts
- Creation of placeholders for expected eTMF documents
- Content upload
- Lifecycle status changes
- Workflow task acquisitions, delegations, and completions
- Creation of document versions
- Creation of scanning transmittals
- Content viewing

For each event, you can see the audited date and the username of the user who was responsible for the event. Depending on the type of event, different information displays. For example, events related to study items display the document type as the Audited Name.

Audit record dates in the UI are displayed in the user's local time zone, which is determined from their machine's setting; while the audit trail dates in exports are shown in UTC

Note: Audit trail records are retained if the associated study is retained in the eTMF.

To view all audit trail events (Application Audit Trail):

A Business Administrator or a user account with View Audit Trail permissions can access an audit trail containing all recorded events in the eTMF.

1. Click the **Actions** icon in the global header and select **View eTMF Configurations**.
2. Click on the page breadcrumb and select **Application Audit Trail** from the menu.
3. (Optional) To export your audit trail, select the **Actions** icon in the item window, then select **Export to Excel**.

To view your personal audit trail:

1. Click your username in the eTMF header and select **View/Edit User Account**.
2. Click **View Audit Trail**.

To view another user's audit trail:

Before you begin: Ensure your user group has the **Manage Users Permissions** enabled.

1. Click the **Actions** icon in the global header and select **View eTMF Configurations**.
2. In the Breadcrumbs, select **User Administration**.
3. On the User Administration Screen, locate the user.
4. Click on the **Actions** icon for the user and select **View Audit Trail**.

To view a document audit trail:

1. In your study item list locate your study item.
2. Click the **Actions** menu icon and select **View Audit Trail**.

Tip: You can open your document and perform the previous steps to view the document audit trail as well.

To view study specific audit trail events:

A Business Administrator or a user account with Export Bulk permissions can generate an export of audit events related to a particular study. This is also referred to as the study audit trail and can only be viewed within a file export.

1. From the User Home page, select your study.
2. In your study item list click the **Actions** icon and select **Study Audit Trail Export**.
3. Apply any of the following filters:

- **Include Entries for Business Documents:** This field is available for users with TMF View Business Documents group permissions. The default value in this field is **No**.
- **Include Entries for Virtually Deleted Documents:** Choose **No** if you do not want to include entries for virtually deleted documents that contain sensitive information. The default value in this field is **Yes**.

- **Export Date Range Start:** Select a date to export study items finalized after the start date.
- **Export Date Range End:** Select a date to export study items finalized before a specific date.

4. Click **Export**.

5. Click the **Actions** icon in the global header and select **View Downloads**.

6. Select your Study Audit Trail Export to download the file to your local machine.