

Viedoc TMF User Guide

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Overview of Viedoc TMF

Overview of Viedoc TMF

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Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

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- [Viedoc User Guide for eTMF Managers](#) (old interface)

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- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Overview

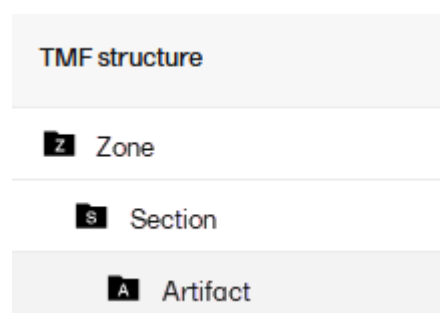
Viedoc [TMF](#) is a digital repository for capturing, managing, sharing, and storing essential documents (records) for your clinical trial.

Viedoc TMF is based on the **TMF Reference Model** by the Clinical Data Interchange Standards Consortium ([CDISC](#)). The TMF Reference Model is an industry consensus catalog of all TMF records. Using the TMF Reference Model ensures compatibility and interoperability with other clinical trial parties, such as CROs.

The TMF Reference Model includes records in all different phases of a clinical trial:

- Before the start of the trial
- During the trial
- After study termination

The TMF Reference Model categorizes records in zones, sections, and artifacts in a hierarchical structure:



The set of zones, sections, and artifacts included is defined in a template file that is maintained by the eTMF Manager.

The TMF can include both the Investigator Site File ([ISF](#)) and the sponsor TMF.

For portability reasons, the TMF Reference Model is defined in an Excel file.

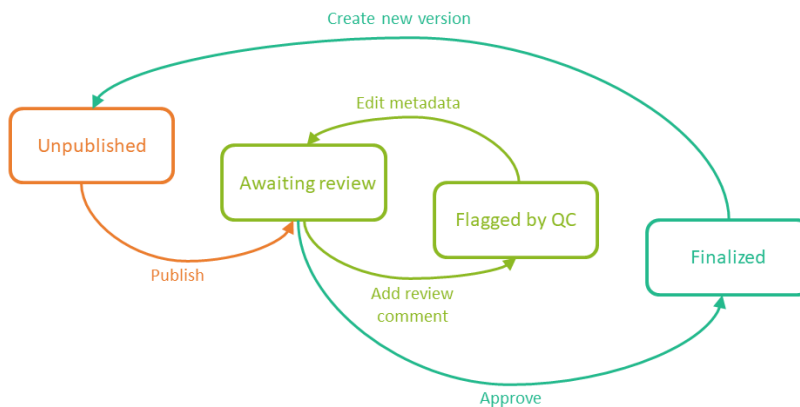
Viedoc TMF also uses Excel files as templates for the TMF structure.

2 Roles and permissions

For detailed information please see [Roles and permissions in Viedoc TMF](#).

3 Record statuses and actions

The following image shows the record version statuses and the actions that change the status of a record version. The initial status of a record when it is uploaded to Viedoc TMF is **Unpublished**.



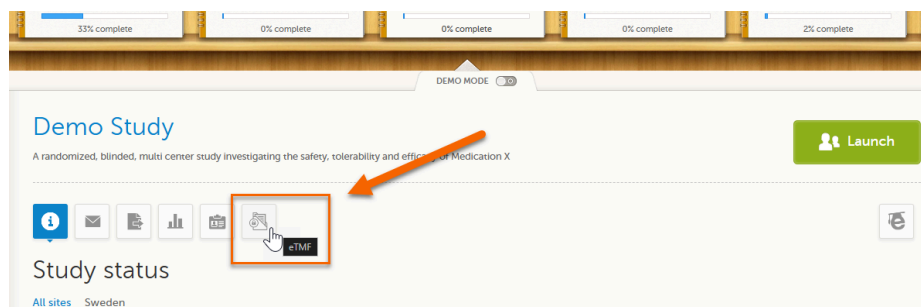
If you edit the metadata for a record version that is **Unpublished** or **Awaiting review**, the record version status is not changed.

It is not possible to edit the metadata of a **Finalized** record. To make changes, a new version needs to be created.

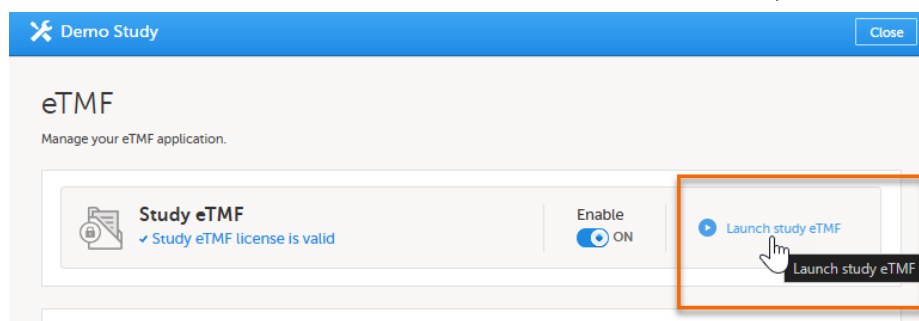
Note! Different actions require different permissions, which means that they are performed by users with different roles.

4 Launching Viedoc TMF

To launch Viedoc TMF for a study log in to Viedoc, select the study from the study slider, and select the **eTMF** icon:



Alternatively, if you have been assigned an eTMF Manager role, you can also launch Viedoc TMF by logging into Viedoc, navigating to Viedoc Admin, selecting the study, opening the eTMF settings and selecting **Launch study eTMF**:

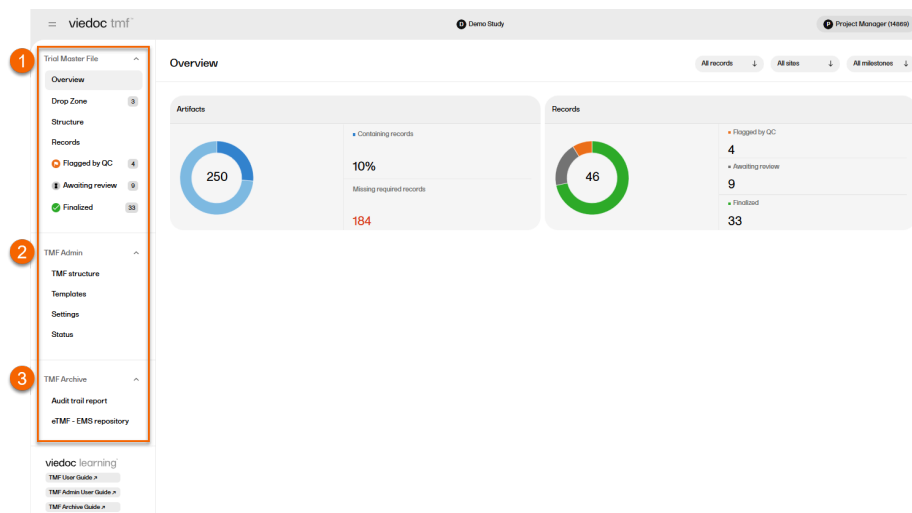


5 Viedoc TMF views

In the left navigation menu, there are three main areas or views in Viedoc TMF:

1. Trial Master File
2. TMF Admin
3. TMF Archive

Access to these are determined by a user's role and permissions. They are described briefly in the sections below.



5.1 Trial Master File

Users with a Viedoc Clinic role that is mapped to a TMF role have access to the Trial Master File area. In the left navigation menu, select to expand **Trial Master File** to see the four pages for managing records in the TMF:

- | | |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Overview page | Shows metrics for artifacts and records in the TMF. Allows the user to filter the metrics by level, site, and milestones. |
| The Drop Zone page | Allows users to upload or "drop" files to a public or private folder (called a "drop zone") and move them into the TMF structure later.

Please see TMF Drop Zone for more information. |
| The Structure page | Allows users to manage records in the TMF structure.

Please see Managing records for more information. |
| The Records page | Provides an table containing the records that you have access to with their metadata.

Please see TMF Records page for more information. |

5.2 TMF Admin

A user with an **eTMF Manager** role or the **Read-only eTMF Admin** permission, has access to TMF Admin. In the left navigation menu, select to expand **TMF Admin** to see the four pages for managing the TMF:

The TMF structure page	<p>The eTMF Manager can manage the TMF structure on this page.</p> <p>Please see Editing a structure for more information.</p>
The Templates page	<p>The eTMF Manager can manage, import and export TMF templates on this page.</p> <p>Please see the TMF Admin User Guide to find several lessons about templates.</p>
The Settings page	<p>Contains settings for Viedoc TMF.</p> <p>Please see TMF settings for more information.</p>
The Status page	<p>Shows the status of the TMF, which can be one of the following:</p> <ul style="list-style-type: none">▪ Enabled: The TMF is enabled but no structure is instantiated yet.▪ Instantiated: The TMF is enabled and there is an instantiated structure. Users who have access to the TMF can work according to their roles and permissions.▪ Locked: The TMF is locked and available for users in read-only mode. Users with permissions to TMF Archive can generate and download the eTMF-EMS repository and the complete audit trail report.

5.3 TMF Archive

A user with permission to **Download audit trail report** have access to TMF Archive. In the left navigation menu, select to expand **TMF Archive** to see the two pages for generating archive reports:

The Audit Trail Report page	Allows users to generate and download a complete audit trail report.
The eTMF-EMS Repository page	Allows users to generate the eTMF - EMS Repository.

Please see [TMF Archive](#) for more information.

6 Viedoc Learning links

In the left navigation menu below the TMF views, users can find links to relevant user guides based on their roles and permissions including:

- [TMF User Guide](#)
- [TMF Admin User Guide](#)
- [TMF Archive Guide](#)

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Roles and permissions in Viedoc TMF

Roles and permissions in Viedoc TMF

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- [Viedoc TMF Admin User Guide](#)

1 Introduction

In Viedoc TMF, roles and permissions determine what a user can or can't see in the application, which actions they can perform, and which records they can access. Proper role assignment ensures secure and efficient record management while maintaining compliance with regulatory requirements.

2 Viedoc system and clinic roles that can access Viedoc TMF

In Viedoc, there are two types of roles:

- **System roles** are predefined by Viedoc and cannot be changed, and give access to various features in Viedoc Admin and Viedoc Designer.
 - The **Study Manager** is the only system role that can assign the **eTMF Manager** role to a user in Viedoc Admin.
 - The **eTMF Manager** is a system role that can manage the TMF settings in Viedoc Admin, map clinic roles to TMF roles, and access the TMF admin area in the TMF application.
- **Clinic roles** (sometimes called study roles or EDC roles) can be customized to each individual study. These roles give access to Viedoc Clinic.
 - The **eTMF manager** can map specific TMF roles and permissions to the different clinic roles, creating customized role-based access. See the [Mapping roles](#) section below for instructions on how to do this.

See [About roles in Viedoc](#) for more information about system and clinic roles in Viedoc.

TMF roles, which are different from Viedoc system and clinic roles, are described in the next section.

3 Viedoc TMF roles and permissions

The user access to Viedoc TMF is determined by the assigned roles and permissions. TMF roles and permissions can work in combination or independently.

3.1 TMF Levels and permissions

Depending on the permission associated with your user role, you can perform different actions on records. Your user role can have permission (no access, read, write, or review) on these TMF levels:

- Study/trial
- Country
- Site

You can only see and access records if you have permissions for the artifact on the corresponding TMF level.

For example, if an artifact is linked to two sites, a user with **write** permission for the artifact for only one of the sites will be able to read but not edit the record. This is due to the fact that the user does not have write permissions for **all** sites that the record is linked to.

3.2 The eTMF Manager role

The eTMF Manager is a Viedoc system role ([see above](#)) and has permissions to manage the TMF application in Viedoc Admin and to manage templates in Viedoc TMF.

3.3 The TMF user roles

The user access to Viedoc TMF is determined by the assigned roles and permissions. The roles and permissions can work in combination or independently. These user roles are defined in the template, which is maintained by the **eTMF Manager**.

The TMF roles are:

- Site staff
- Sponsor study
- Sponsor country
- Sponsor site
- Reviewer
- Sponsor Data Manager
- Sponsor unblinded

The respective permissions for these TMF roles are specified in the Excel template file, on the Role sheets. For more information, see the [Roles sheets](#) section in the Customizing a template lesson.

3.4 The TMF permissions

These permissions are defined in **Viedoc Admin** and are assigned to users by the **eTMF Manager**. See [Assigning roles and permissions in Viedoc Admin](#) below for instructions on how to do this.

Permissions in Viedoc TMF can work in combination with roles or independently, providing granular control over user actions:

Archive sponsor TMF	Allows users to access the TMF Archive view and archive artifacts that are listed as Sponsor side. (This is set in the Edit artifact window or in the template file on the sheet V 3.1.0, column M Sponsor Document).
Archive investigator TMF	Allows users to access the TMF Archive view and archive artifacts that are listed as Investigator side. (This is set in the Edit artifact window or in the template file on the sheet V 3.1.0, column N Investigator Document).

Read-only TMF Admin	<p>Allows user to inspect the structure, templates, and other settings in the TMF Admin view in read-only mode.</p> <p>A user with this permission can access the TMF Admin view and is able to:</p> <ul style="list-style-type: none"> ■ View a selected/instantiated structure ■ Export templates and structure ■ View the settings tab
Read-only Trial Master File	<p>Provides users read-only access to the whole TMF structure and all the "available" records (published and unpublished records linked to a level the user has access to within their scope) in the TMF.</p> <p>Note! This permission overrides all NO ACCESS permissions. Additionally, a user with Read-only Trial Master File permission in combination with a role that grants them WRITE or REVIEW access to a record will still have these permissions.</p>
Download audit trail	Allows users to access the TMF Archive view and generate and download the complete audit trail report.
Manage drop zone	Allows users to manage the files in the shared Drop Zone.
Manage record sharing for Viedoc Clinic users	Allows users to share records with Viedoc Clinic users.
Manage record sharing for Viedoc Me users	Allows users to share records with Viedoc Me users.

For TMF access use cases and frequently asked questions, please see [TMF access use cases](#).

4 Assigning Roles and Permissions in Viedoc Admin

Viedoc TMF user roles are assigned and managed in **Viedoc Admin**.

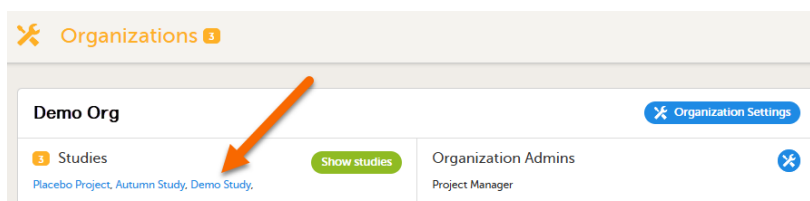
Only the **eTMF Manager** has permission to assign and manage TMF user roles for a specific study.

Note! If a role or permission is changed while the user is actively using Viedoc TMF, the user with the changed role/permissions will need to close and reopen Viedoc TMF for the changes to take affect.

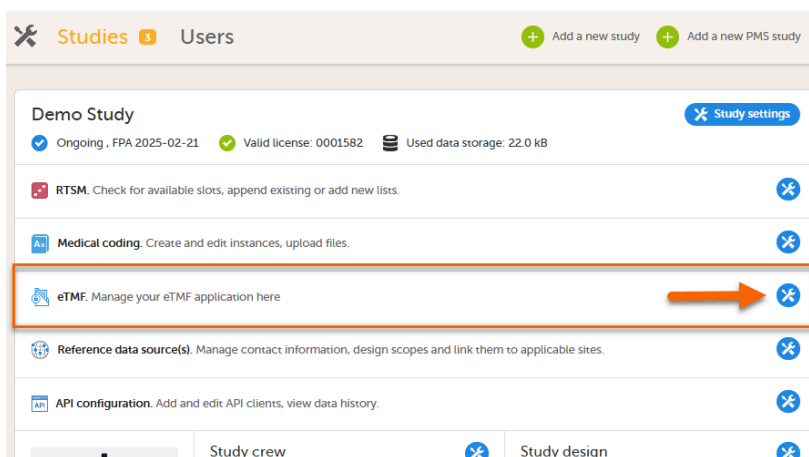
4.1 Mapping clinic roles to TMF roles and permissions

To map the Viedoc clinic roles to TMF roles and permissions:

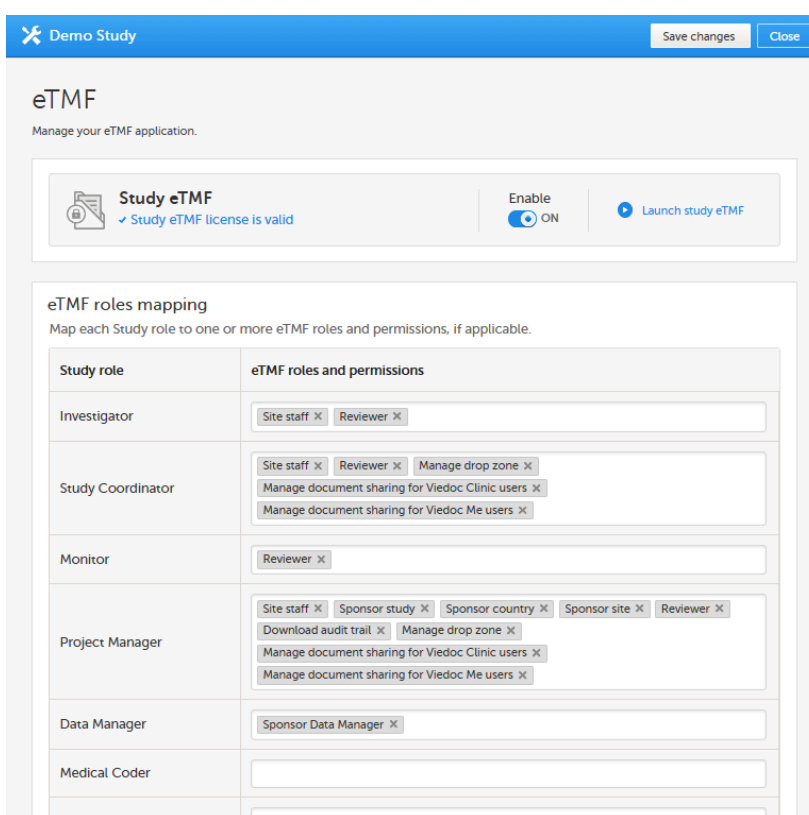
- 1 Go to Viedoc Admin, and select a study to open the study overview page:



2 Select the eTMF settings button:



3 In the eTMF roles mapping area, select the TMF role(s) and/or permission(s) that you want to map to the Viedoc clinic (study) roles:



Note! The Viedoc study roles correspond to the Clinic roles for the study, and are set in the study design. The TMF roles correspond to the roles specified in the TMF template file. You can map a study role to one or several TMF roles and permissions.

4 Select **Save changes**.

4.2 Modifying and revoking roles

- To **modify a role**, follow the same steps above and select a new role or permission.
- To **remove a user's access**, follow the same steps above and remove the role or permission from their associated study role.

4.3 Best practices for assigning permissions

- Assign roles based on job responsibilities—avoid giving excessive permissions.
- Regularly review user roles to ensure compliance and security.
- Use **custom roles** when predefined options don't meet operational needs.
- Limit **eTMF Manager** access to only those responsible for system-wide TMF settings.

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5 TMF roles, permissions and tasks

The following table lists several examples of tasks that study users can face, together with the TMF roles, the Viedoc Clinic site groups, and the TMF level access that they would need to perform the respective task.

For more information about site groups, see [Managing users](#) and [Managing study sites](#) in the Viedoc Admin User Guide.

Study role	Task	TMF role	Viedoc Clinic site group	TMF level access	Permissions	Comments
Study coordinator General site user	Drop records in the shared drop zone	Site staff - customized with no access for all artifacts	Site	No access to all artifacts	None	
Study coordinator General site user	View, file, and classify site-level records, view some artifacts on country and study levels, archive the Investigator site TMF	Site staff	Site	Write access to pre-defined artifacts on site level, read access to pre-defined artifacts on study, site, and country levels	1. Archive Investigator TMF	
Project manager	File study-level records, view all sponsor-side records, archive the sponsor TMF, download audit trail, and see TMF settings and structure	Sponsor study	All production sites*		1. Download audit trail 2. Archive sponsor TMF 3. Read-only TMF Admin	*Clinic access needs to be on study level and not every site one by one, otherwise the write permission will be translated to read permission.

Study role	Task	TMF role	Viedoc Clinic site group	TMF level access	Permissions	Comments
Monitor	File site-level records, view all records for the study, my country, and my site, manage drop zone records, review site level records	Sponsor site Reviewer*	Site**	Write and review access on site level Read access on all levels	1. Manage drop zone	*Although the role sheet grants review rights for study and country level records too, the end user will only have read rights to those records, as long as they are not invited on study or country level for their clinic role. **Clinic access needs to be given to all applicable sites.
Country manager Trial manager	File country-level records, view all sponsor-side records at all levels and review all records	Sponsor country Reviewer	All production sites*			*Clinic access needs to be on study level and not every site one by one, otherwise the review permission will be translated to read permission.

Study role	Task	TMF role	Viedoc Clinic site group	TMF level access	Permissions	Comments
Read-only role Regulatory inspector	Read-only access to all records* and settings Access to audit trail	No role, permissions only	All production sites**		1. Read-only Trial Master File* 2. Read-only TMF Admin 3. Download audit trail	*If read-only Trial Master File permission is assigned, any NO ACCESS permission will be overridden by read access by the system. This means that all artifacts set as optional or required (including blinded and investigator-side artifacts) will be visible. These permissions should be reserved for a role that requires all access, such as a regulatory inspector. **Clinic access needs to be on study level and not every site one by one, otherwise the review permission will be translated to read permission.
Unblinded role Sponsor or statistician	View, file, and classify blinded records only on all levels	Sponsor unblinded	All production sites*	Write access to blinded records on study level and site level (when applicable) No access to non-applicable records on all levels	1. Download audit trail	*Clinic access needs to be on study level and not every site one by one, otherwise the review permission will be translated to read permission.

For TMF access use cases and frequently asked questions, please see [TMF access use cases](#).

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The Overview page

The Overview page

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[2. Metrics on the Overview page](#)

[3. Filtering metrics](#)

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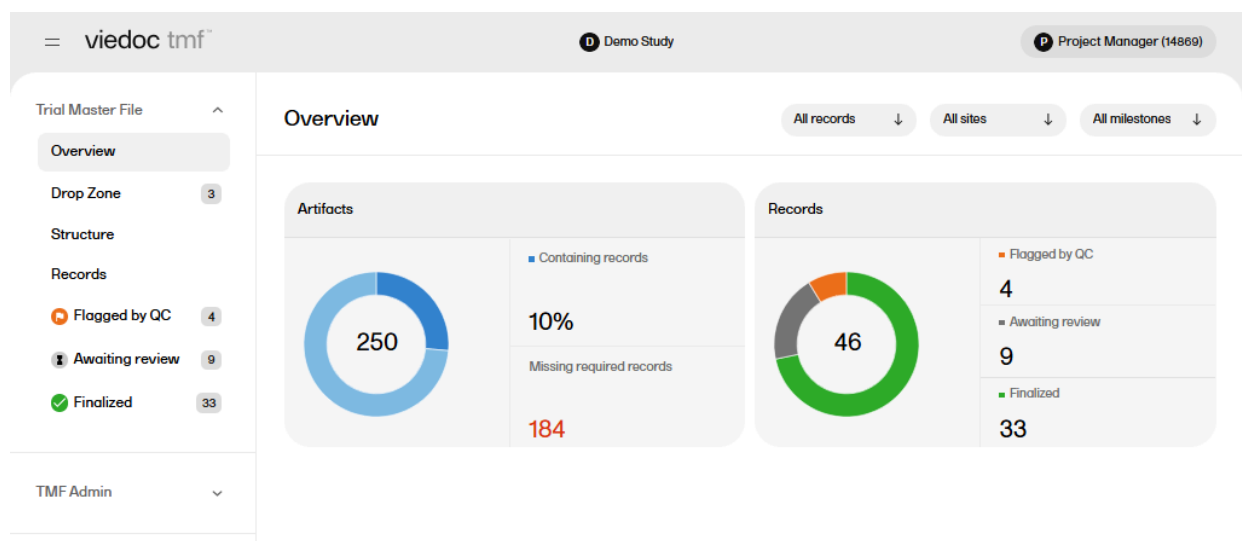
- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Introduction

The **Overview** page displays metrics and graphs for the TMF. On this page you can:

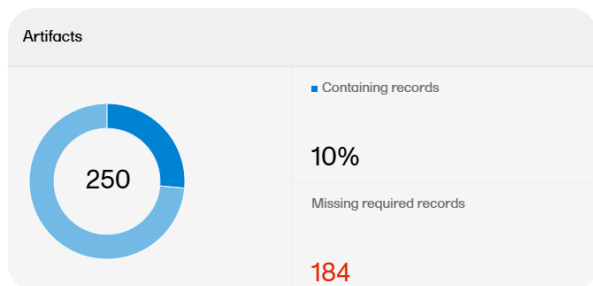
- Filter metrics by level, site or milestones

To open the **Overview page**, select to expand **Trial Master File** in the left navigation menu and select the **Overview** page.



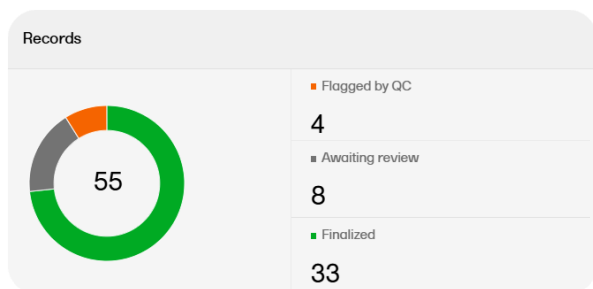
2 Metrics on the Overview page

There are artifact-level and record-level metrics available on the **Overview** page.



The artifact metrics available on the **Overview** page are as follows:

- Total number of artifacts in the TMF structure
- Percent of artifacts that contain records
- Number of artifacts that are missing required records



The records metrics on the **Overview** page are as follows:

- Total number of records uploaded into the TMF structure
- Number of records Flagged by QC
- Number of records Awaiting review
- Number of finalized records

3 Filtering metrics

It is possible to filter the records metrics that are displayed by TMF level, sites, and milestones. To filter the records metrics, select one or more of the filters at the top of the page to open the dropdown, and select the options you would like to filter by. The records metrics will be updated with each filter that is applied.

All records



All sites



All milestones



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TMF Drop Zone

TMF Drop Zone

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1. Introduction

[1.1 Shared and private drop zones](#)

[2. Uploading a file to the Drop Zone](#)

[3. Deleting a file from the Drop Zone](#)

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- [Viedoc TMF Admin User Guide](#)

1 Introduction

Drop zones are folders outside the TMF structure where you can upload files to manage them later. Files can only be moved from the drop zones to the structure and not the other way around.

Anyone who has any kind of access to the study TMF can upload files to the drop zones. However, moving files from the drop zones to the structure is similar to uploading records to artifacts in the structure, in the sense that both require that the user has **write** access to the artifact in question.

In the left navigation menu, select to expand **Trial Master File**, and select the **Drop Zone** page.

The screenshot shows the Viedoc TMF interface. The left sidebar has a 'Trial Master File' section with options: Overview, Drop Zone (selected), Structure, Records, Flagged by QC, Awaiting review, and Finalized. Below this is a 'viedoc learning' section with 'TMF User Guide' and a 'Switch to old interface' link. The main content area is titled 'Drop Zone [Shared]' and has a toggle for 'Shared' (selected) and 'Private'. A large purple box with the text 'Drag-and-drop or click to upload files' is in the center. Below this is a table of files:

Name	Type	Uploaded
Quality_Plan_Draft.docx	DOCX	15 Apr 2025 18:14 by TMF User (32514)
Data_Management_Plan.pdf	PDF	28 Feb 2025 09:28 by TMF User (32514)
QP_SW_20250201 abc_Amnd.xlsx	XLSX	28 Feb 2025 09:22 by Project Manager (14869)

1.1 Shared and private drop zones

The shared and private drop zones can be enabled or disabled by a user with a TMF Admin role in [TMF Settings](#).

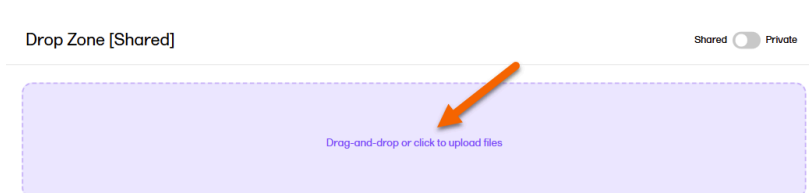
- The **Shared drop zone**: Files that are uploaded to the shared drop zone can be accessed and managed by the user who uploaded them, as well as the users who have the Manage drop zone permission.
- The **Private drop zone**: Files that are uploaded to the private drop zone can only be accessed and managed by the user who uploaded them.

If both shared and private drop zones are enabled in TMF Settings, select the toggle button in the top right of the page to switch between the two options.

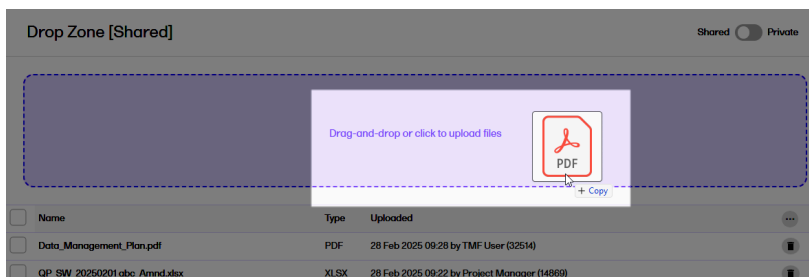
2 Uploading a file to the Drop Zone

To upload a file to a drop zone:

- 1 Select the **Upload** area on the **Drop Zone** page:



- 2 Select the file(s) that you want to upload, and select **Open**.
- 3 Alternatively, to upload file(s), drag them from your file explorer and drop them in the drop zone:



Note! When placing files from within a zipped folder into a drop zone, the system will not recognize the file. It will recognize the zipped folder and extract the files. Unzip the folder, and then select the files you want to drop into the the drop zone.

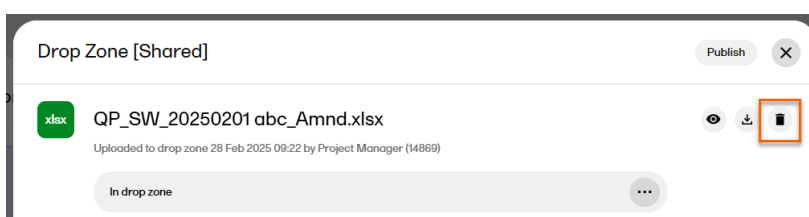
3 Deleting a file from the Drop Zone

To delete a file from a drop zone:

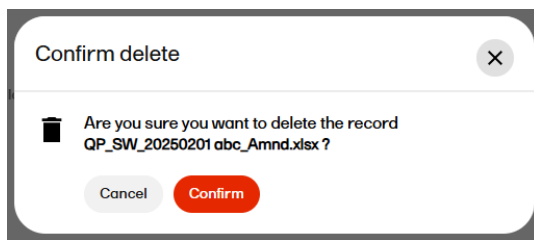
- 1 Select the trash can icon on the row of the file that you want to delete.

<input type="checkbox"/>	Name	Type	Uploaded	...
<input type="checkbox"/>	Data_Management_Plan.pdf	PDF	28 Feb 2025 09:28 by TMF User (32514)	
<input type="checkbox"/>	QP_SW_20250201 abc_Amnd.xlsx	XLSX	28 Feb 2025 09:22 by Project Manager (14869)	
<input type="checkbox"/>	Monitoring_Plan.pdf	PDF	28 Feb 2025 09:21 by Project Manager (14869)	

- 2 Alternatively, open the file by selecting it, and then select the trash can icon in the record properties window.



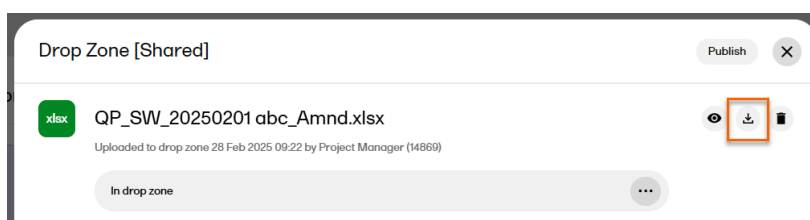
- 3 Confirm the deletion.



4 Downloading a file from the Drop Zone

To download a file from a drop zone:

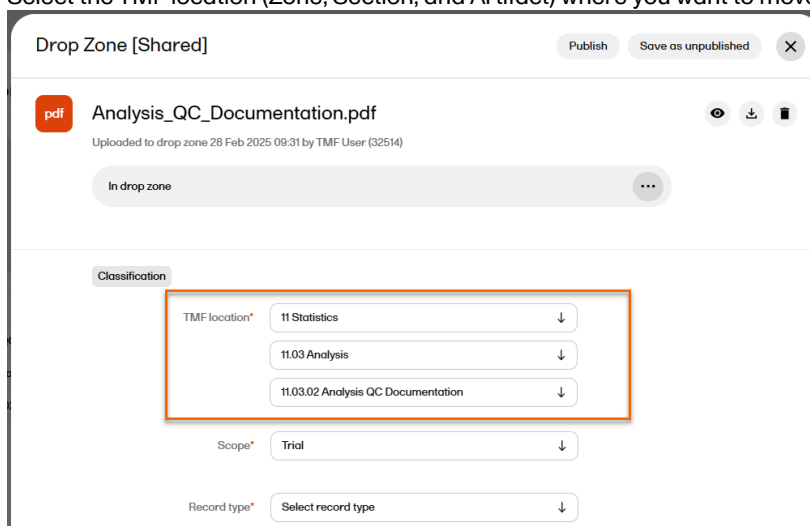
- 1 Select a record to open the record properties window.
- 2 Select the download icon:



5 Moving a file from the Drop Zone to the TMF structure

To move a file from a drop zone to the structure:

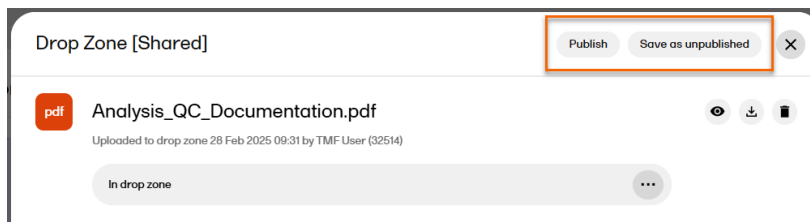
- 1 Select a record to open the record properties window.
- 2 Select the TMF location (Zone, Section, and Artifact) where you want to move the file.



Note! Only artifacts that accept the file type are available on the **Select Artifact** dropdown menu.

The properties of that artifact will then be populated in the record properties window. You can either enter values for the metadata properties or leave them empty.

- 3 Select **Save as unpublished** to create a new unpublished record in the selected location with the file that was moved from the drop zone.



- 4 Alternatively, fill in all the mandatory fields and select **Publish**. A new record with the status *Awaiting review* will be created at the selected location with the file that was moved from the drop zone.

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The Structure page

The Structure page

Published by Viedoc System 2025-12-02

1. Introduction

2. Searching and filtering in the Structure page

2.1 Navigating the structure

2.2 Using the filters

3. Icons on the Structure page

4. Uploading files into the structure

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

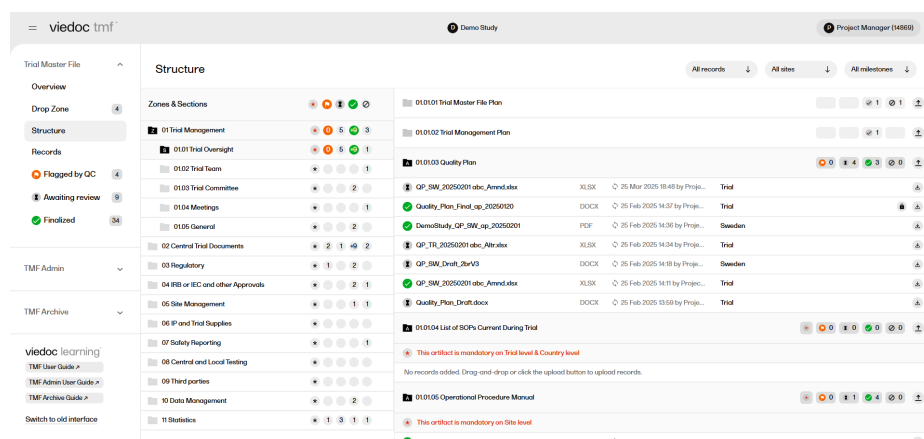
- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Introduction

The **Structure** page shows all of the records that you have access to, organized in the zones, sections, and artifacts defined in the TMF structure. On this page you can:

- Filter records by level, site or milestones
- Import and export files into specific artifacts
- Take actions on the records from the **Actions** column (that is always pinned to the right), or by selecting a row to open the **Records properties** window.

To open the **Structure page**, select to expand **Trial Master File** in the left navigation menu and select the **Structure** page.



The zones, sections and artifacts are represented as folders which can be selected to expand or collapse them.

2 Searching and filtering in the Structure page

There are two main ways to find the record(s) you are looking for in the Structure page: navigating through the folders in the structure and using the filters.

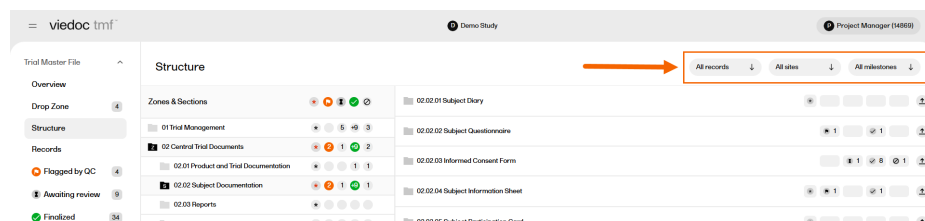
2.1 Navigating the structure

If you know which zone, section or artifact a record has been uploaded to, simply select each folder to expand it, and navigate through the TMF structure to see the records uploaded into each artifact.

The same method can be used to browse the structure to determine if records are missing from specific artifacts.

2.2 Using the filters

The Structure page includes filters that allow you to sort the records by level, sites, or milestones.



Select each filter to expand it, then select the options you would like to filter the records with.

3 Icons on the Structure page

There are icons on each row within the structure that represent the number of records with a certain status in each zone, section or artifact.

Zones & Sections					
01 Trial Management	★	0	5	+9	3
01.01 Trial Oversight	★	0	5	+9	1
01.02 Trial Team	★				1
01.03 Trial Committee	★			2	

The icons represent records with the following statuses:



Artifact missing required records. For artifacts that are mandatory at the site, country, or trial level, this icon indicates that the mandatory requirements have not been met. Once the required records have been uploaded to the artifact, this icon disappears. If an artifact does not have mandatory records, this icon will not be displayed.

Note! if the artifact is mandatory at the site level, then a record(s) must be uploaded and assigned to *all* of the sites in the study.



The number of records that have been **Flagged by QC**.



The number of records that are **Awaiting review**.



The number of records that have been finalized.



The number of records that are unpublished.

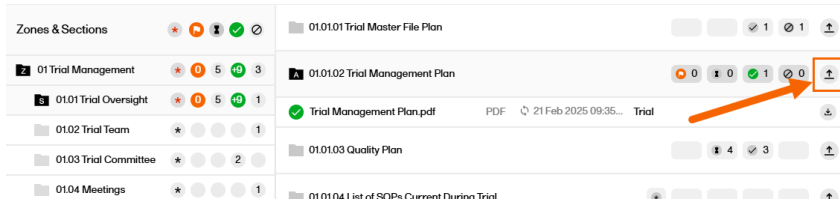
4 Uploading files into the structure

Uploading records to Viedoc TMF requires **write** permission for the artifact on the TMF level that the record is linked to. For more information about TMF permissions, see [Roles and permissions in Viedoc TMF](#).

Files can be uploaded directly into a specific artifact. Alternatively, if you do not know which zone, section, or artifact to place the record in, you can use the drop zones. For more information, please see [TMF Drop zone](#).

To upload a record:

- 1 In the **Structure** page, select the upload button for the artifact:

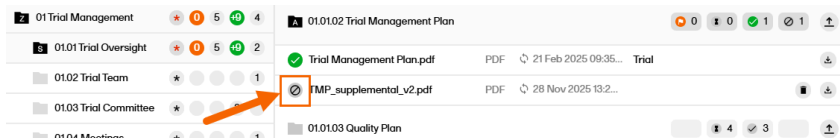


- 2 Browse to the file(s) that you want to upload and select **Open**.

Note! An artifact might have restrictions on which file types are allowed. Some file formats are [blacklisted](#).

- 3 Alternatively, drag the file from your file explorer and drop it directly in the TMF artifact. It is possible to upload multiple files at the same time.

- 4 When the file has been successfully scanned for viruses, it is uploaded in an **Unpublished** status.



Notes!

- When a record is unpublished and not linked to a specific trial, country, or site, only the user who uploaded it can see and access it. However, if the same record becomes categorized, it will become accessible to users who have access to the TMF level that the record is linked to.
- You can see the files that are being uploaded, even when there are filters set. Reloading the web page does not reset the filters.

Note! It is not possible to upload files from inside a zipped folder.

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The Records page

The Records page

Published by Viedoc System 2025-04-24

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[3.4 Sorting the column contents](#)

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[5.5 Copying data](#)

[5.6 Exporting data](#)

[6. The columns on the Records page](#)

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

- [Viedoc TMF User Guide](#)
 - [Viedoc TMF Admin User Guide](#)
-

1 Introduction

The **Records** page provides an overview of the records that you have access to together with their metadata in a table or grid. On this page you can:

- Sort and filter columns and data
- Copy and export data from page
- Take actions on the records from the **Actions** column (that is always pinned to the right), or by selecting a row to open the **Records properties** window.

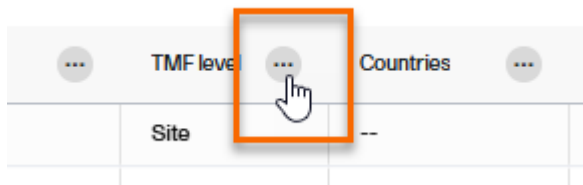
To open the **Records page**, select to expand **Trial Master File** in the left navigation menu and select the **Records** page.

2 Filter Pages

3 Column Options

24/79

To view the options available for a column, select the icon with three dots at the top of the column:

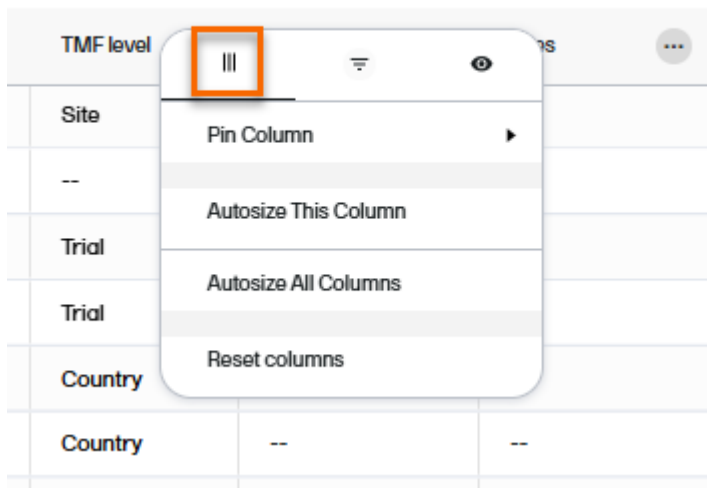


A menu with three tabs will be displayed, which are described in the next subsections:

3.1 Autosize or pin columns

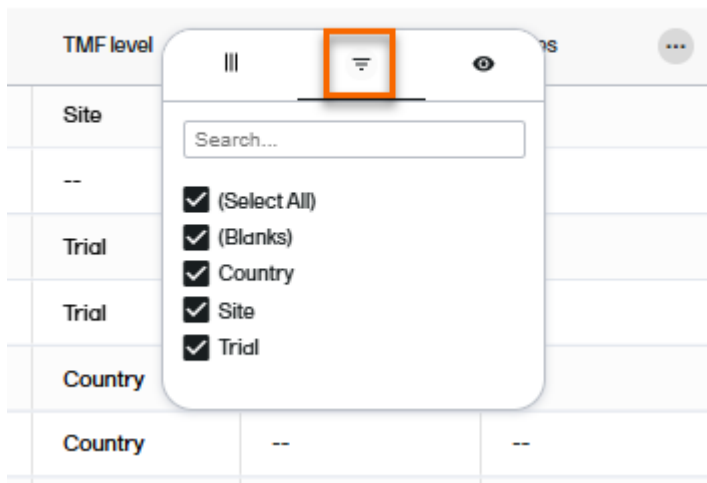
The first tab in the column options menu allows you to:

- Pin a column to the left or right of the page, or unpin a pinned column
- Autosize the selected column
- Autosize all columns
- Reset any changes made to the columns



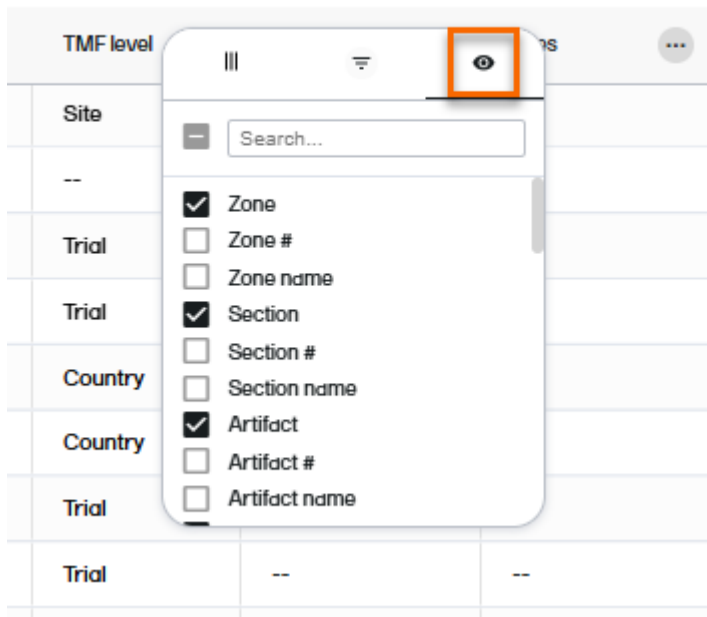
3.2 Filter columns

The second tab in the column options menu allows you to filter data in the selected column. Select the contents that you want included in the column, and deselect those that you want hidden. When a filter has been applied to a column, a filter icon is visible in the column header.



3.3 Selecting which columns to display

The third tab in the column options menu allows you to select which columns you want displayed or hidden.



Note! A list of [available columns](#) is provided at the end of this lesson.

3.4 Sorting the column contents

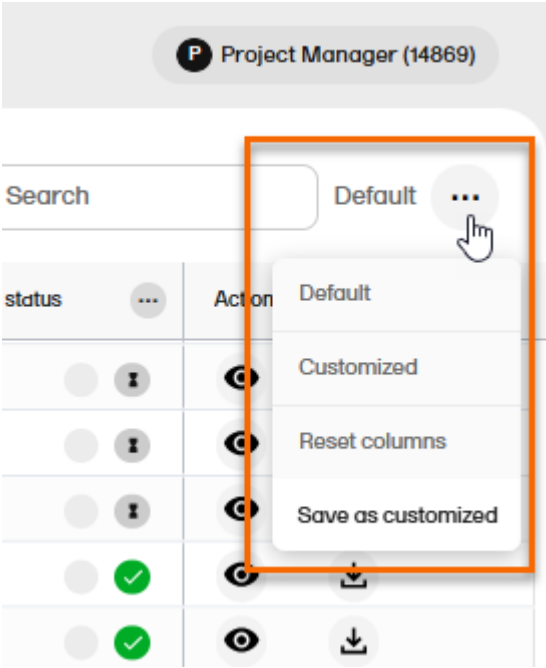
To sort the data by column contents in ascending order, select the column header. Select it again to sort in descending order. Selecting for a third time removes the column sort order.

To rearrange the order of the columns on the page, simply select a column header and drag the column sideways. To reset the order of the columns to the initial state, select **Reset Columns** on the column options menu, available from the column header.

4 The View menu

A customized view of the **Records** page can be saved and displayed using the **View menu**. This can be useful if you have filtered, sorted, or sized the columns and want to be able to re-use your viewing preferences.

To open the **View menu**, select the menu icon in the top right of the **Records** page:



These are the available menu options:

Menu option	Description
Default	<p>Displays the default view, as provided by the system.</p> <p>This view is displayed:</p> <ul style="list-style-type: none">▪ When you perform a search on the Structure page.▪ When you perform a search on the Records page, and you haven't saved a customized view.▪ When you reload the Records page, and you haven't saved a customized view.▪ When you select any of the Filter pages
Default+	<p>Indicates that changes have been made to the default view, but the changes have not been saved as a customized view. To save the changes, select Save as customized.</p>
Customized	<p>Displays the saved customized view.</p> <p>This view is retained between login sessions. If the page is reloaded, the customized view is shown if available, otherwise the default view is shown.</p> <p>Note! This option is not available if you haven't saved a customized view.</p>
Customized+	<p>Indicates that changes have been made to the customized view, but the changes have not been saved. To save the changes, select Save as customized.</p>
Reset columns	<p>Resets the view to the latest used of the default or the customized views.</p>
Save as customized	<p>Saves the current view as a user-specific customized view. Each user can save their own tailored viewing preferences.</p> <p>This option is not available when the TMF is locked.</p>

Note! If you perform any further search on the **Records** page, or switch between pages in the navigation menu, the system displays your last selected view.

5

Copying or exporting data

5.1 Copying data

To copy the data in a table cell on the **Records** page:

- 1 Right-click in the cell
- 2 Select **Copy** to copy the contents of the table cell to your clipboard
- 3 Select **Copy with Headers** to copy the contents of the table cell and the column header to your clipboard







5.2 Exporting data

To export the data that is displayed on the **Records** page:

- 1 Right-click anywhere in the table and select **Export** and then **CSV Export** or **Excel Export**.
- 2 A file of the selected type is then available for download from your browser.

6 The columns on the Records page

There are several columns available to show or hide on the **Records** page:

Column	Description
Zone	This column shows either the zone folder icon  , a shared drop zone icon  , or a private drop zone icon  . When you hover over the icon, a tooltip shows the zone number and the zone name. For drop zone icons, the tooltip shows shared or private drop zone.
Zone #	The zone number.
Zone name	The name of the zone as set in the structure.
Section	This column shows the section folder icon  . When you hover over the icon, a tooltip shows the section number and the section name.
Section #	The section number
Section name	The name of the section as set in the structure.
Artifact	This column shows the artifact folder icon  . When you hover over the icon, a tooltip shows the artifact number and the artifact name.
Artifact #	The artifact number
Artifact name	The name of the artifact as set in the structure.
Filetype	The filetype icon  . When you hover over the icon a tooltip text shows the filetype.
Filetype name	The filetype name in text, for example pdf or xlsx.
Name	<p>This column shows:</p> <ul style="list-style-type: none"> ▪ Display label. ▪ If Display label is not applicable, then it shows the record name. ▪ If neither Display label nor record name are applicable, then it shows the Original file name.

Column	Description
Display label	This label represents how the record is displayed on the Trial Master File view.
Record name	The name of the record as set by the user in the corresponding Record properties window.
Download label	The name of the latest version of the record when downloaded.
Archive label	The name of the record in the archive.
Dating convention	The dating convention label that is applicable to the record .
Dating convention value	The date value of the dating convention metadata in the format YYYY-mm-DD.
Last modified datetime	The date and time when the record was last modified, in the format YYYY-mm-DD HH:MM.
Last modified by	The user name of the user who last modified the record
Last reviewed datetime	The date and time when the record moved to the status <i>Flagged by QC</i> , in the format YYYY-mm-DD HH:MM.
Last reviewed by	The user name of the user who last commented on the record .
Uploaded to drop zone datetime	The date and time when the file was uploaded to a drop zone, in the format YYYY-mm-DD HH:MM.
Uploaded to TMF datetime	The date and time when the file was moved to the TMF structure, in the format YYYY-mm-DD HH:MM.
TMF level	One of Trial, Country, or Site.
Record type	For main artifacts, the column shows the artifact name. For sub-artifacts, the column shows the sub-artifact name. For other types, the column shows the customized name.
Countries	The names of the countries that the record is linked to.
Country codes	The country codes of the countries that the record is linked to.
Sites	The names of the sites that the record is linked to.
Site codes	The site codes of the sites that the record is linked to.
Record version	The record version number as set by the user in the Record properties window.
Record system version	The system version of the record.
Record Id	The record's unique Id within the study TMF.
Original file name	The original name of the file when it was uploaded.
File size	The size of the file.

Column	Description
File date	The date and time when the latest version of the file was uploaded to the TMF structure, in the format YYYY-mm-DD HH:MM.
Milestone	The milestone that the artifact is linked to. Milestones are assigned at the artifact level, however, different milestones can be assigned to different levels within the artifact (site, trial, country). The milestone in this column refers to the level that the record is filed in.
Milestone group	The milestone group for the milestone that the artifact is linked to.
Record status	<p>This column shows the record status icon. It can be one of the following:</p> <ul style="list-style-type: none">▪ Unpublished▪ Awaiting review▪ Flagged by QC▪ Finalized▪ Finalized and locked
Actions	<p>This column is pinned to the right and cannot be removed. It shows the action icons according to the actions that can be performed on the record according to the user permissions.</p> <p>Select the icons to:</p> <ul style="list-style-type: none">▪ Delete, if the record is unpublished▪ Download▪ Preview, if the preview is supported for the filetype.
ICH code	The code according to the International Council for Harmonisation
Unresolved notes count	The number of unresolved notes for a record

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Managing records

Managing records

Published by Viedoc System 2025-09-24

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 - [2. Uploading records](#)
 - [3. Searching and filtering records](#)
 - [3.1 Using milestones to filter records](#)
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 - [6. Creating a new version of a record](#)
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 - [8. Publishing a record](#)
 - [9. Deleting a record](#)
 - [10. Downloading a record](#)
-

- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

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 - [Viedoc TMF Admin User Guide](#)
-

1 Introduction

There are three places to work with records in the **Trial Master File**: the **Structure** page, the **Records** page, and the **Drop Zone**. The following sections provide information on managing records in each area.

2 Uploading records

Uploading records to Viedoc TMF requires **write** permission for the artifact on the TMF level that the record is linked to. For more information, see [Roles and permissions in Viedoc TMF](#).

There are two ways to upload records into the TMF:

- **TMF Structure**: Files can be uploaded directly into a specific artifact. For more information, see the [Uploading files into the structure](#) section in The Structure page lesson.
 - **Drop Zone**: Alternatively, if you do not know which zone, section, or artifact to place the record in, you can use the drop zones. For more information, see [Working with drop zones](#).
-

3 Searching and filtering records

To find records in the TMF you can search directly using the search field in the upper-right of the **Records** page, or use filters in both the **Structure** page and in the **Records** page.

For more information, go to [Searching and filtering](#) in the **Structure** page, or [Filtering columns](#) in the **Records** page.

3.1 Using milestones to filter records

Milestones and milestone groups are the tools used in the TMF for sorting and filtering records. Milestones are assigned at the artifact level in TMF Admin, and all records added to an artifact will be linked to the same milestone. An artifact can also have different milestones for each TMF level it is applicable to (trial, site, and/or country).

Milestones can be defined in any way that is appropriate for your study. In the Viedoc TMF template there are 12 milestones that are divided into four milestone groups (start up phase, conduct, close out and other). Assigning these to artifacts allows records to be linked to a specific timeline in the study or other categories.

Milestones may be used when searching for or filtering records in the **Records page** and also when filtering audit trail reports or EMS repositories.

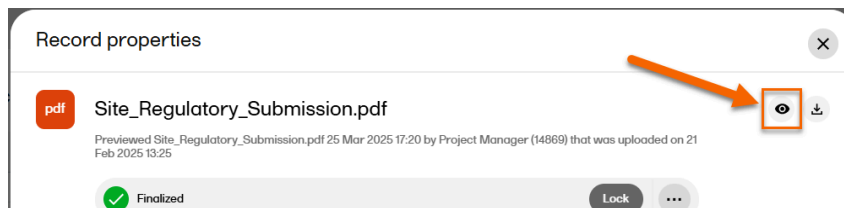
Note! If no milestones are assigned to an artifact, records in this artifact will not be included in the audit trail report or the EMS repository when the milestones filter is applied. To extract these records, a separate report can be generated with the milestone filter removed. For more information see the [TMF archive lesson](#).

4 Previewing a record

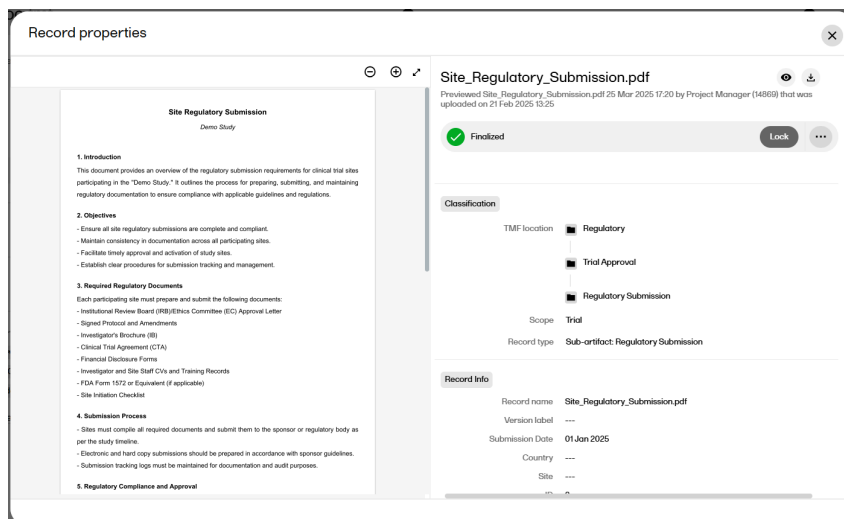
The record preview feature allows you view the contents of a file without downloading it. The preview shows the latest version of files in each record version.

To preview a record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select a record to open the **Record properties** window.
- 2 Select the eye icon to open the record preview:



- 3 The preview opens to the left of the window:



- 4 To close the preview, select the **Preview** button again.

Note! The preview does not support files larger than 2 GB.

Note! All preview actions are logged in the audit trail. For more information, see the [TMF Archive](#) lesson.

4.1 Supported filetypes for record preview

The record preview is supported for the following filetypes:

- bmp
- doc
- docx
- jpeg
- jpg
- pdf
- png
- ppt
- pptx
- tif
- tiff
- txt
- xls
- xlsx
- xml
- zip

5 Editing record properties

Editing record properties in Viedoc TMF requires **write** permission for the artifact on the TMF level that the record is linked to. For more information, see [Roles and permissions in Viedoc TMF](#).

Tip! The upload button on artifact level indicates that you have **write** permission for the artifact.

Note! it is not possible to edit a finalized record. To make changes, a new record version must be created. For more information, see [Creating a new version of a record](#) below.

To edit the record properties:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select a record to open the **Record properties** window.

3 The **Record properties** window is displayed:

The screenshot shows the 'Record properties' window for a file named 'QP_SW_20250201 abc_Amnd.xlsx'. The window is divided into several sections, each with a numbered callout:

- 1:** File icon (xlsx) and title bar with 'Publish', 'Save as unpublished', and a close button.
- 2:** Record status: 'Unpublished' with a lock icon and a menu button (three dots).
- 3:** Notes section: 'This is a note. Added 25 Mar 2025 18:10 by Project Manager (14869)' with a 'Resolve' button.
- 4:** More options menu (three dots).
- 5:** Classification section with dropdowns for 'TMF location' (01 Trial Management), '01.01 Trial Oversight', '01.01.03 Quality Plan', 'Scope' (Trial), and 'Record type' (Quality Documentation).
- 6:** Record Info section with fields for 'Record name' (Use artifact name, Use original file name, Custom name), 'Version label', 'Version Date' (01-Mar-2025), 'ID' (38), 'Display label', 'Download label', 'Archive label', and 'TMF side' (Sponsor, Investigator).
- 7:** File Info section with fields for 'Original file name', 'File size' (8.66 KB), 'File date' (25 Feb 2025 14:11), 'File version' (1), and 'File integrity' (AERfm0V9G0mV4zSTUx0bgg==).
- 8:** Record sharing section with 'Enable for' options: None (selected), Viedoc Clinic users, and Viedoc Me users.
- 9:** History section showing 'Uploaded as unpublished 25 Feb 2025 14:11 by Project Manager (14869)'.

The sections in the **Record properties** window are:

1. The **Preview, delete, and download** buttons
2. The **record status** (Unpublished, Awaiting review, Flagged by QC, or Finalized)
3. The **notes** section
4. The **Record actions** menu. **Note!** the available menu options depend on the record status and your permissions.
5. **Classification**
 - **TMF location:** The zone, section, and artifact of the record
 - **Scope:** The scope of the record (Site, Trial, or Country).
 - If you choose Country or Site, you will be prompted to also choose which country or site to link the record to.
 - You can only choose a country or site that you have access to.
 - A record can be linked to more than one site or to more than one country.
 - When a record is linked to a TMF level, users with at least READ permissions on that level can access the record, even when the record is *Unpublished*.

- The eTMF Manager can make a setting to automatically populate this field (when there is only one TMF level option available for the user for the selected record).
- **Record type:** The available record types are Main Artifact, Sub-artifacts (if any), and Other. If you select Other, you can enter a customized record type.

6. Record Info

- **Record name:** The available options are:
 - **Use sub-artifact name** - as specified in the TMF template
 - **Use original file name** - the file name including the file name extension
 - **Custom name** - Select this option to enter a customized record name.

Note! When using the custom name option, it is not necessary to add the file extension in the custom name, the system will add the file extension automatically. Including the file extension in the name will result in the file extension being displayed twice in the archive export. For example if the custom name you create is "file.pdf" then in the archive it will display as "file.pdf.pdf".

- **Version label:** A user-defined version label
- **Version Date**
- **ID:** An integer value that represents the record's unique ID within the study TMF
- **Display label:** Represents how the record is displayed in the Trial Master File view
- **Download label:** The name of the latest version of the record when downloaded
- **Archive label:** The name of the record in the archive

Note! If any of the three labels above are not configured by the eTMF Manager, the default is the record name as defined by the user. When the labels are configured to include metadata of the record, changes made to the metadata that affect these labels will be reflected on the labels dynamically in the **Record properties** window.

- **TMF side:** Indicates whether artifact is filed under Sponsor side or Investigator side.

7. File Info: Contains information about the uploaded file. File date is the date and time when the file was uploaded. If the record is in edit mode, you can select the upload button to browse for a new version of the file. If you upload a new file, the record status will be changed to *Awaiting review*.

8. Record Sharing: Select to enable record sharing with Viedoc Clinic users or Viedoc Me users.

9. The **History** section is the audit trail for the selected record version. Changes to the record version are logged here together with information about the date and time they were made and by which user. Record note actions are not included in the history. **Note!** In this section, you can not see the name of a site that you do not have access to, but you can see the site ID.

- 4 Make your edits, and then select **Publish** or **Save as unpublished** at the top of the window.

When a record is published, the record status is changed to *Awaiting review*. It is now available for all TMF users with at least **read** permission for that artifact.

Note! Before a record can be published, all required fields in the **Record properties** must be filled in. The required fields are marked with red.

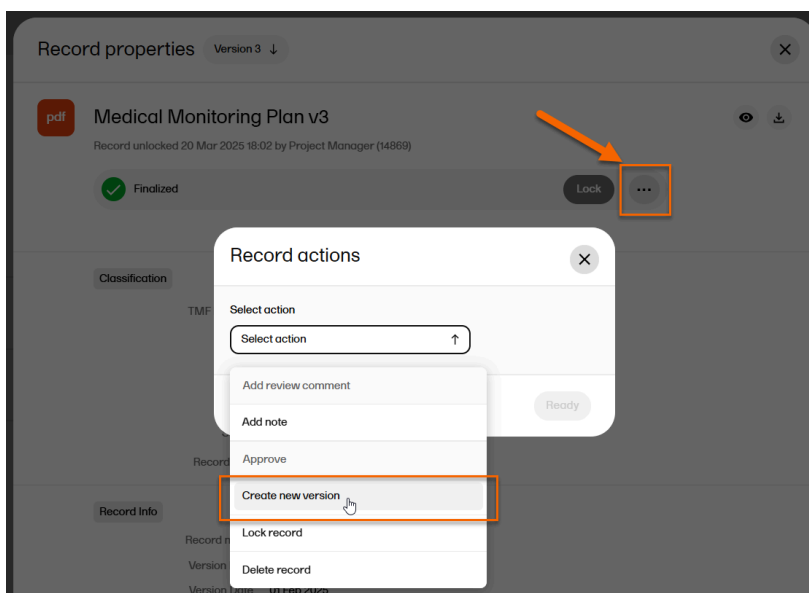
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6 Creating a new version of a record

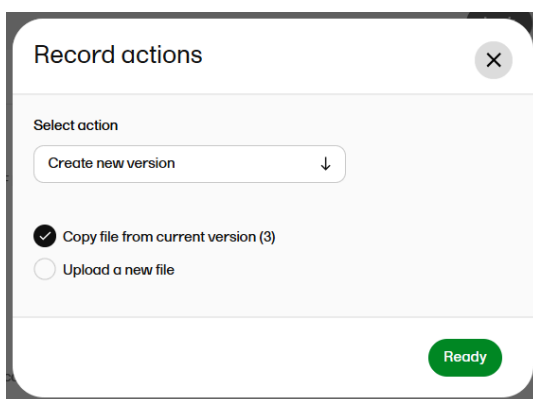
To create a new version of a finalized record:

- 1 From the **Structure** page or the **Records** page, select a record to open the **Record properties** window.
- 2 At the top of the window, select **...** to open the **Record actions** menu.

- 3 From the menu, select **Create new version**.



- 4 Select whether you want to copy the file from the previous version or upload a new file.



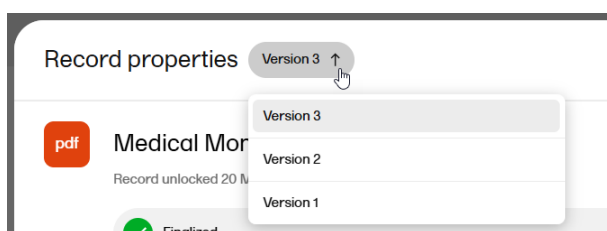
- 5 Select **Ready**.

The new record version is saved in an *unpublished* status.

6.1 Navigating between record versions

When you open the **Record properties** window, the latest version of the record is displayed by default.

To navigate between record versions, use the version dropdown menu at the top of the **Record properties** window:



7 Adding notes to a record

Record notes are a way to communicate with other users about records without affecting the record status. The notes actions are not recorded in the record history.

These are the permissions needed for adding or resolving notes:

- For a record in the TMF structure, you need **write** or **review** permission for the record.
- For a record in a drop zone, you need to have access to the record.

To add a note to a record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select a record to open the **Record properties** window.
- 2 At the top of the window, select . . . to open the **Record actions** menu.
- 3 Select **Add note** from the menu.

- 4 Enter your note text and select **Save**.
- 5 The note is then displayed like this:

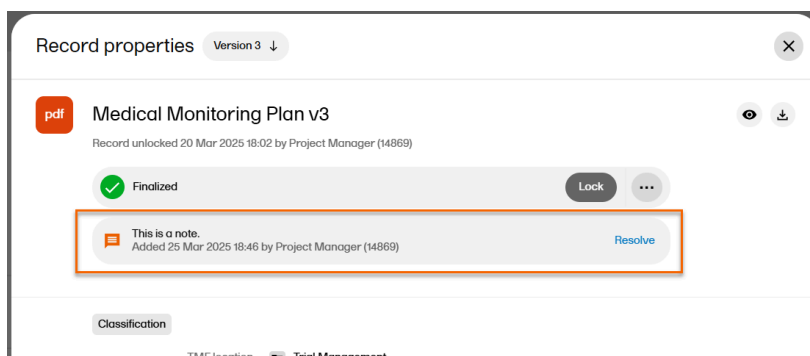
Note! The note is associated with the selected record version.

7.1 Resolving notes

To resolve a note in a record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select a record to open the **Record properties** window.

- 2 Select **Resolve** for the note that you want to resolve.



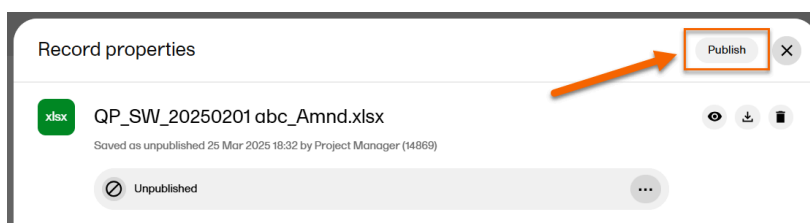
The note is then immediately removed.

8 Publishing a record

Publishing a record in Viedoc TMF requires **write** permission for the artifact on the TMF level that the record is linked to. For more information, see [Roles and permissions in Viedoc TMF](#).

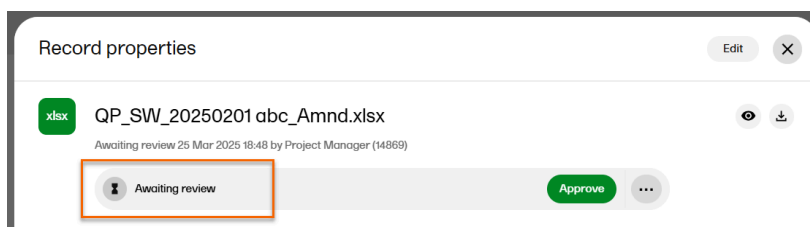
To publish a record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select a record to open the **Record properties** window.
- 2 Make sure all mandatory fields (marked with red) are filled in.
- 3 Select **Publish** at the top of the window:



- 4 When the record is published, it is available for all TMF users with at least **read** permissions for that artifact and with access to the TMF level that the record is linked to.

The record status is now *Awaiting review*.



9 Deleting a record

Deleting a record in Viedoc TMF requires **write** permission for the artifact on the TMF level that the record is linked to. For more information, see [Roles and permissions in Viedoc TMF](#).

To delete an *unpublished* record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, navigate to the record you want to delete, and select the **delete** icon on the same row as the record:



Alternatively, select the record to open the **Record properties** window, select **...** to open the **Record actions** menu, and select **Delete record**.

- 2 Select **Confirm** to delete.

To delete a *published* record:

- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, select the record to open the **Record properties** window, select **...** to open the **Record actions** menu, and select **Delete record**.
- 2 Enter a reason for deletion.
- 3 Select **Delete record**.

10 Downloading a record

Downloading a record from Viedoc TMF requires **read**, **review**, or **write** permission for the artifact on the TMF level that the record is linked to. For more information, see [Roles and permissions in Viedoc TMF](#).

To download a record:

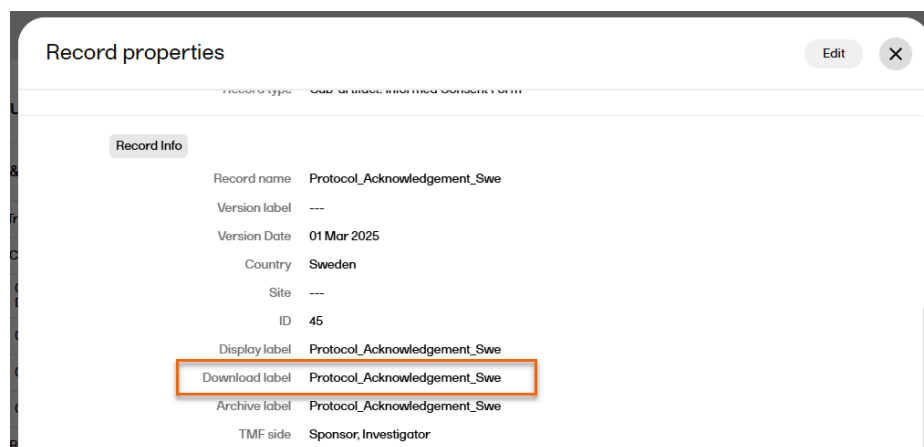
- 1 From the **Structure** page, the **Records** page, or the **Drop Zone**, navigate to the record you want to download, and select the **download** icon on the same row as the record:



Alternatively, select the record to open the **Record properties** window, and select the **download** icon to download the record from there.

- 2 The record is then downloaded.

Note! When downloaded, the name of the latest version of the record is according to the download label in the **Record properties** window:



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Records "Awaiting review"

Records "Awaiting review"

Published by Viedoc System 2025-04-24

[1. Introduction](#)

[2. Locating records that are awaiting review](#)

[3. Reviewing a record](#)

[4. Approving a record](#)

[5. Locking and unlocking records](#)

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

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- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Introduction

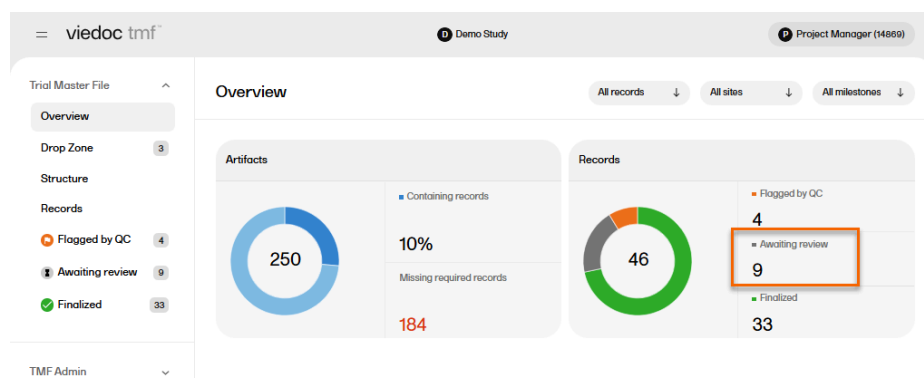
Once an *Unpublished* record is edited and published, or a record *Flagged for QC* has been edited and published, the record status will change to *Awaiting review*. Reviewing and approving a record in Viedoc TMF requires **review** permission for the artifact in the same scope (trial, country, or site) that the record is assigned to. Once approved, the record status will change to *Finalized*.

For more information on statuses, please see [Record statuses and actions](#).

For more information about permissions, please see [Roles and permissions in Viedoc TMF](#).

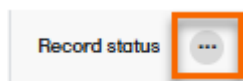
2 Locating records that are awaiting review

In the **Overview** page, the records metrics area shows how many records are *Awaiting review*.

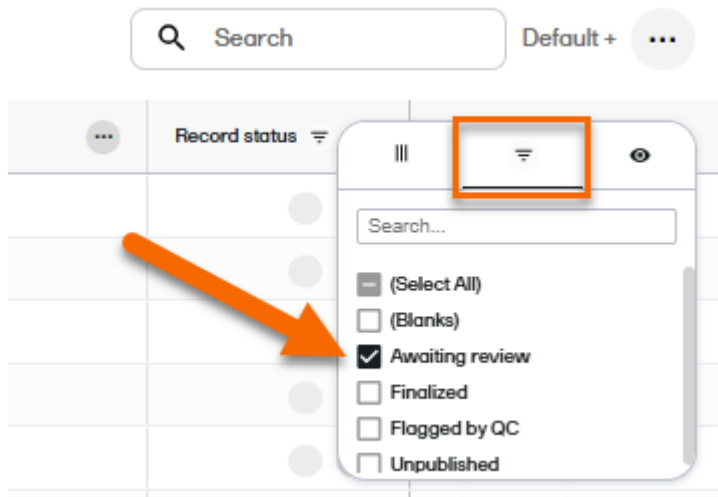


To locate the records that are *Awaiting review*:

- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** page.
- 2 On the **Records** page, locate the column **Record status**, and select to open the column options menu.



- 3 Select the filter tab, and then deselect all statuses except **Awaiting review**.



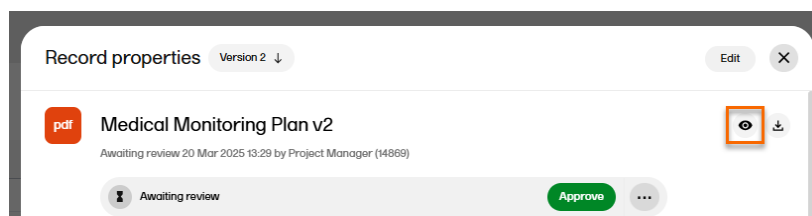
- 4 The **Records** page now shows a list of all the records that are *Awaiting review*.

3 Reviewing a record

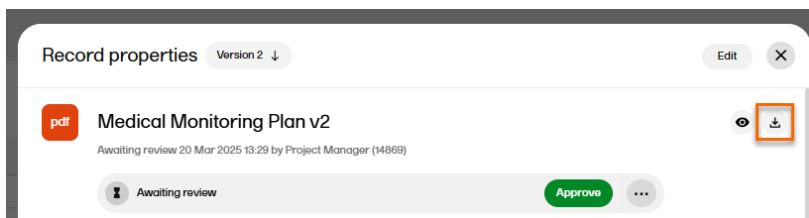
To review a record with the status *Awaiting review*:

- 1 Select a record on the **Records** page to open the **Record properties** window in read-only mode.
- 2 Review the record and make sure all the metadata is correct.
- 3 To view the the latest version of the uploaded file, select the **Preview** icon in the top right corner of the window.

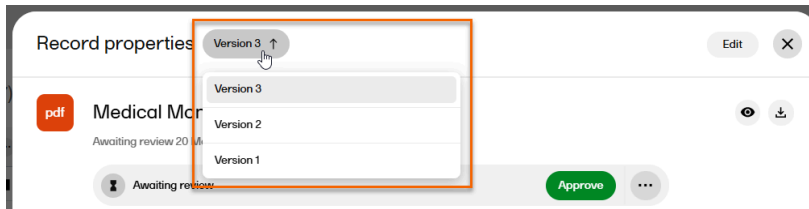
For more information, see previewing a record in the managing records lesson.



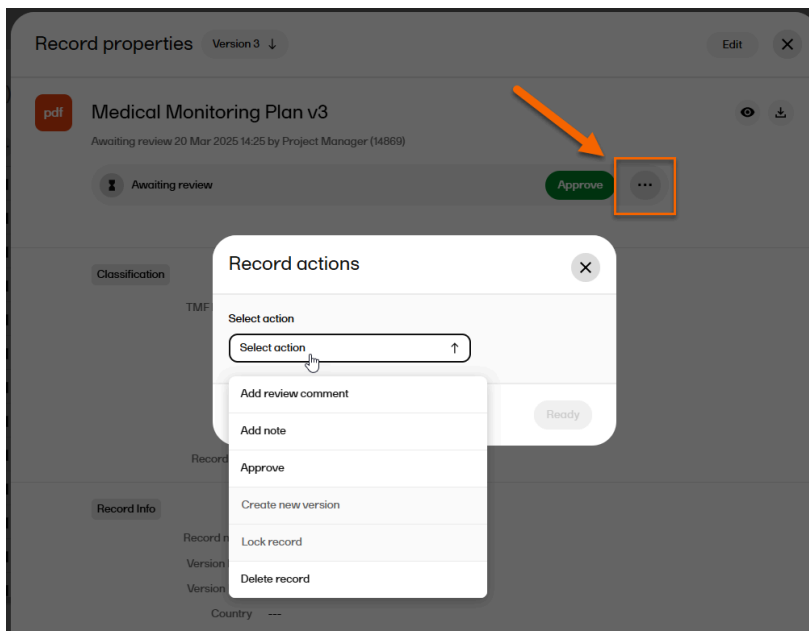
- 4 To download the file, select the **download** icon in the top right corner of the window:



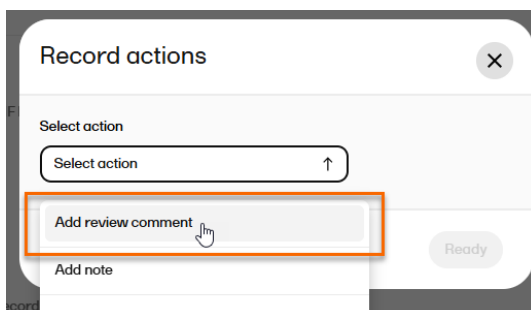
- 5 If the record has multiple versions, you can navigate between the different versions by selecting the **Version dropdown** menu at the top of the **Record properties** window.



- 6 Select the **Record actions** menu to see several options that are available:



- 7 If you need to add a review comment, select **Add review comment** from the **Record actions** menu:



- 8 Write your comment and select **Ready**.

- 9 **Note!** If you add a review comment and save the record, the record status is changed to *Flagged by QC*.

To change the status back to *Awaiting review*, a user with **write** permission needs to edit to the record metadata or upload another file.

- 10 If there is no need for a review comment, the record is ready to be approved (see next section).

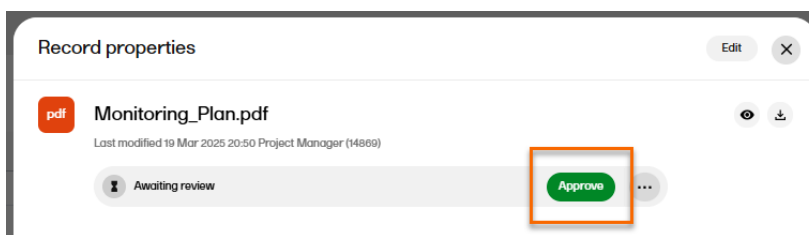
4 Approving a record

Approving a record in Viedoc TMF requires **review** permission for the artifact in the same scope (trial, country, or site) that the record is assigned to. For more information, see [Roles and permissions in Viedoc TMF](#).

To approve a record with the status *Awaiting review*:

- 1 Select the record to open the **Record properties** window.

- 2 In the **Record properties** window, select **Approve**:



- 3 The record status is now *Finalized*.

Note! Finalized records cannot be edited. To make changes, a new record version must be created.

5 Locking and unlocking records

After a record has been approved and finalized, it can be locked so no more changes can be made.

Note! If the TMF is configured to *Automatically lock records on approve* (see [TMF settings](#) for more information), the record will automatically be locked when it is approved.

For more information please see [Locking and unlocking records](#).

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Records "Flagged by QC"

Records "Flagged by QC"

Published by Viedoc System 2025-04-24

[1. Introduction](#)

[2. Locating records that are Flagged by QC](#)

[2.1 Resolving issues](#)

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Introduction

A record can be *Flagged by QC* to indicate that a change needs to happen before it can be finalized. Please see [Record statuses and actions](#) for more information.

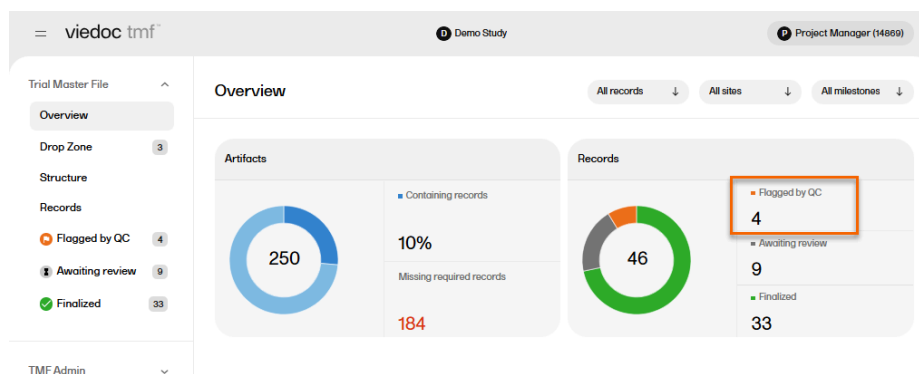
The workflow and permissions for this are as follows:

1. A user with **review** permissions for the artifact in the same scope (trial, country, or site) that the record is assigned to can add a review comment, which will change the record status to *Flagged by QC*.
2. A user with **write** permissions for the artifact in the same scope (trial, country, or site) that the record is assigned to can then make changes to the metadata or upload a new file to address the review comment, which will change the record status to *Awaiting review*.
3. A user with **Review** permissions for the artifact in the same scope (trial, country, or site) that the record is assigned to can **Approve** the record, which will change the record status to *Finalized*.

For more information about permissions, please see [Roles and permissions in Viedoc TMF](#).

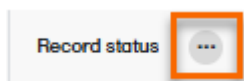
2 Locating records that are Flagged by QC

In the **Overview** page, the records metrics area shows how many records are *Flagged by QC*.

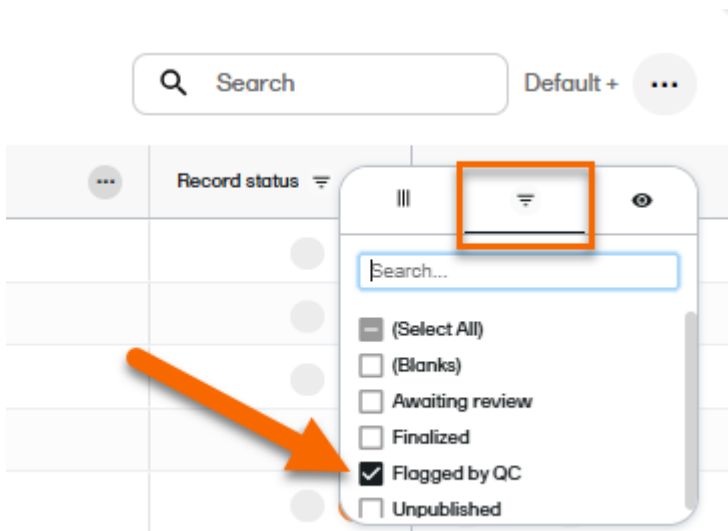


To locate the records that are *Flagged by QC*:

- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** page.
- 2 On the **Records** page, locate the column **Record status**, and select to open the column options menu.



- 3 Select the filter tab, and then deselect all statuses except **Flagged by QC**.



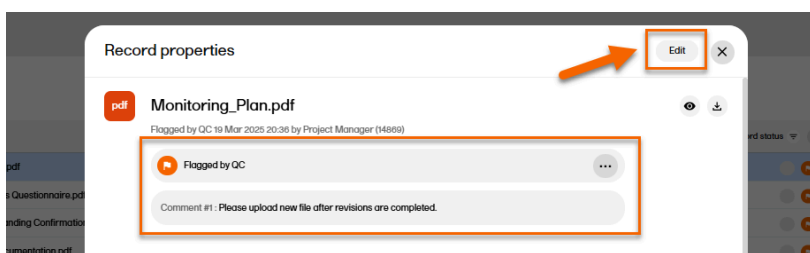
- 4 The **Records** page now shows a list of all the records that are *Flagged by QC*.

2.1 Resolving issues

To resolve issues for records that are *Flagged by QC*, you need to edit the record metadata.

To edit the record metadata:

- 1 Select the record to open the **Record properties**.
- 2 If there is a review comment, you can see it at the top of the Record properties window.



- 3 Select **Edit** in the top right corner of the window.

- 4 In the **Record properties** window, edit the applicable record metadata.

To upload another file, select the upload button in the **File Info** area.

Record properties [Cancel] [X]

Version label

Version Date* 01-Feb-2025

ID

Display label

Download label

Archive label

TMF side ☒ Sponsor ☐ Investigator

File Info

Original file name

File size

File date

File version

File integrity

- 5 When you have made the necessary changes, select **Save changes**.

Record properties [Save changes] [Cancel] [X]

Monitoring_Plan.pdf

Flagged by QC 19 Mar 2025 20:36 by Project Manager (14869)

Flagged by QC

Comment #1: Please upload new file after revisions are completed.

- 6 When the changes have been saved, the record status is changed to *Awaiting review*.

Record properties [Edit] [X]

Monitoring_Plan.pdf

Last modified 19 Mar 2025 20:50 Project Manager (14869)

Awaiting review

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Locking and unlocking records

Locking and unlocking records

Published by Viedoc System 2025-03-26

[1. Introduction](#)

[2. Locking a record](#)

[3. Unlocking a record](#)

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- [Viedoc TMF Admin User Guide](#)

1 Introduction

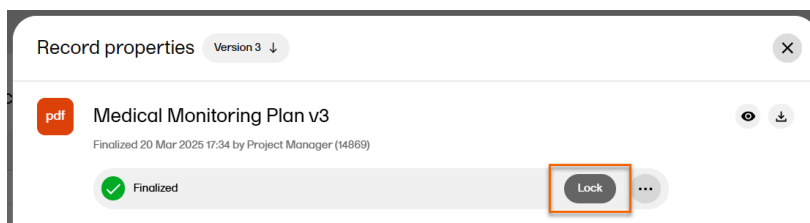
After a record has been finalized, you can lock it to prevent any further changes. It is also possible to unlock a record at any time.

Note! If the TMF is configured to *Automatically lock records on approve* (see [TMF settings](#) for more information), the record automatically locks when it is approved.

2 Locking a record

To lock a record:

- 1 Select a *finalized* record to open the **Record properties** window.
- 2 In the **Record properties** window, select **Lock**.



- 3 The **Lock** button now changes into an **Unlock** button.

Note! It is not possible to create new versions of locked records.

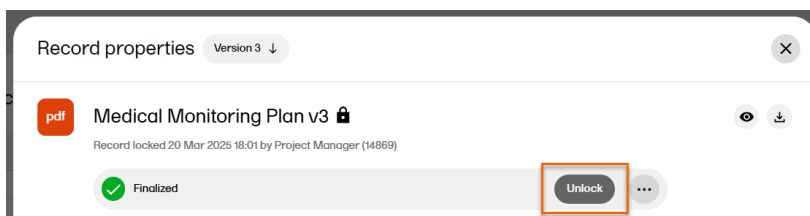
3 Unlocking a record

To enable editing of a locked record, you can unlock it.

To unlock a record:

- 1 Select the locked record to open the **Record properties** window.
- 2 If the TMF has *Give reason for unlocking records* setting *disabled* (see [TMF settings](#) for more information), the **Unlock** button will appear.

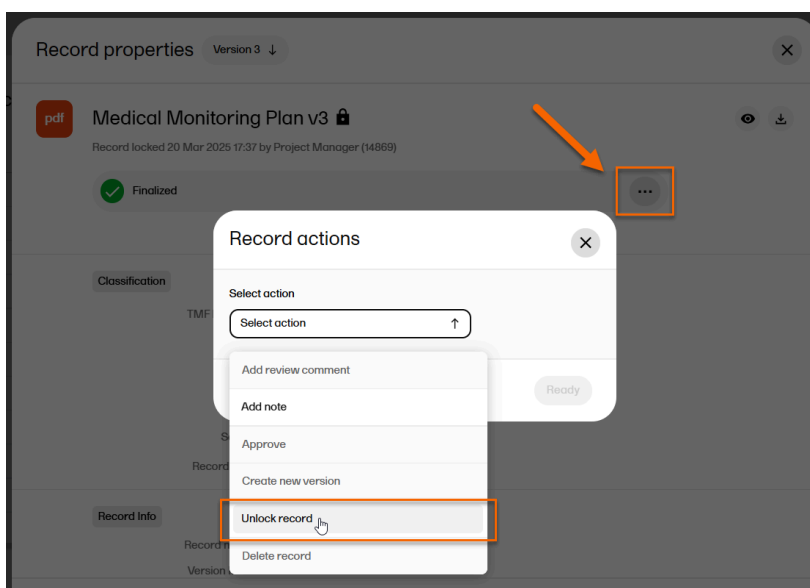
Select the **Unlock** button:



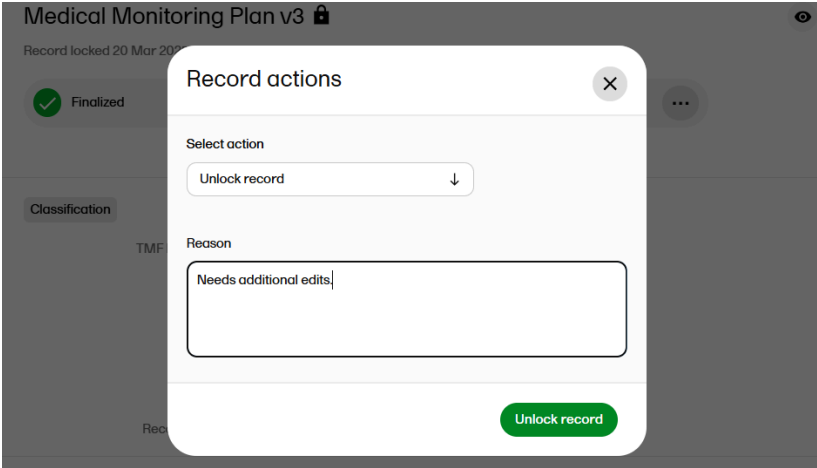
The record is now unlocked.

- 3 If the TMF has *Give reason for unlocking records* setting *enabled* (see [TMF settings](#) for more information), the **Unlock** button is not displayed.

Instead, select to open the **Record actions** menu, and from the dropdown select **Unlock record**:



- 4
- Type the reason for unlocking the record and select **Unlock Record** to confirm.



The record is now unlocked, and the unlock reason is recorded in the audit trail report.

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Sharing records with Viedoc Share

Sharing records with Viedoc Share

Published by Viedoc System 2025-09-24

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[1.1 Definitions](#)

[1.2 Prerequisites](#)

[1.3 Long Term Validation of signatures](#)

[2. Sharing workflow](#)

[3. Configuring a record for sharing](#)

[4. The Sharing section in the Record properties window](#)

[5. Adding form fields](#)

[5.4 Creating a radio button](#)

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[6. Sharing a record](#)

[7. Viewing the binder properties](#)

[8. Downloading the record](#)

[9. Revoking a binder](#)

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- [Viedoc User Guide for eTMF Managers](#) (old interface)

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- [Viedoc TMF Admin User Guide](#)

1 Introduction

The Viedoc Share feature is available to TMF users for sharing records with Viedoc Me users, or with Viedoc Clinic users, for information sharing or for collecting signatures.

1.1 Definitions

The following terms are used for reference:

- **Sharer** - a TMF user with *Manage sharing* permission
- **Binder** - a digital envelope that includes a finalized record version that is filed to the TMF
- **Recipient** - a Viedoc Clinic or a Viedoc Me user from the same scope as the sharer
- **Co-signatory** - a Viedoc Clinic user from the same scope as that sharer. The co-signatory can sign a record after all of the binder's recipients have signed

1.2 Prerequisites

A TMF user can share records if the eTMF Manager assigns one of the following permissions to their role in Viedoc Admin:

- **Manage document sharing for Viedoc Clinic users**
- **Manage document sharing for Viedoc Me users**

See [Roles and permissions in Viedoc TMF](#) for more information

A record can only be shared if:

- the corresponding artifact has been configured for sharing (done by the eTMF Manager)
- the record has been configured for sharing ([see configuring a record for sharing](#) in the TMF Admin User Guide)
- the record has been **finalized**
- the Sharer has permissions for the same scope (trial, country, site) as the Viedoc Me user or the Viedoc Clinic user

Supported file types:

Viedoc Share supports all file types that can be uploaded into the TMF. For a list of file types that cannot be uploaded to the TMF, please see [Blacklisted file formats](#).

1.3 Long Term Validation of signatures

When a shared record is digitally signed by the recipient, Long-Term Validation (LTV) is embedded into the PDF, ensuring that signatures remain verifiable even after certificate expiration.

This happens automatically, with no extra steps are required from the user. A trusted timestamp is applied at the time of signing, and signatures display as valid in standard PDF viewers such as Adobe Acrobat. If an error occurs during validation or timestamping, the signed document cannot be downloaded, ensuring the integrity and compliance of the signed output.

2 Sharing workflow

1. Viedoc Admin: An Admin user assigns permission to a TMF user to **Manage document sharing for Viedoc Clinic users** and/or **Viedoc Me users**. This is the **Sharer**.
2. Viedoc TMF > TMF Admin view > Edit artifact. The eTMF Manager enables record sharing for Viedoc Clinic and/or Viedoc Me users.
3. Viedoc TMF > Trial Master File view > Record properties. A user with WRITE access:
 - Configures a record to be shared with either Viedoc Clinic users or Viedoc Me users
 - (Optional) Adds form fields
 - Publishes and finalizes the record
 - Creates **binder(s)** and shares them with **recipients** and **co-signatories**
4. **Recipients** receive a an email with a link to Viedoc Share where they can read, complete fields, and/or and sign the record using a one-time code.
5. For Viedoc Me users, a link to Viedoc Share is also available under **Documents** on the main page of Viedoc Me.
6. If a co-signatory is required, after all recipients have completed required fields and signed the record, the **co-signatory** receives an email that the record has been signed by the recipient, then also signs it.
7. The signed records are included in the corresponding side of the TMF-EMS archive (Investigator and/or Sponsor).

3 Configuring a record for sharing

Before a record is published, it can be configured for sharing. A TMF user with WRITE access to a record must enable the sharing before other TMF end users can share the record.

To configure a record for sharing:

- 1 In the left navigation menu, select **Trial Master File** to expand it, and select the **Records** or the **Structure** page.

Navigate to the *unpublished* record, and select it to open the **Record properties** window.

- 2 In the **Record sharing** section, select the users that the record can be shared with - either Viedoc Clinic users or Viedoc Me users.

Record sharing

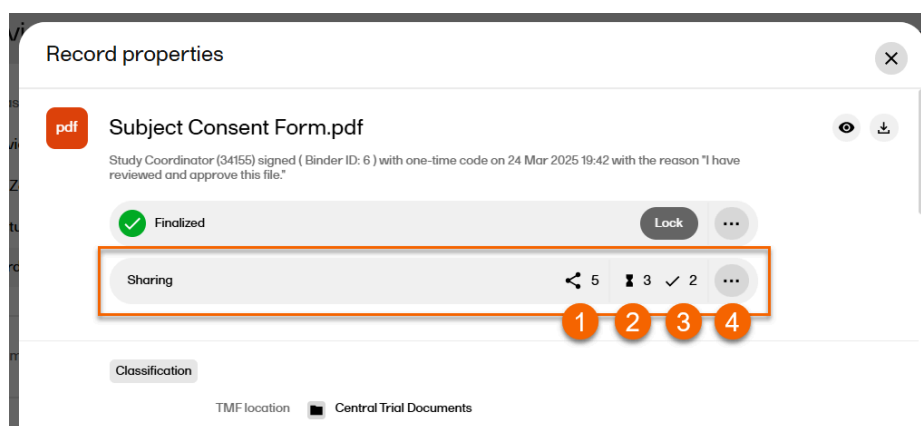
Enable for* ☐ None ☐ Viedoc Clinic users ☒ Viedoc Me users

- 3 Select **Publish** or **Save as unpublished**, as needed.

Note! Only an *unpublished* record can be configured for sharing and have form fields added (see [Adding form fields](#) below). If a record has already been published and/or finalized, create a new version of the record, configure for sharing and/or add form fields, then publish and finalize again.

4 The Sharing section in the Record properties window

A TMF user with Manage sharing permission will see a **Sharing** section at the top of the **Record properties** window.



The **Sharing** section contains the following:

1. The number of active shared binders accessible by the Sharer.
2. The number of pending actions for binders accessible by the Sharer (only displayed if the number is greater than 0).
3. The number of actions done for binders accessible by the Sharer (only displayed if the number is greater than 0).
4. Select ... to open the Sharing window with an overview of the existing binders. This is also where new binders can be created.

5 Adding form fields

Form fields such as radio buttons, checkboxes or open text fields can be added to an *unpublished* record once it has been added to an artifact. These fields can be customized and set as optional or required for the recipient. If fields are set as required, the recipient cannot sign the record until all required fields have been completed.

Notes!

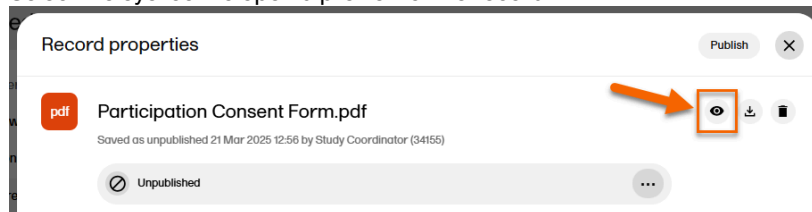
- Form fields can only be added to .pdf files.
- Form fields and settings may be changed while a record remains unpublished. Once a record is published, fields may not be edited or added.
- Form fields can only be completed by Viedoc Me users, not Clinic users

To add form fields to a record:

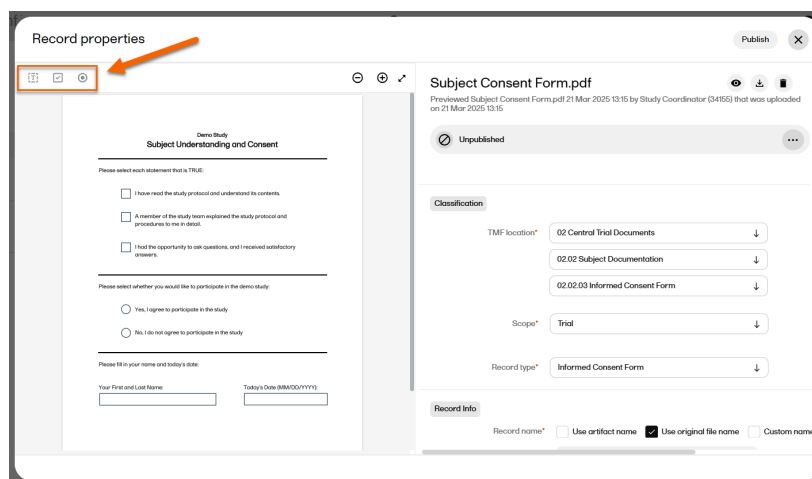
- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** or the **Structure** page.

Navigate to the *unpublished* record, and select it to open the **Record properties** window.

- 2 Select the eye icon to open a preview of the record:



- 3 On the far left, the options for adding/editing fields are displayed:



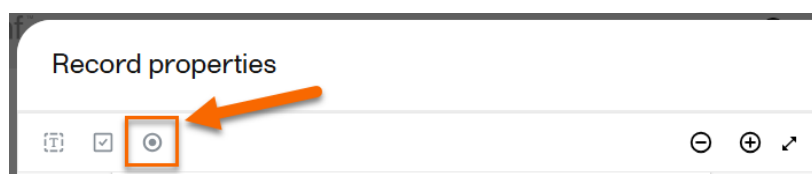
Types of form fields available:

- **Radio buttons** allow recipients to select a single option from a predefined set of choices, ensuring only one selection is made.
- **Checkboxes** allow recipients to select multiple options independently from a list, allowing for one, several, or all choices to be selected.
- **Open text fields** provide recipients with a space to input free-form text, accommodating responses that require personalized or detailed information.

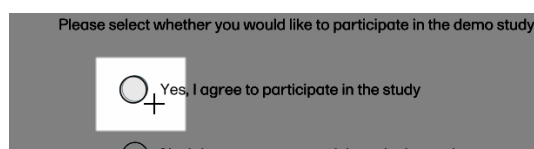
5.1 Creating a radio button

To create a radio button:

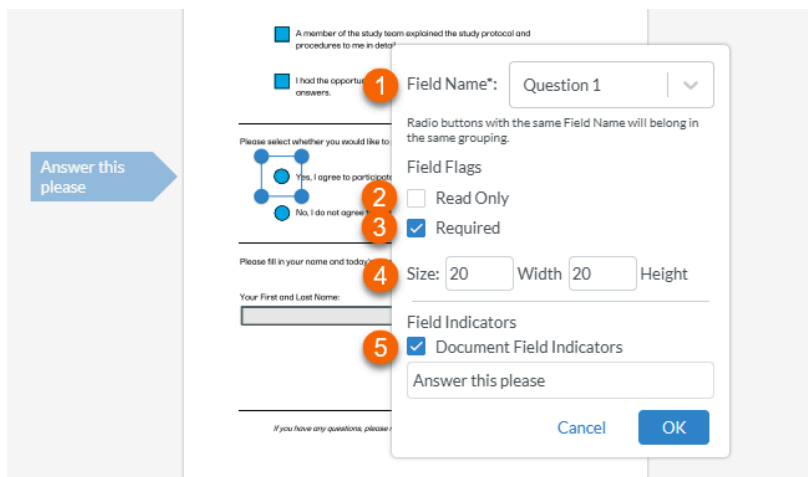
- 1 While previewing the record, select **Radio button**:



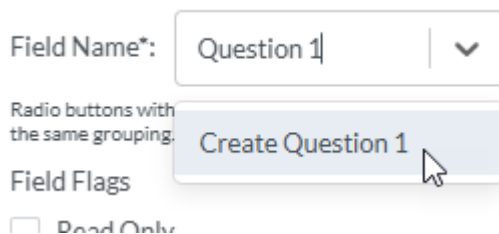
- 2 Drag the cursor to create the field shape (the size and position can be edited later).



3 Once the shape is created, an edit window is displayed:



1. To name the radio button, select inside the text box to the right of **Field Name** and type the name (for example "Question 1"). Then select the option that appears below to create the field name.



Note! For radio buttons to function properly, options belonging to the same question must have the same field name. For example, both "yes" and "no" radio buttons belonging to the first question must both be named "Question 1", and the next set of "yes" and "no" radio buttons belonging to the second question must both be named "Question 2".

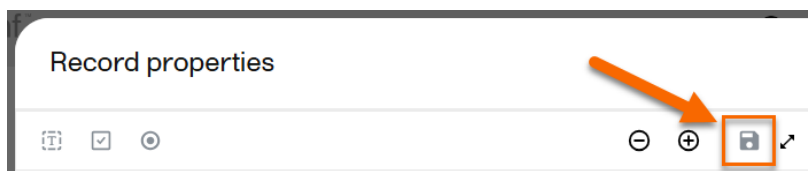
2. Setting the field as **Read Only** prevents the recipient from selecting or deselecting the button

3. Setting the field as **Required** prevents the recipient from signing the record until all of the required fields have been filled in.

4. Setting the **Size** controls the size of the radio button.

5. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. **Note!** This may not be visible if the recipient is viewing the record on a mobile device.

4 After completing all of the relevant fields and settings, select **Save**:

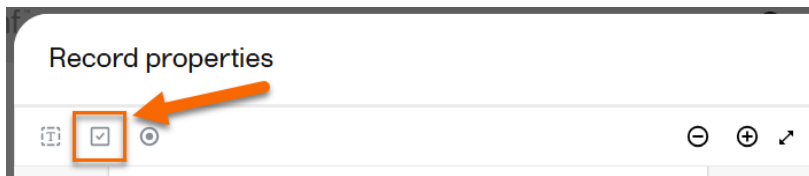


Note! You must save the form fields before publishing, saving as unpublished, or closing the record, otherwise the changes to the form fields will be lost.

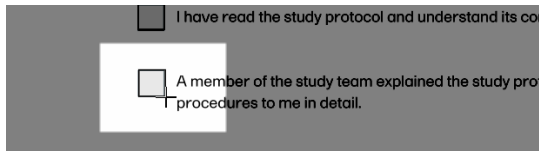
5.2 Creating a checkbox

To create a checkbox:

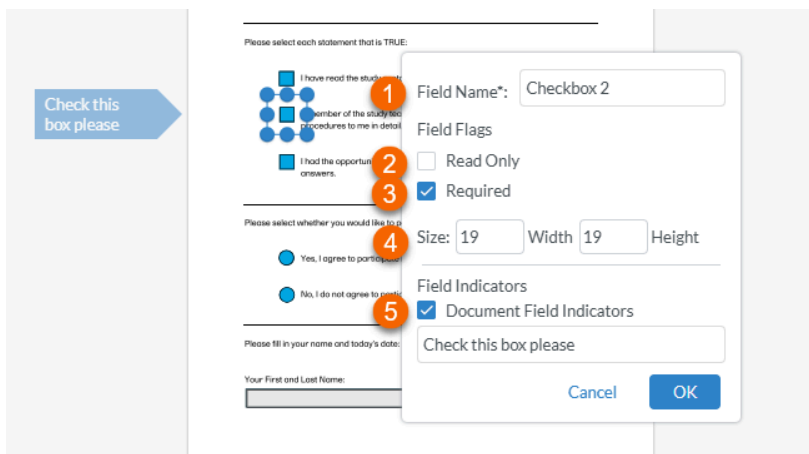
- 1 While previewing the record, select **Checkbox**:



- 2 Drag the cursor to create the field shape (the size and position can be edited later).



- 3 Once the shape is created, an edit window is displayed:



1. To name the checkbox, select inside the text box to the right of **Field Name** and type the name (for example "CheckBox1". **Note!** Checkboxes must have unique field names. If you give a checkbox the same name as another checkbox in the same record, you will not be able to save the checkbox.

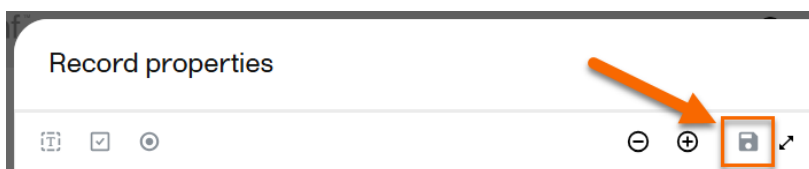
2. Setting the field as **Read Only** prevents the recipient to select or deselect the checkbox.

3. Setting the field as **Required** prevents the recipient from signing the record until all required fields have been completed. **Note!** If a required checkbox is left blank, the recipient will not be able to sign the record.

4. Setting the **Size** controls the size of the checkbox

5. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. **Note!** This may not be visible if the recipient is viewing the record on a mobile device.

- 4 After completing all of the relevant fields and settings, select **Save**:

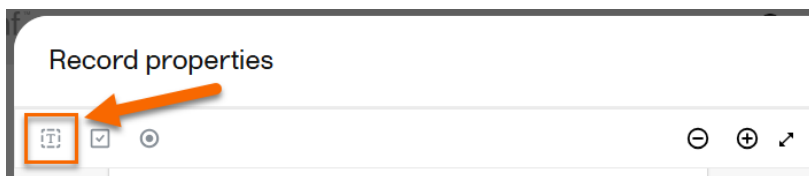


Note! You must save the form fields before publishing, saving as unpublished, or closing the record, otherwise the changes to the form fields will be lost.

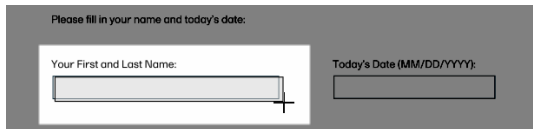
5.3 Creating a text field

To create a text field:

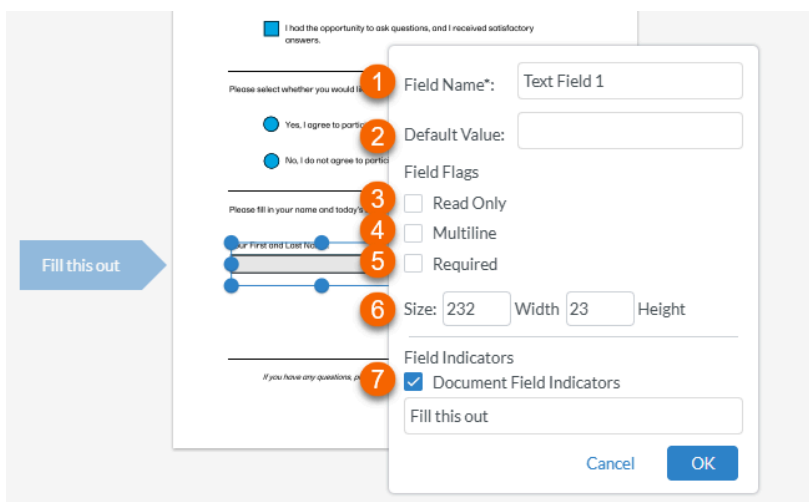
1 Select **Text Field**:



2 Drag the cursor to create the field shape (size and position can be edited later).



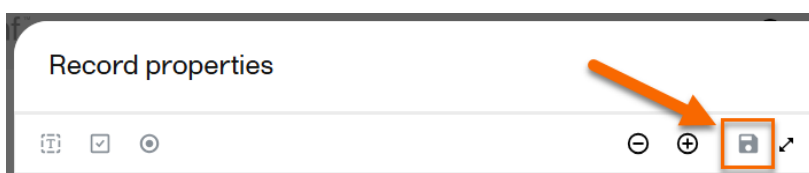
3 Once the shape is created, an edit window is displayed:



Edit the options for the text field as needed:

1. To name the text field, select inside the text box to the right of **Field Name** and type the name (for example "TextFormField 1"). **Note!** Text field names do not affect the functionality as the radio button names do.
2. Entering a **Default Value** autofills the text field with any text you enter here.
3. Setting the field as **Read Only** prevents the recipient from typing any text in the text field.
4. Setting the field as **Multiline** allows for multiple lines of text to be entered.
5. Setting the field as **Required** prevents the recipient from signing the record until all of the required fields have been completed.
6. Setting the **size** controls the size of the text field
7. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. **Note!** This may not be visible if the recipient is viewing the record on a mobile device.

4 After completing all of the relevant fields and settings, select **Save**:



Note! You must save the form fields before publishing, saving as unpublished, or closing the record, otherwise the changes to the form fields will be lost.

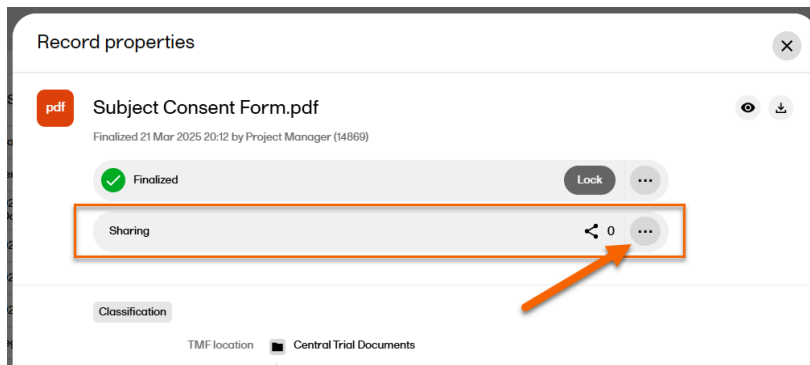
6 Sharing a record

To share a record with a Viedoc Me user or a Viedoc Clinic user:

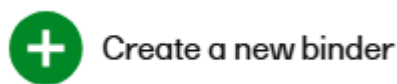
- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** or the **Structure** page.

Navigate to the *finalized* record, and select it to open the **Record properties** window.

- 2 In the **Sharing** section at the top of the window, select **...** to open the **Sharing** window.

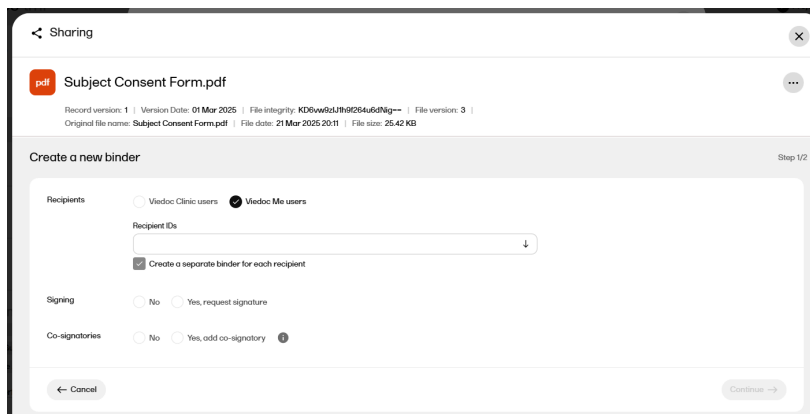


- 3 Select **Create a new binder**:

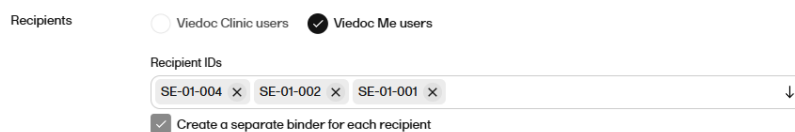


Or, if the record already has shared binders, select the **+** icon.

- 4 For **Recipients** select either **Viedoc Clinic users** or **Viedoc Me users**.



- 5 For **Recipient IDs** select the user(s) that you want to share the record with from the dropdown.



Notes!

- If you select more than one user, the option **Create a separate binder for each recipient** will be automatically selected and non-editable. This is because the recipients should not share any study information with each other.
- You can only select users within the same scope as yourself.
- If a Viedoc Me or Clinic user is added while you are actively using Viedoc TMF, you will need to close and reopen Viedoc TMF for the users to appear in the sharing dropdown.

- 6 For **Signing**, select whether or not to request a signature.

Note! If the record is included in an artifact that is only on the Sponsor side of the TMF (or on neither Sponsor nor Investigator side), and the record version is set to be shared with Viedoc Me users, it is *not* possible to collect signatures. This is because the signatures can include information that could compromise the data integrity of the Viedoc Me users.

- 7 If you selected **Yes** in the previous step, select a **Reason for the signature** from the dropdown.

Signing ☐ No ☒ Yes, request signature

Reason for the signature

I have read and understood the contents of the file.

- 8 For **Co-signatories**, select whether or not a co-signatory is required.

Note! The co-signatory cannot sign the record if you selected **No** for the recipient signature.

- 9 If you selected **Yes** in the previous step, select the co-signatory or co-signatories from the dropdown.

Note! You can only select users within the same scope as yourself.

- 10 If you selected to have a cosignatory, select a **Reason for the co-signature** from the dropdown.

Co-signatories ☐ No ☒ Yes, add co-signatory ⓘ

Co-signatory IDs

Study Coordinator (34155) X

Reason for the co-signature

I have reviewed and approve this file.

- 11 Select **Continue** to see an overview of the sharing details.

← Sharing X

pdf Subject Consent Form.pdf ...

Record version: 1 | Version Date: 01 Mar 2025 | File integrity: KD6vw9zJ1h9f264u6dNig-- | File version: 3 |
Original file name: Subject Consent Form.pdf | File date: 21 Mar 2025 20:11 | File size: 25.42 KB

Create a new binder Step 2/2

Number of new binders: 1 | Total number of recipients: 3 | Signature required: Yes | Total number of co-signatories: 1

Recipients:
SE-01-004 - Norrköping, SE-01-002 - Norrköping, SE-01-001 - Norrköping

Reason for signature:
I confirm that I have read and understand the contents of the document. I agree to take part in the study.

Co-signatories:
Study Coordinator (34155) - Study Coordinator

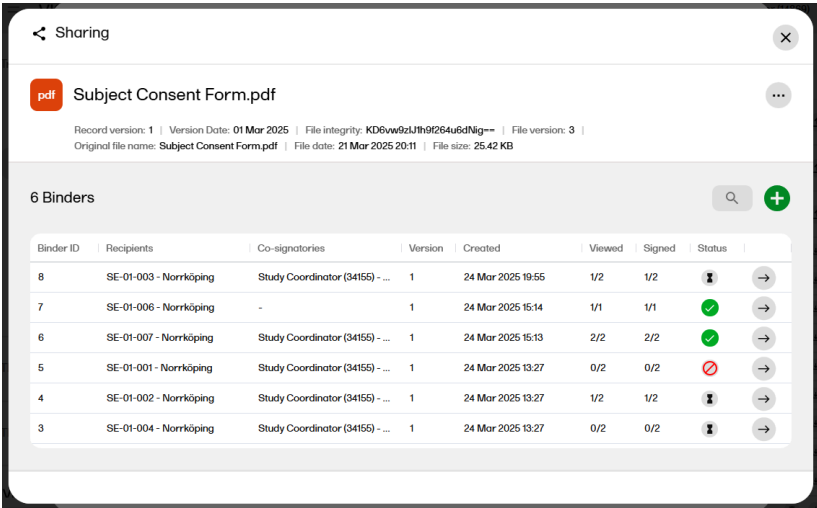
Reason for co-signature:
I have reviewed and approve this file.

← Back Confirm

- 12 If the sharing details are correct, select **Confirm**.

Otherwise, you can select **Back** and edit.

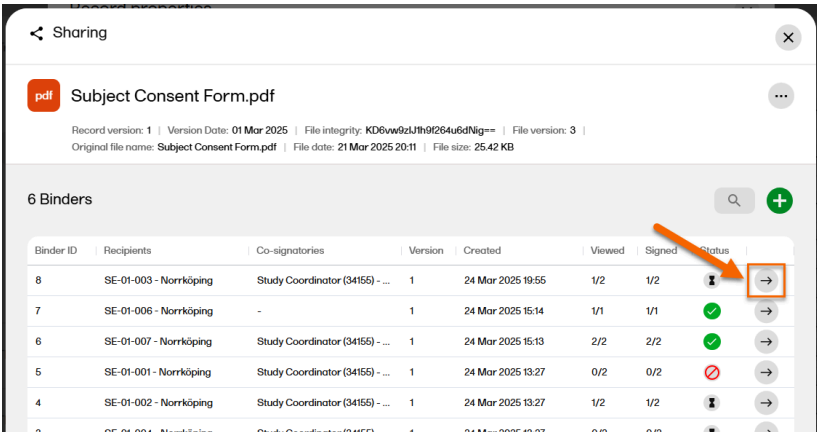
- 13
- After confirming, a binder summary is displayed and an email is sent to each of the recipients with a link to Viedoc Share where the record can be viewed and/or signed.



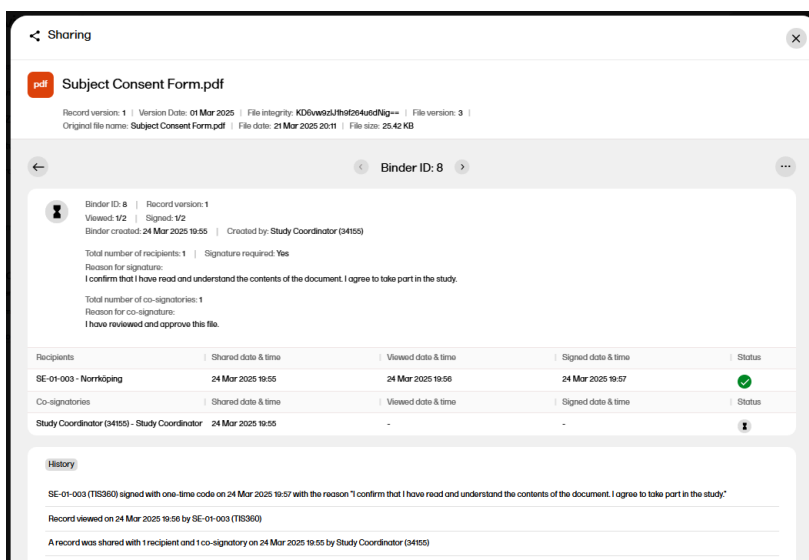
7 Viewing the binder properties

- 1
- In the left navigation menu, select to expand **Trial Master File**, and select the **Records** or the **Structure** page.

Navigate to the record, and select it to open the **Record properties** window.
- 2
- In the **Sharing** section at the top of the window, select **...** to open the **Sharing** window.
- 3
- Select the arrow icon to open the **Binder properties** window.



- 4 The binder properties are displayed, including the history with all actions for the binder.



8 Downloading the record

To download the shared record from the binder:

- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** or the **Structure** page.

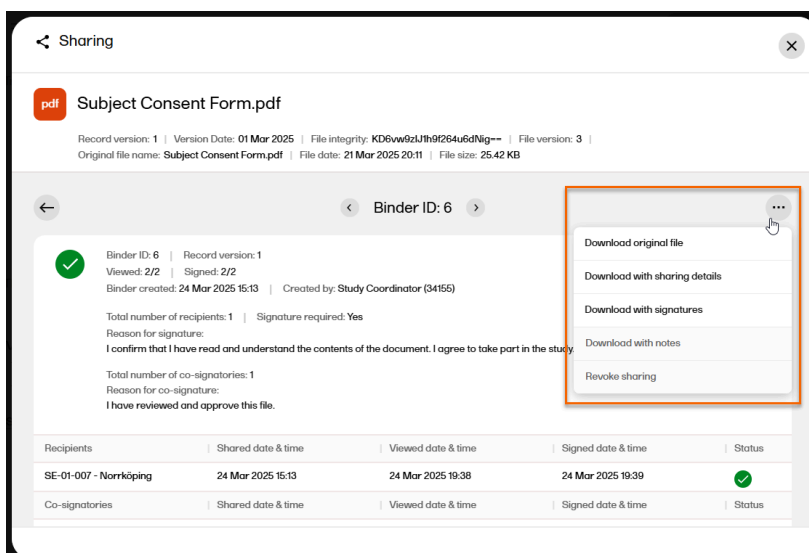
Navigate to the record, and select it to open the **Record properties** window.

- 2 In the **Sharing** section at the top of the window, select **...** to open the **Sharing** window.

- 3 Select the arrow icon to open the **Binder properties** window.



- 4 In the top right corner, select **...** to open the binder menu.



5 Select the download option:

- **Download original file** downloads the original file to your computer.
- **Download with sharing details** downloads a zipped folder to your computer. The zipped folder contains the original file and a PDF with the sharing details.
- **Download with signatures** downloads a PDF file to your computer. This menu item is only available if all recipients and co-signatories have signed the record. The PDF contains the original file and a cover page with the signatures. This is an example of such a cover page:



9 Revoking a binder

A binder can be revoked if you want to share a newer version of a record or to cancel the sharing when a record version has been shared by mistake.

Note! If the record in the binder has been signed, even if it's by only one recipient, the binder cannot be revoked.

To revoke a binder:

- 1 In the left navigation menu, select to expand **Trial Master File**, and select the **Records** or the **Structure** page.

Navigate to the record, and select it to open the **Record properties** window.

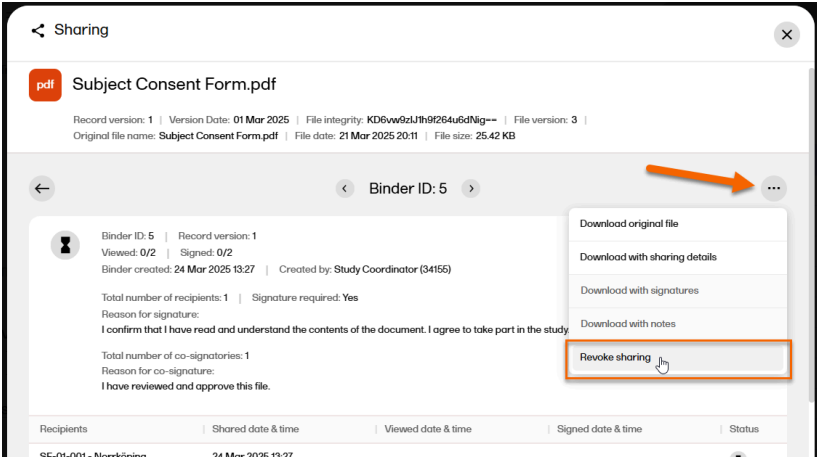
- 2 In the **Sharing** section at the top of the window, select **...** to open the **Sharing** window.

- 3 Select the arrow icon to open the **Binder properties** window.

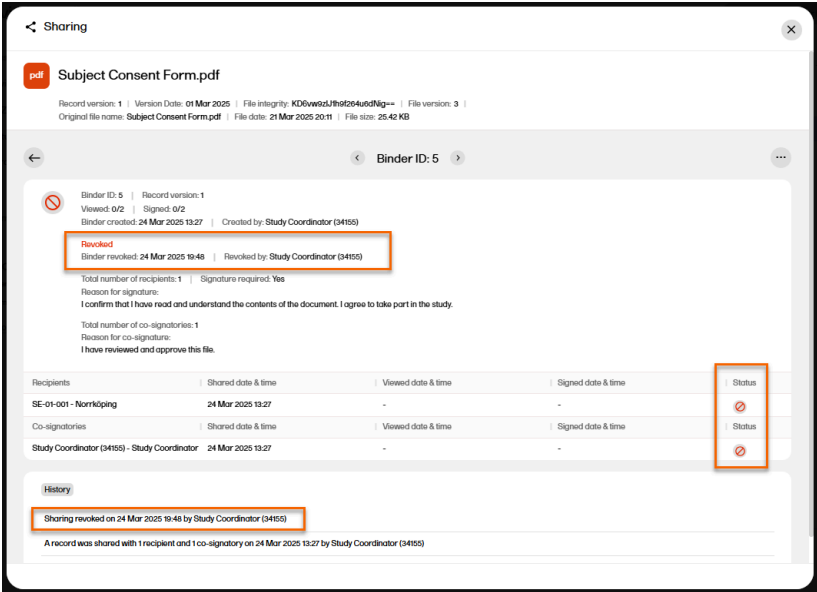
Binder ID	Recipients	Co-signatories	Version	Created	Viewed	Signed	Status
7	SE-01-006 - Norrköping	-	1	24 Mar 2025 15:14	1/1	1/1	✓ →
6	SE-01-007 - Norrköping	Study Coordinator (34155) - ...	1	24 Mar 2025 15:13	2/2	2/2	✓ →
5	SE-01-001 - Norrköping	Study Coordinator (34155) - ...	1	24 Mar 2025 13:27	0/2	0/2	🔒 →
4	SE-01-002 - Norrköping	Study Coordinator (34155) - ...	1	24 Mar 2025 13:27	1/2	1/2	🔒 →

- 4 In the top right corner, select **...** to open the binder menu.

5 Select **Revoke sharing**.



6 The binder properties are displayed, and you can now see that the binder is revoked.



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TMF Archive

TMF Archive

Published by Viedoc System 2025-08-19

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[3.7 The zipped folder structure and content](#)

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

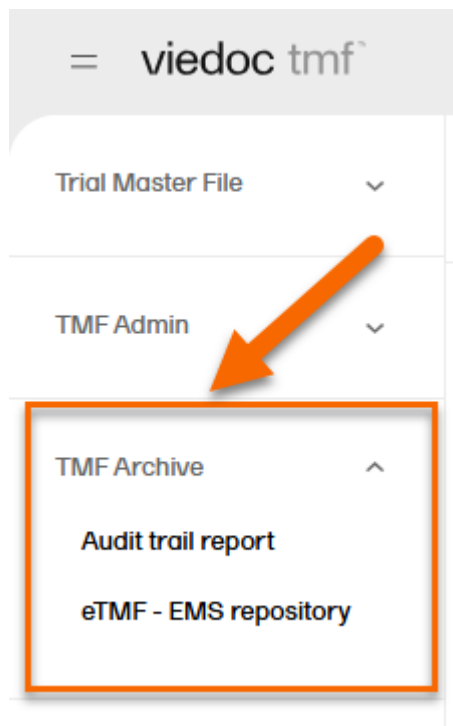
- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

- [Viedoc TMF User Guide](#)
 - [Viedoc TMF Admin User Guide](#)
-

1 TMF Archive

Users with the appropriate permissions for managing the TMF Archive area of Viedoc TMF will see the following in the left navigation menu:



The next sections describe how to generate the Audit trail report and the eTMF-EMS repository.

1.1 Naming conventions

It is best practice to use the [record name templates](#) in TMF settings as naming conventions, to ensure all data that you want to appear are included in file names in the archive and repository.

If an archive template name is defined in TMF settings, when archiving, the latest template will be applied to the files in the zipped folder.

By default, if a record name template is *not* defined for the **archive template**:

- The filename in the zipped folder will be the same as the latest record name set in record properties
- All files in the zipped folder will have the version of the file as a suffix.
- If there are multiple records with the same name in the same folder in the archive, they will be indicated with -n so that none of them will be overwritten.
- Files in the zipped folder will never be overwritten.
- If a system variable used in the template doesn't exist for a record, that variable will be empty in the template.
- When there is an ongoing archive operation, if the eTMF Manager defines a new archive template, this change will not affect the ongoing archive operations, it will only affect the upcoming archives.

2 Audit trail report

2.1 Introduction

A complete audit trail report can be generated and downloaded in Excel format. It includes a complete list of actions done on:

- the structure, templates, and settings by the TMF Managers
- the records included in the TMF by the users
- generating and downloading the complete audit trail report and the eTMF-EMS repository

The report respects the user roles and access to records, sites, and countries.

2.2 Generating and downloading the report

In the left navigation menu, select to expand **TMF Archive** and select the **Audit trail report** page.

To generate the complete audit trail report:

The screenshot shows the Viedoc TMF interface. On the left sidebar, the 'Audit trail report' option is highlighted. The main content area shows the 'Audit trail report' section with a file download button and a 'Generate a new file' section. The 'Generate a new file' section has dropdown menus for 'Trial level records', 'Country level records', and 'Site level records', and a 'Filter by' dropdown for 'Milestones'. A 'Generate' button is at the bottom of this section. A 'Download' button is next to the generated file 'CompleteAuditTrailReport-Demo Study-20250225135552.xlsx'.

- 1 Set the options for the records' audit trails to be included. You can choose to include records that are filed on trial/country/site levels according to your permissions to those.
- 2 Set the milestones/milestone groups you would like to filter by.
- 3 Select **Generate**.
- 4 Select **Download** on the generated file to download the report.

2.3 Included sheets

Each sheet in the complete audit trail report corresponds to the actions done by users in the TMF. The report is self-explanatory, but in the following sections you can find detailed information about each sheet in the file:

2.3.1 Report Info

This sheet includes general information about the report and the study. The **First document added date/time** and **Last document added date/time** show when the first and last records were uploaded to the TMF. This is shown regardless of whether the audit trail of these records is included or not in the report.

Complete Audit Trail Info					
Items	Settings				
Originator	VEDOC				
Instance	https://abc.viedoc.net				
System version	4.67.2108.150				
Printed by					
Printed date/time	2021-08-06 09:20:54				
Study name	Unicorns				
Study GUID	74qhi3f37-xao2-421b-ajec-e4f2c5ba7cac				
First document added date/time	2021-08-04 12:36:00				
Last document added date/time	2021-08-05 09:16:14				
Included documents	Trial level, All countries, All sites				
Filtered by	All milestones				

All dates in this report are according to the UTC standard.

Disclaimer: The overall structure of this report with regards to names and the order of columns can change to reflect future extensions and development of the eTMF. This report includes a detailed audit trail of the eTMF. Every change that has been made to the content (and structure) of the eTMF is listed in this report.

2.3.2 Trial Master File

This sheet includes information about all the actions done by users on records in the Trial Master File view. Note that the actions that are included in this sheet are done on:

This sheet includes actions done by eTMF Managers on the instantiated structure. If the user doesn't have access to TMF Admin, this sheet is empty.

2.3.6 Archive Management

[illegible]

This sheet includes the actions done by TMF Managers on the Settings tab in TMF Admin. If the user doesn't have access to TMF Admin, this sheet is empty.

	A	B	C	D	E	F
1	User Actions on Settings					
2	Action	Date/time	Old Value	New Value	Done By	
3	Edit Settings	2021-08-05 09:44:06	Enable Milestones filter = true	Enable Milestones filter = false		
4	Edit Settings	2021-08-05 09:43:50	Enable Milestones filter = false	Enable Milestones filter = true		
5						
6						
7	User changelog of eTMF settings.					
8						
9						
10						
11						
12						
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19						
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29						
30						

2.3.8 Status management

This sheet includes the actions done by TMF Managers on the Status tab in TMF Admin. If the user doesn't have access to TMF Admin, this sheet is empty.

	A	B	C	D	E	F	G	H	I	J	K	L
1	User Actions on eTMF Status											
2	Action	Date/time	Old Value	New Value	Reason	Done By						
3	Edit status	2022-02-01 12:17:59	Locked	Instantiated	Unlocking the eTMF to finalize a document							
4	Edit status	2022-02-01 10:49:35	Instantiated	Locked	Locking the eTMF for archiving							
5	Edit status	2021-08-16 11:29:23	Enabled	Instantiated	Initiate structure							
6	Edit status	2021-08-16 11:26:36		Enabled	Enable eTMF							
7												
8	User changelog of eTMF status.											
9												
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3 eTMF-EMS repository

3.1 Introduction

The eTMF-EMS repository can be used for archiving the sponsor and/or investigator side of the study and/or exporting the records that are included in the structure. It is compatible with the Exchange Mechanism Standard (EMS). Read more about the EMS [here](#).

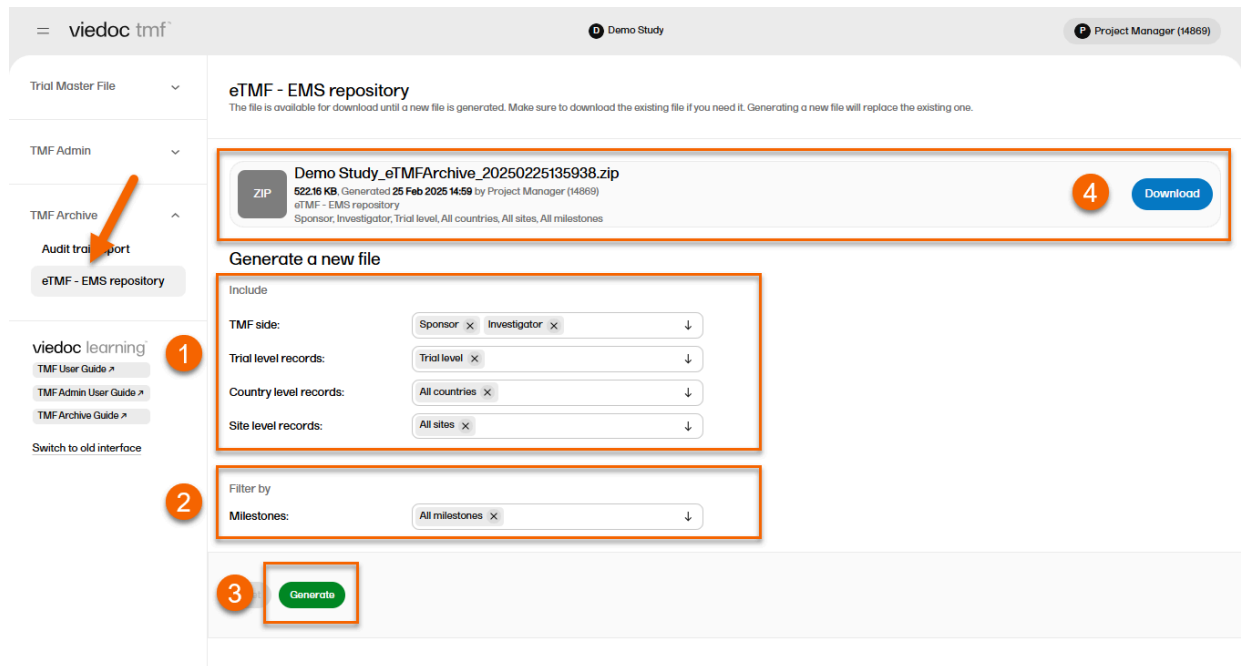
The eTMF-EMS repository respects the user roles and access to records, sites, countries, and TMF side.

3.2 Generating and downloading the EMS repository

In the left navigation menu, select to expand **TMF Archive** and select the **eTMF-EMS Repository** page.


To generate the repository:

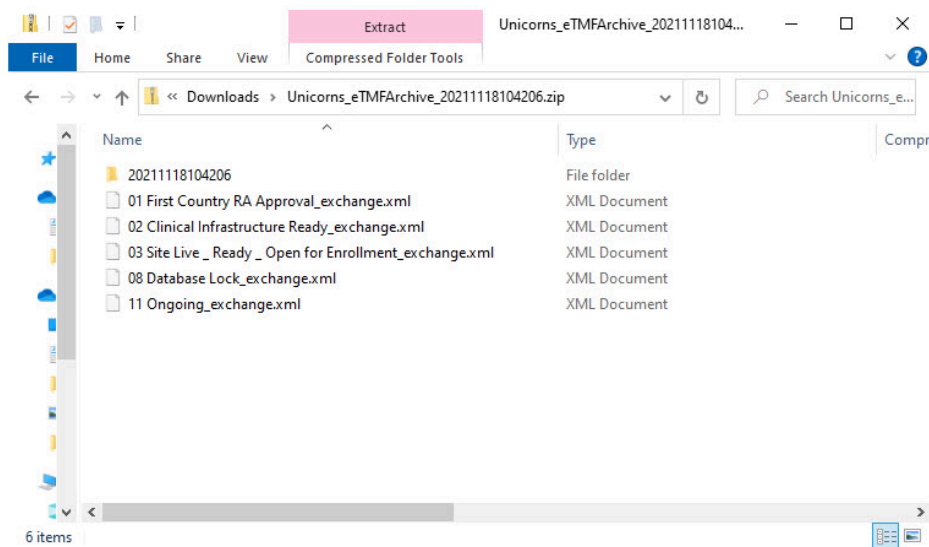
- 1 Set the options for the records you want to include in the archive. You can choose to include records that are filed to the investigator or sponsor side of the TMF, and records that are filed on trial/country/site levels according to your permissions to those.
- 2 Set the milestones/milestone groups you would like to filter by.
- 3 Select **Generate**.
- 4 Select **Download** on the generated file to download the zipped folder.



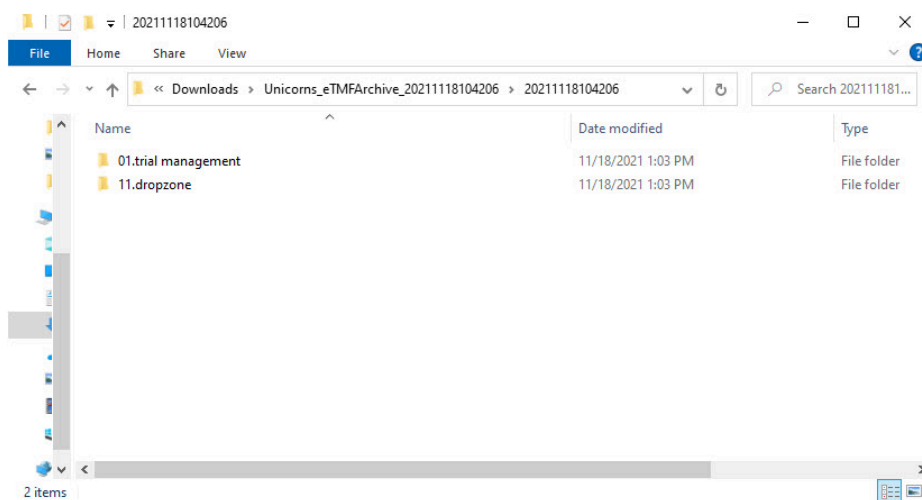
3.3 The zipped folder structure and content

The zipped folder structure mirrors the TMF structure used for the study as follows:

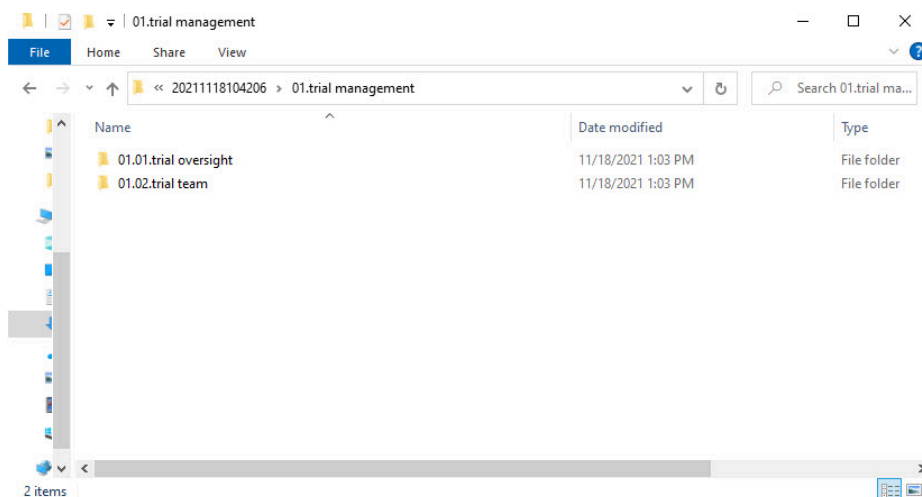
- **Level 1** – this level includes:
 - The main zipped folder with a name in the format: StudyName_eTMFArchive_Datetimestamp
 - StudyName - the study name
 - eTMFArchive - static text
 - Datetimestamp - the UTC date and time of generating the eTMF-EMS repository in the format YYYYmmDDHHMMss
-  Unicorns_eTMFArchive_20211118104206.zip
- **Level 2** – this level includes:
 - A subfolder that has the name TransferID (datetime stamp of generating the eTMF-EMS repository) in the format YYYYmmDDHHMMss
 - An exchange.xml file for each chosen milestone. You can read about the content of the xml files and find an example [here](#).



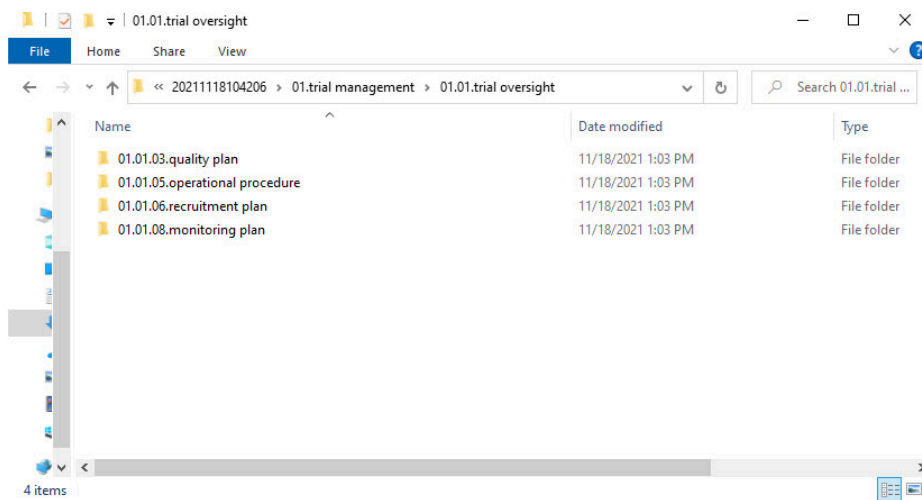
- **Level 3** – this level includes:
 - A folder with `ZoneID.ZoneName` for each included zone from the structure



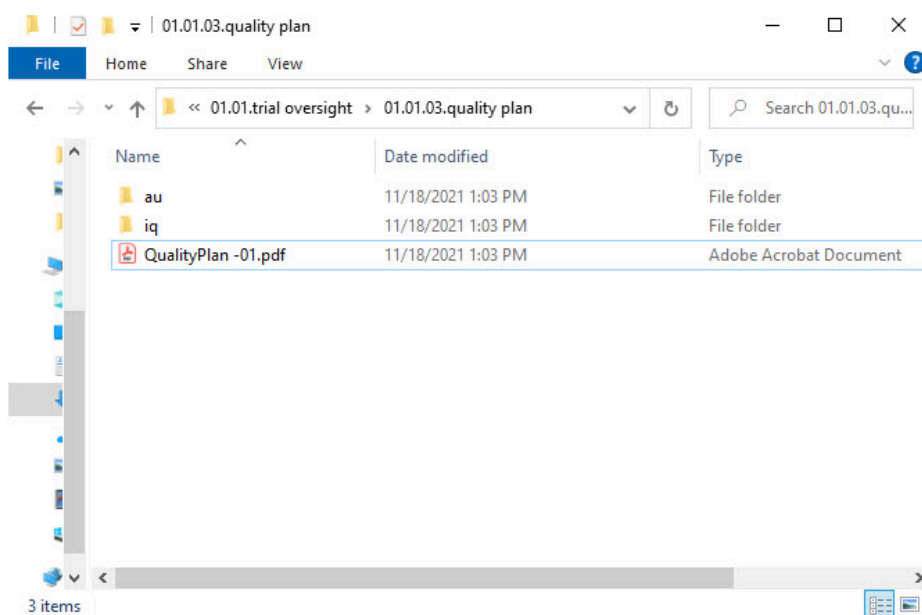
- **Level 4** – this level includes:
 - A folder with `ZoneID.SectionID.SectionName` for each included section from the structure



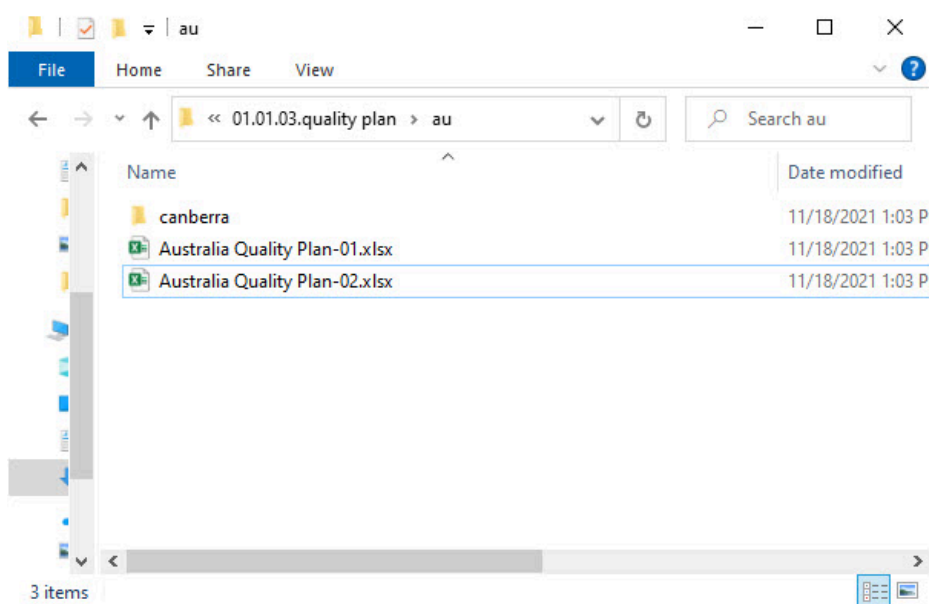
- **Level 5** – this level includes:
 - A folder with `ZoneID.SectionID.ArtifactID.ArtifactName` for each included artifact from the structure



- **Level 6** – this level includes:
 - records filed to this artifact on trial level
 - A subfolder for signed records*
 - Subfolders for included countries with country code as their names

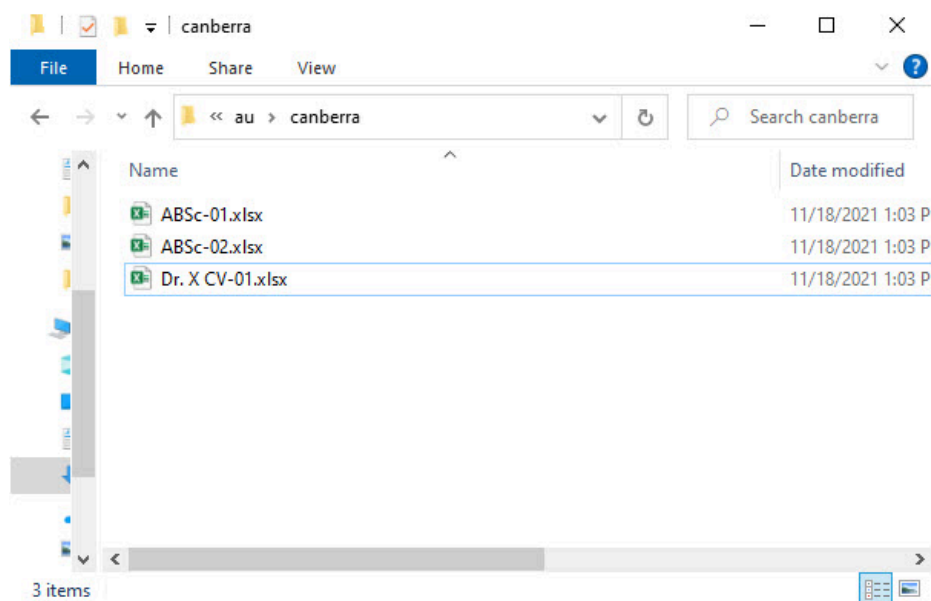


- **Level 7** – this level includes:
 - records filed to the artifact and linked to this specific country
 - A subfolder for signed records*
 - Subfolders for sites in this country with site names as their names



- **Level 8** – this level includes:

- A subfolder for signed records*
- Records filed to the artifact and linked to this specific site



*The files that are signed by Viedoc Me users are only included when archiving the Investigator side of the TMF.

The zipped folder includes all the versions of records included in the structure. The name of the files will be as follows:

CurrentDocumentName-SystemVersion.extension , where:

- CurrentDocumentName is the latest record name
- SystemVersion is the integer value of the version set by the system for this file

If there are multiple records with the same name filed to the same artifact and linked to the same levels, the system will add (n) as a suffix to the record name to ensure that all files are included in the zipped folder and no files are overwritten.

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TMF roles and permissions use cases

TMF roles and permissions use cases

Published by Viedoc System 2025-04-16

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[3.2 Why can the end user see the artifact but not upload or edit?](#)

[3.3 Why can the end user see the artifact but not review or approve?](#)

[3.4 Why can the end user only see their own records in the drop zone?](#)

[3.5 Why can the end user manage the drop zone records but not see applicable artifacts or not choose the wanted TMF level when classifying the record?](#)

Note! This page contains information and instructions for the new TMF user interface. If you are using the old interface, please go to the relevant user guides:

- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

Want to browse more information for the new interface? Please go to the new TMF user guides:

- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Introduction

This lesson contains scenarios and frequently asked questions about roles and permissions in Viedoc TMF. For detailed information and explanations about roles and permissions, please see [Roles and permissions in Viedoc TMF](#).

2 Scenarios and use cases

The following table contains examples of common use case scenarios together with the requisites for performing them.

Scenario	Requisites
Drop zone: As a General site user , I want to be able to drop site-generated or site-signed records in the drop zone.	<ul style="list-style-type: none">▪ The user is invited to a clinic role for a specific site.▪ The TMF role mapped has NO ACCESS for all levels and artifacts.

Scenario	Requisites
<p>eISF: As a General site user, I want to be able to file pre-defined records on site level, view some artifacts on study and country levels and archive the Investigator site TMF/eISF.</p>	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role for a specific site. ▪ The TMF role mapped has WRITE access to pre-defined artifacts on site level, READ access to pre-defined artifacts on Study level and Country level. The role sheet Site staff can act as a starting point. ▪ The TMF role mapped has the permission Archive investigator TMF. ▪ Artifact is Optional or Required in the sheet Viedoc Extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.
<p>As a Project manager, I want to be able to file records at study level, view all sponsor-side records at all levels in the study, archive the TMF (sponsor side), download the audit trail, and see the TMF settings and structure.</p>	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role that has a mapped TMF role with WRITE access to Study and READ access to Country and Site in the role sheets. Role SPONSOR-STUDY can act as a starting point. ▪ The user needs to be invited on study level (All sites) in Viedoc to gain WRITE access. Otherwise, the WRITE permission will be translated to READ. ▪ The user is invited to a clinic role that has the mapped TMF permissions Archive sponsor TMF, Download audit trail, and Read-only Trial Master File. ▪ Artifact is Optional or Required in the sheet Viedoc extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.
<p>As a Monitor, I do not have access to patient information records on site level. I file site-level records that belong on the sponsor-side TMF, view records for my country and the study, manage drop zone records, and review site-level records.</p>	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role that has a mapped TMF role with WRITE access to Site and READ access to Country and Study in the role sheets. The sheet Role SPONSOR-SITE can act as a starting point. ▪ The user is invited to a clinic role that has a TMF role with REVIEW access to all artifacts that the review is to be performed on. The sheet Role SPONSOR-REVIEWER can act as a starting point. ▪ The user needs to be invited to all applicable sites in Viedoc. ▪ The user is invited to a clinic role that has the mapped TMF permission Manage drop zone. ▪ Artifact is Optional or Required in the sheet Viedoc extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.

Scenario	Requisites
As a Country Manager or a Trial Manager , I want to be able to file records at country level, view all sponsor-side records at all levels in the study, and review all sponsor-side records.	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role that has a mapped TMF role with WRITE access to Country and READ access to Study and Site in the role sheets. The sheet Role SPONSOR-COUNTRY can act as a starting point. ▪ The user is invited to a clinic role that has a TMF role with REVIEW access to all artifacts that the review is to be performed on. The sheet Role SPONSOR-REVIEWER can act as a starting point. ▪ The user needs to be invited on study level (All sites) in Viedoc to gain REVIEW access to all records per the role sheet. Otherwise, the REVIEW permission will be translated to READ. ▪ Artifact is Optional or Required in the sheet Viedoc extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.
As a Regulatory Inspector , I want to have read-only access to all records (sponsor side and investigator side), TMF settings, and access to the audit trail.	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role that has the mapped TMF permission Read-only Trial Master File, Read-only TMF Admin and Download audit trail. ▪ The user needs to be invited on study level (All production sites) in Viedoc. ▪ Artifact is Optional or Required in the sheet Viedoc extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.
As an Unblinded Statistician , I want to view, file, and classify blinded records only on all levels.	<ul style="list-style-type: none"> ▪ The user is invited to a clinic role that has a mapped TMF role with WRITE and READ access to unblinded artifacts in the role sheets. The sheet Role SPONSOR-UNBLINDED can act as a starting point. ▪ The user needs to be invited on study level (All sites) in Viedoc to gain WRITE access to all records per the role sheet. Otherwise, the WRITE permission will be translated to READ. ▪ Artifact is Optional or Required in Viedoc extensions, as Not Permitted in Viedoc extensions will override any permission in the role sheets to NO ACCESS.

3 Frequently asked questions

3.1 Why can't the end user see the artifact?

Check	To resolve
Check that the user is invited to a clinic role with a mapped TMF role with at least Read to the artifact at the expected level.	Invite the user to a clinic role with a mapped TMF role with read/write permissions to the artifact or edit the roles and accesses for the artifact in TMF Admin maintenance mode.
Check that the artifact itself is Optional or Required at the expected level, as Not permitted records will override any role access for the artifact.	Edit the trial/country/site level settings for the artifact in TMF Admin maintenance mode.

3.2 Why can the end user see the artifact but not upload or edit?

Check	To resolve
Check that the user is invited to a clinic role with a mapped TMF role with Write access to the artifact at the expected level.	Invite the user to a clinic role with a mapped TMF role with write permission to the artifact or edit the roles and accesses for the artifact in TMF Admin maintenance mode.
Check that the user is invited to a clinic role on at least Country level (for write permission to Country level records) or Study level, All production sites (for write permission to Study level records), otherwise Write will be translated to Read.	Invite the user to a clinic role on at least Country level (for write permission to Country level records) or Study level, All production sites (for write permission to Study level records).

3.3 Why can the end user see the artifact but not review or approve?

Check	To resolve
Check that the user is invited to a clinic role with a mapped TMF role with Review access to the artifact at the expected level.	Invite the user to a clinic role with a mapped TMF role with review permission to the artifact or edit the roles and accesses for the artifact in TMF Admin maintenance mode.
Check that the user is invited to a clinic role on at least Country level (for review permission to Country level records) or Study level, All production sites (for review permission to Study level records, otherwise Review will be translated to Read.	Invite the user to a clinic role on at least Country level (for write permission to Country level records) or Study level, All production sites (for write permission to Study level records).

3.4 Why can the end user only see their own records in the drop zone?

Check	To resolve
Check that the user is invited to a clinic role with a mapped TMF permission Manage drop zone.	Map the Manage drop zone permission to the applicable clinic role.

3.5 Why can the end user manage the drop zone records but not see applicable artifacts or not choose the wanted TMF level when classifying the record?

Check	To resolve
Check that the user is invited to a clinic role with a mapped TMF role with Write access to the artifact at the expected level.	Invite the user to a clinic role with a mapped TMF role with write permission to the artifact or edit the roles and accesses for the artifact in TMF Admin maintenance mode.
Check that the user is invited to a clinic role on at least Country level (for write permission to Country level records) or Study level, All production sites (for write permission to Study level records, otherwise Write will be translated to Read.	Invite the user to a clinic role on at least Country level (for write permission to Country level records) or Study level, All production sites (for write permission to Study level records).

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