

Viedoc TMF Admin 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:

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

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- [Viedoc TMF Admin User Guide](#)

1 Overview

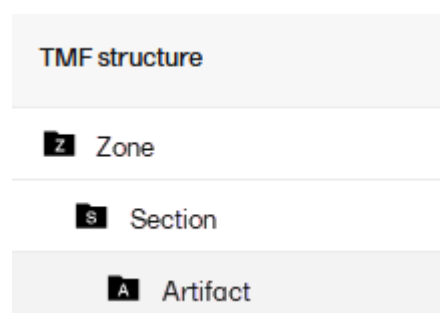
Viedoc [TMF](#) is a digital repository for capturing, managing, sharing, and storing essential documents (records) for your clinical trial.

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.

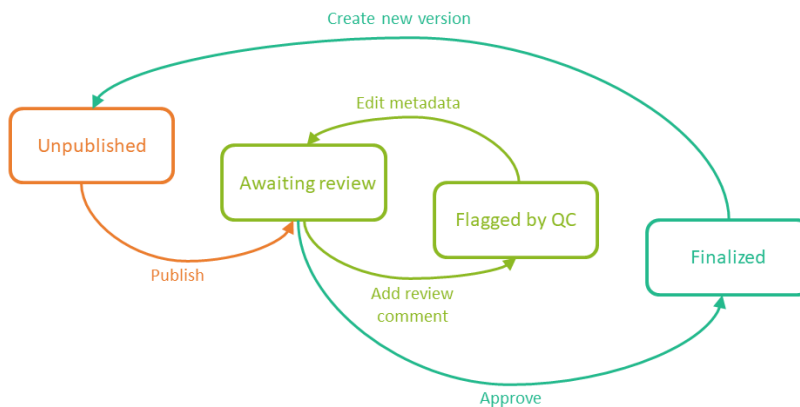
Viedoc TMF also uses Excel files as templates for the TMF structure.

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 The initial status of a record when it is uploaded to Viedoc TMF is **Unpublished**.



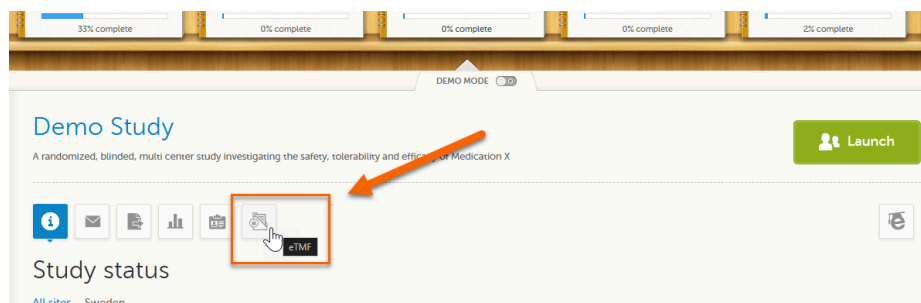
If you edit the metadata for a record version that is **Unpublished** or **Awaiting review**, the record version status is not changed.

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

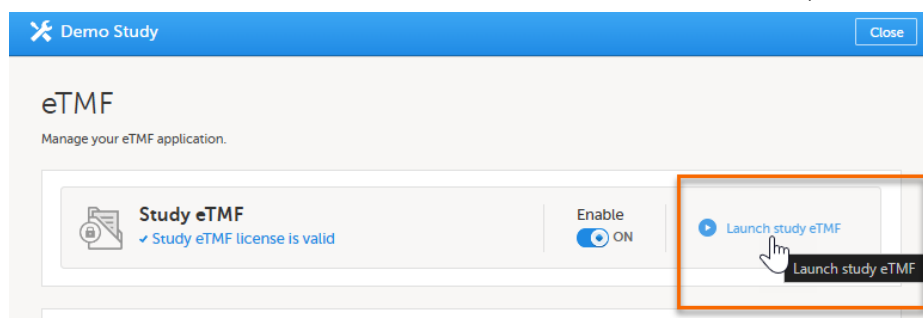
Note! Different actions require different permissions, which means that they are performed by users with different roles.

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**:

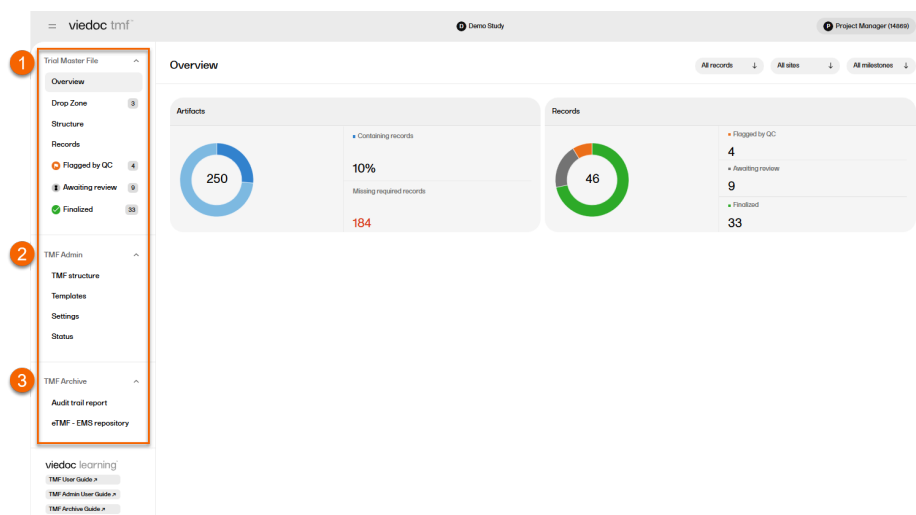


5 Viedoc TMF views

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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- [2. Viedoc system and clinic roles that can access Viedoc TMF](#)
- [3. Viedoc TMF roles and permissions](#)
 - [3.1 TMF Levels and permissions](#)
 - [3.2 The eTMF Manager role](#)
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- [4. Assigning Roles and Permissions in Viedoc Admin](#)
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 - [4.6 Modifying and revoking roles](#)
 - [4.7 Best practices for assigning permissions](#)
- [5. TMF roles, permissions and tasks](#)

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-

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 Allows user to inspect the structure, templates, and other settings in the TMF Admin view in read-only mode.

A user with this permission can access the TMF Admin view and is able to:

- View a selected/instantiated structure
- Export templates and structure
- View the settings tab

Read-only Trial Master File 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.

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.

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**.

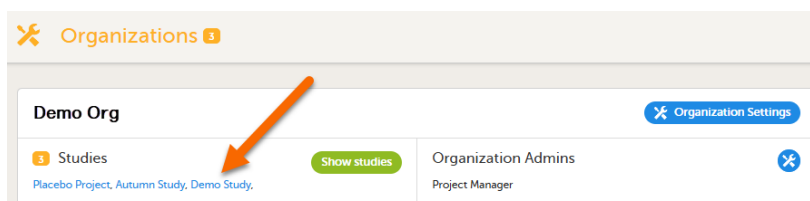
Only the **eTMF Manager** has permission to assign and manage TMF user roles for a specific study.

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.

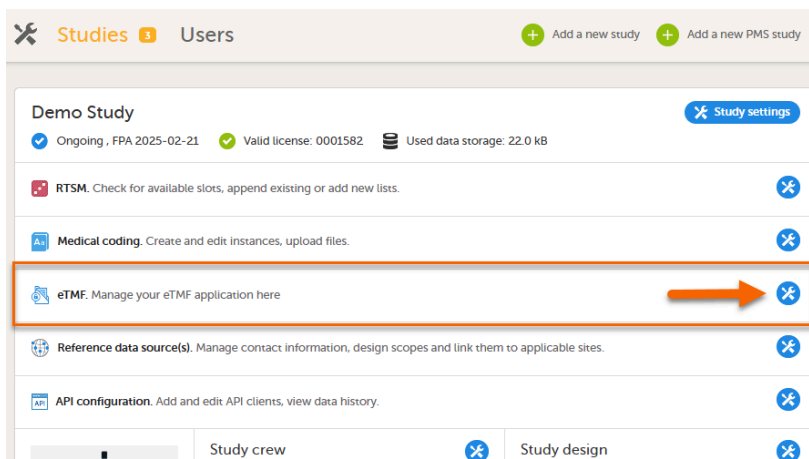
4.1 Mapping clinic roles to TMF roles and permissions

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

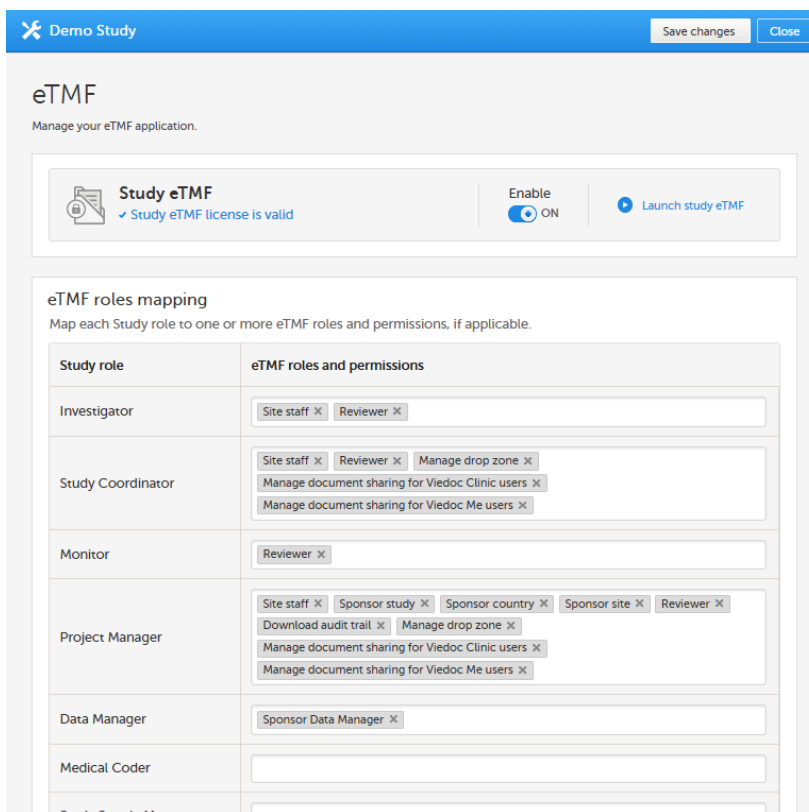
- 1 Go to Viedoc Admin, and select a study to open the study overview page:



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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Quick guide for setting up Viedoc TMF

Quick guide for setting up Viedoc TMF

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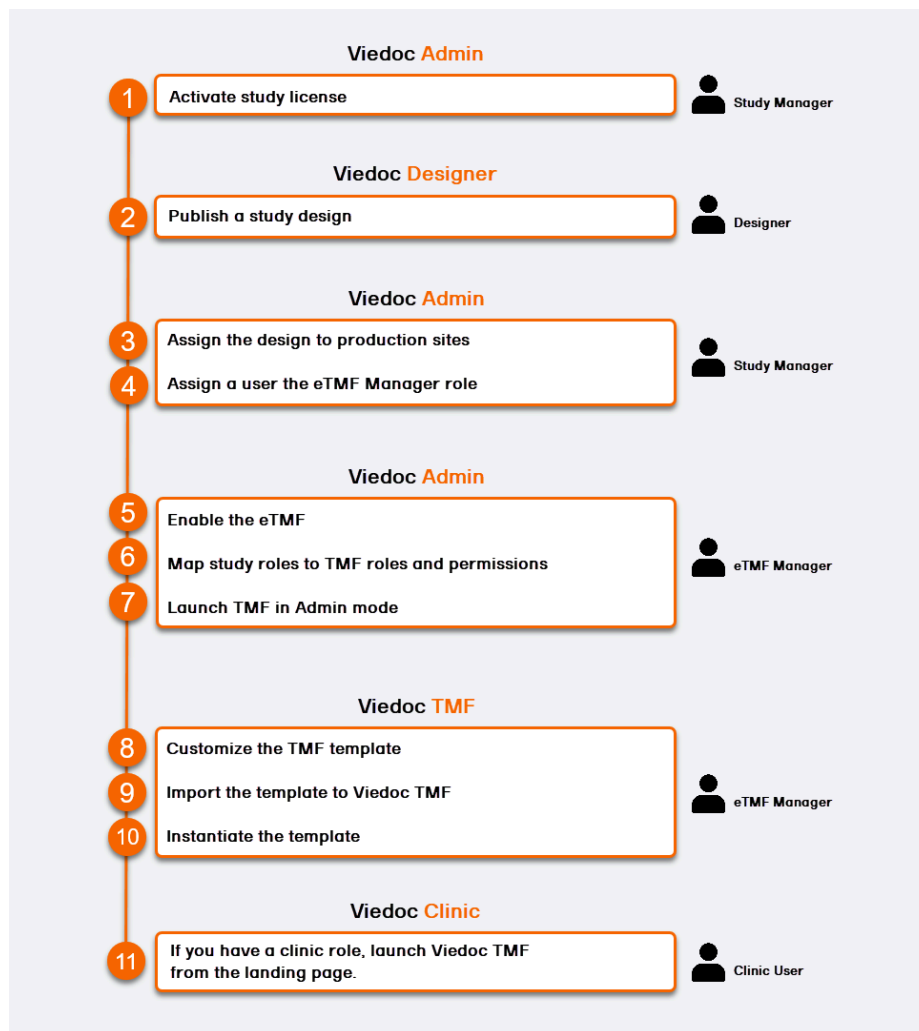
- [Viedoc eTMF User Guide](#) (old interface)
- [Viedoc User Guide for eTMF Managers](#) (old interface)

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](#)
-

Overview

To set up Viedoc TMF, please follow the quick guide below. For detailed instructions, see the sections below and referenced links.



1 Activate your study license

This step is performed by the **Study Manager** in **Viedoc Admin**.

To set up Viedoc TMF, you must have an activated valid study license, with eTMF listed as an included feature.

1. **If your study license has not been activated**, the Study Manager will need to perform this step in order to set up Viedoc TMF. To do this, fill in your license number in the **Reference ID** field in [Study Settings](#) in Viedoc Admin, then select **Save Changes**.
2. **Once your study license is activated**, open Study Settings again, and confirm the license is valid and the eTMF icon displays under features.

2 Publish a study design

This step is performed by the **Designer** in **Viedoc Designer**.

Note! To publish the CRF design, you only need to have the roles configured and enabled, and a form added to the start event in your workflow (the form can be without any items at this stage). The actual CRF design can be added in subsequent versions.

See [Publishing a study design](#).

3 Assign the design to production sites

This step is performed by the **Study Manager** in **Viedoc Admin**.

Note! At least one production site must be added to the study before assigning a design. See [Adding a study site](#) for instructions.

See [Assigning a study design](#).

4 Assign an eTMF Manager

This step is performed by the **Study Manager** in **Viedoc Admin**.

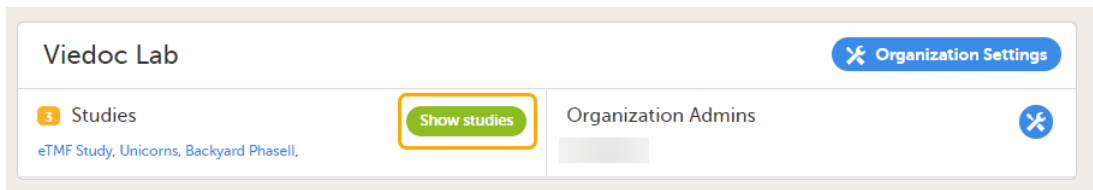
Assign the eTMF Manager *system role* to a user.

See [Assigning users to system roles and/or clinic roles](#).

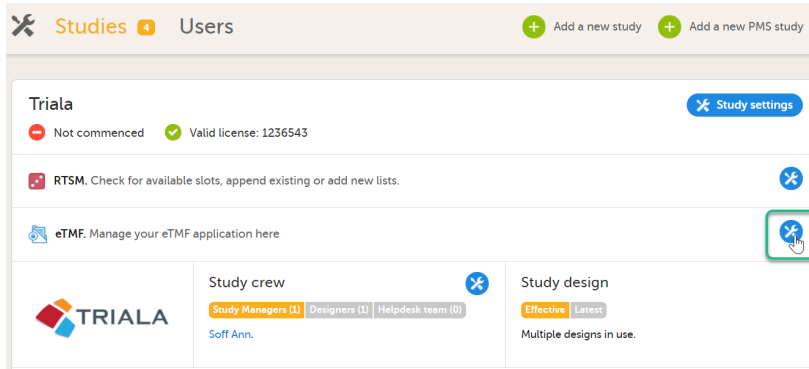
5 Enable the TMF

This step is performed by the **eTMF Manager** in **Viedoc Admin**.

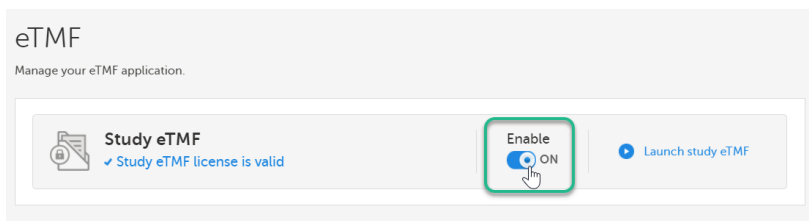
- 1 In Viedoc Admin, select **Show studies**, then open the study details page:



- 2 In the study details page, select the tools symbol in the **eTMF** area:



- 3 Toggle the **Enable** switch to **ON** in the TMF settings window:



6 Map study roles to TMF roles and permissions

This step is performed by the **eTMF Manager** in **Viedoc Admin**.

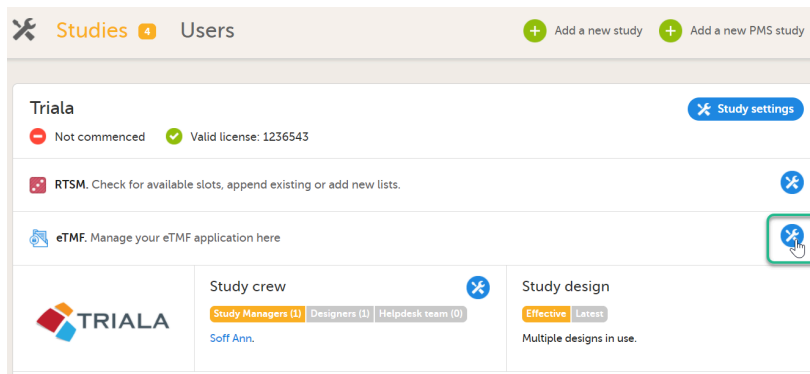
- 1 In the **eTMF roles mapping** area, select the TMF roles and permissions that you want to map to the Viedoc study roles:
- 2 Select **Save changes**.

Note! To launch Viedoc TMF from the study landing page in the future, the user will need to be assigned a Clinic role that is mapped to a TMF role.

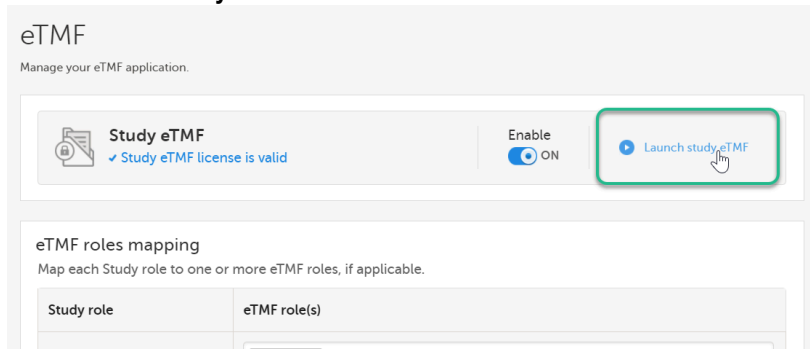
7 Launch TMF in Admin mode

This step is performed by the **eTMF Manager** in **Viedoc Admin**.

- 1 On the study details page, select the tools symbol in the **TMF** area:



- 2 Select **Launch study eTMF**:



8 Customize and import the TMF template

All the steps in this section are performed by the **eTMF Manager** in **Viedoc TMF**.

8.1 Download the baseline template

The first time you set up your Viedoc TMF, you begin with a baseline template provided by Viedoc. It is recommended that the TMF template is customized to your specific documentation needs.

See [Viedoc-provided templates](#) to download the template.

8.2 Customize the template

The template can be customized for your study or organization's specific needs. For example, you can edit, add, or delete zones, sections, and artifacts. See [Customizing a template](#) for more information.

8.3 Exporting and customizing an existing template

If there is a template that was previously imported, it can be exported in order to customize it, then imported again.

See [Exporting a template](#) for more information.

9 Import the template

This step is performed by the **eTMF Manager** in **Viedoc TMF**.

Once customized, import the template to TMF. See [Importing a template](#) for more information.

10 Instantiate the structure

This step is performed by the **eTMF Manager** in Viedoc TMF.

See [Instantiating a structure](#) for more information.

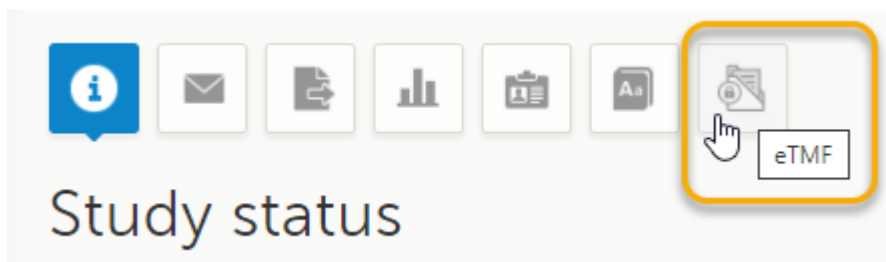
The template is now applied to the trial and the TMF structure is available for end users to work with.

Note! Once a structure is instantiated, it can not be uninstantiated.

11 Launch TMF in production mode

This step is performed by a **Clinic user** with a mapped TMF role in **Viedoc Clinic**.

Select a study from the landing page. Select the **eTMF** icon:



The TMF application opens.

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Quick guide for preparing for regulatory inspections

Quick guide for preparing for regulatory inspections

Published by Viedoc System 2023-04-25

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- [2. Configure Logistics permissions if used](#)
- [3. Invite a Regulatory Inspector](#)
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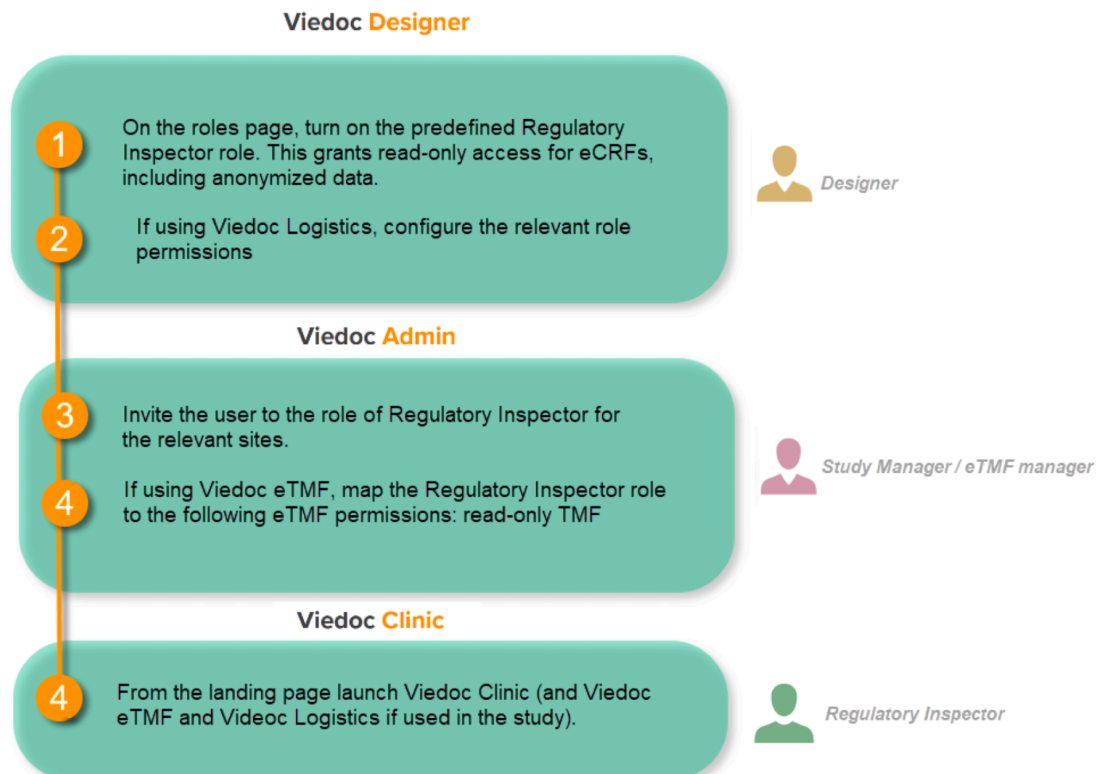
Thorough preparation for inspection of the EDC system used in a clinical trial is of great importance. The regulatory authorities see the EDC system used for a clinical trial as an important computerized system with regards to both patient safety and data integrity.

To assist in this process, Viedoc has developed the Viedoc Inspection Readiness Packet ([VIRP](#)) which provides you with the information you need to prepare for a regulatory inspection and to fulfil regulatory expectations and requirements. The VIRP introduction describes the contents of VIRP in more detail, and also talks about additional documentation you should provide. The VIRP introduction is included in VIRP.

If you decide to use VIRP we provide an eLearning lesson which describes the information needed step-by-step in order to fulfil inspector expectations: [Inspection Readiness When Working in Viedoc](#)

You can read about how to download the Viedoc Inspection Readiness Packet here: [VIRP](#)

You will need to give full read-only access and invite the inspector to the Regulatory Inspector role in the Viedoc system as described below.



1 Configure the role

This step is performed by the **Designer**.

To allow the Regulatory Inspector viewing access to study data, their role must be configured with read-only and view anonymized and blinded data permissions on the **Roles** page.

Note!

- The role of Regulatory Inspector must be turned on in Designer.
- By default, a set of predefined roles is set up by the system, and can be modified for your study. Permissions for the role of Regulatory Inspector should be set to **READ-ONLY** access to all parts of the system, including the eTMF (if it is used) and the eLearning.

2 Configure Logistics permissions if used

If the study uses Viedoc Logistics, the following role permissions in Logistics Rights for the Regulatory Inspector role must be configured on the **Roles** page:

- View IP (**Investigational Product**) on study level,
- View IP on site level
- View subject ID when allocated
- View blinded info (e.g. Active/Placebo).

See [Configuring roles](#).

Note! Should the inspector also require access to Viedoc Admin or Viedoc Designer, you are always welcome to contact your Viedoc representative if you need assistance.

3 Invite a Regulatory Inspector


This step is performed by the **Study Manager**.

Note! For randomized studies, the inspector should also be invited to the study with the role of Unblinded Statistician, in order to have access to the randomization lists and be able to download them in Viedoc Admin.


See [Managing users](#).

4 Map eTMF permissions if used


If the study is using the eTMF, map the Regulatory Inspector study role to an eTMF role with the permissions read-only, **TMF Admin**, read-only, **Trial Master File** and **Download audit trail**.




Manage your eTMF application.



Study eTMF
 ✓ Study eTMF license is valid

Enable
 ON

 Launch study eTMF

eTMF roles mapping

Map each Study role to one or more eTMF roles and permissions, if applicable.

Study role	eTMF roles and permissions
Investigator	<div> <div>Site staff ✕</div> <div>Sponsor study ✕</div> <div>Sponsor country ✕</div> <div>Sponsor site ✕</div> <div>Reviewer ✕</div> <div>Archive sponsor TMF ✕</div> <div>Archive investigator TMF ✕</div> <div>Download audit trail ✕</div> <div>Manage drop zone ✕</div> </div>
Monitor	
Project Manager	
Regulatory Inspector	<div> <div>Read-only TMF Admin ✕</div> <div>Read-only Trial Master File ✕</div> <div>Download audit trail ✕</div> </div>
Site Reviewer	

This step is performed by the **Study Manager/eTMF Manager**.

5 Launch Viedoc

Launch Viedoc Clinic and Viedoc eTMF and Viedoc Logistics (if used in the study) from the [landing page](#).

This step is performed by the **Regulatory Inspector**.



TMF settings

TMF Settings

Published by Viedoc System 2025-09-24

- [1. TMF Settings](#)
 - [2. Filters](#)
 - [3. Review Process](#)
 - [4. Drop Zone](#)
 - [5. Record name templates](#)
 - [6. Record properties](#)
 - [7. 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:

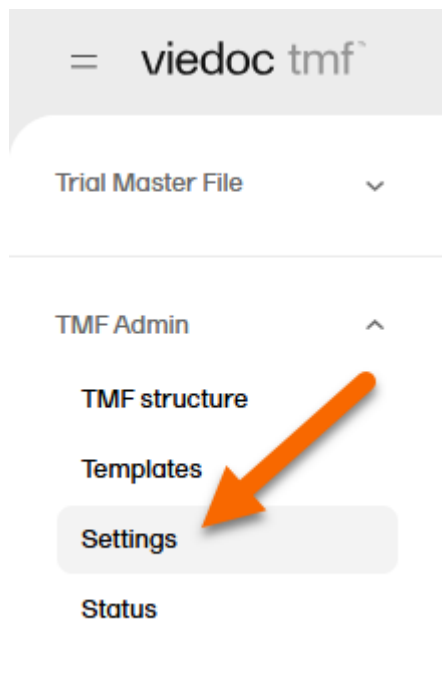
- [Viedoc TMF User Guide](#)
 - [Viedoc TMF Admin User Guide](#)
-

1 TMF Settings

Users with the TMF Admin permissions can configure settings for the TMF including specific system behaviors in different scenarios.

Note! To configure the patterns for time, date, and date & time, use the general study setting in Viedoc Admin. For more information, see [General Study Settings](#).

In the left navigation menu, select to expand **TMF Admin**, and select the **Settings** page:



The next sections describe each option on the settings page in detail.

2 Filters

Filters

☒ Enable milestones filter

- **Enable milestones filter** - enabled by default. Switching this on will make the milestones filter available for users in the Trial Master File view. For more information about milestones see [Managing Milestones](#) in the Editing a Structure lesson.

3 Review Process

Review process

☐ Automatically lock records on approve

☒ Give reason for unlocking records

- **Automatically lock records on approve** - disabled by default. Switching this on will lock records automatically when the reviewer approves them.
- **Give reason for unlocking records** - disabled by default. Switching this on will prompt the reviewer to enter a mandatory reason when unlocking a locked record.

4 Drop Zone

Drop Zone

☒ Enable shared drop zone

☐ Enable private drop zone

- **Enable shared drop zone** - enabled by default. Switching this on makes the shared drop zone available for users to drop files in. Files that are uploaded to the shared drop zone to be accessible and managed by the user who uploaded them as well as the users who have the **Manage drop zone** permission.
- **Enable private drop zone** - disabled by default. Switching this on makes the private drop zone available for users to drop files in. Files that are uploaded to the private drop zone are only accessible and can only be managed by the user who uploaded them.

For more information about using drop zones, see [TMF Drop Zone](#).

5 Record name templates

In this setting, you can define templates for record names, which are used to display customized file names in three scenarios:

- **Display template:** the name for records displayed in the TMF structure.
- **Download template:** the file name used when downloading the latest version of a record.
- **Archive template:** the file name for records downloaded in the TMF-EMS repository. The name of records in the archive will always be followed by a hyphen and the latest version of the record, that is {DocumentVersion}. For example: "Quality Report-01.xlsx", "Quality Report-02.xlsx", etc.

Note! For more information on the implications of record name templates on the TMF archive and the eTMF-EMS repository, please see the naming conventions section in [TMF archive](#).

The templates can include any set of static characters and record name variables. If a name variable value is not available for a record, it will appear as an empty value by the system. If no template is defined, the system will use the name that was originally configured for the record.

Viedoc TMF supports the following set of record name variables:

Variable	Description
{StudyName}	Study name
{CountryCode}	If the record is linked to many countries, the value will be "Multiple countries"
{CountryName}	If the record is linked to many countries, the value will be "Multiple countries"
{SiteCode}	If the record is linked to many countries, the value will be "Multiple sites"
{SiteName}	If the record is linked to many countries, the value will be "Multiple sites"
{VersionLabel}	User-defined version
{DocumentVersion}	The latest version of the record
{FileVersion}	The number of files uploaded to a record
{DocumentStatus}	Unpublished/Awaiting review/Flagged by QC/Finalized
{ZoneNumber}	Zone #
{ZoneName}	Zone name
{SectionNumber}	Section #
{SectionName}	Section name
{ArtifactNumber}	Artifact #
{ArtifactName}	Artifact name
{SubArtifactName}	Sub-artifact/Other name depending on the record type
{TMFLevel}	TMF level
{DatingConventionLabel}	Dating convention label
{DatingConventionValue}	Dating convention value in the format YYYYMMDD
{DocumentName}	<p>The defined record name by the user in the Record properties.</p> <p>Note! This is the latest record name, not the uploaded file name. Even if previous versions of the same record had different file names, the record name of each previous version will appear with the latest record name</p>
{DocumentId}	The record counter ID

viedoc tmf Demo Study Project Manager (14869)

Oops! There was an error saving this page, please check the fields below and try again.

Trial Master File

TMF Admin

TMF structure

Templates

Settings

Status

TMF Archive

viedoc learning

TMF User Guide ↗

TMF Admin User Guide ↗

TMF Archive Guide ↗

Drop Zone

☒ Enable shared drop zone

☒ Enable private drop zone

Record name templates

Display template: {DocumentName}_{CountryCode}-{SiteCode}_{DatingConv}

Download template: {StudyName}_{DocumentName}_{CountryCode}-{SiteCode}_{DatingConv}

Archive template: {StudyName}_{CountryCode}-{SiteCode}_{DatingConv}

Archive template includes the following unknown record name variables: {StudyName}.

6 Record properties

Record properties

☒ Populate TMF level value automatically

- Selecting this option automatically fills in the field **TMF level** in the **Record properties** window in the Trial Master File view (when there is only one TMF level option available for the user for the selected record). This means that users will not need to explicitly select a TMF level for records that they upload or move.

This option is **deselected by default** for studies that started before the release of Viedoc 4.70. For studies starting after the release of Viedoc 4.70, the option is **selected by default**.

7 Structure

Structure

☒ Show zone, section, and artifact numbers (TMF Admin and Structure page)

- When this option is selected, the **Structure** page in the Trial Master File view and the **TMF structure** tab in the TMF Admin view display the zone, section, and artifact numbers and names in the same way as in the tooltip text that is displayed when hovering over them.

The option is **deselected by default** for studies that started before the release of Viedoc 4.73. For studies starting after the release of Viedoc 4.73, the option is **selected by default**.

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Locking and unlocking the TMF

Locking and unlocking the TMF

Published by Viedoc System 2025-09-17

[1. Introduction](#)

[2. Locking the TMF](#)

[3. Unlocking the TMF](#)

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

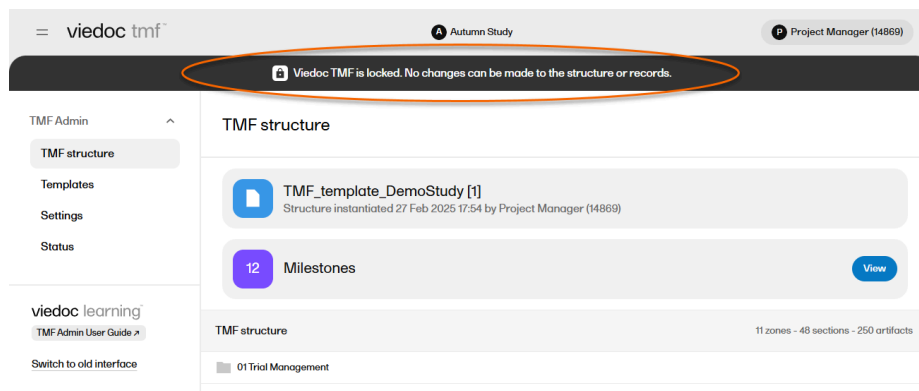
When the TMF is ready to be archived, an eTMF Manager can **lock** the TMF.

The TMF can be considered complete and ready for archiving when all the records are available, reviewed, and finalized, and no more records are to be added to the study.

When the TMF is locked, it is available to users who have access to it in read-only mode. This means that records can still be viewed by users who have access to them according to their roles and permissions. It is still possible to grant users access to the TMF. However, no changes can be made to the records, nor to the TMF structure, templates, or settings.

Users who have access to the TMF Archive can still generate the eTMF-EMS repository and the complete audit trail report.

When the TMF is locked, an information message is visible to indicate that the system is locked and available in read-only mode:



Note! It is possible to unlock a locked TMF and then lock it again.

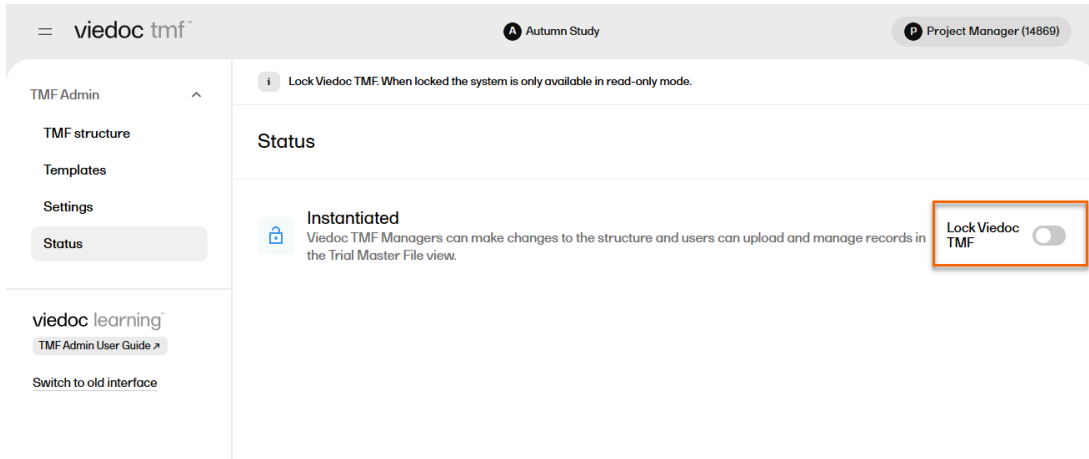
For traceability purposes, all lock and unlock actions are audit trailed and available in the complete audit trail report. You can generate and download the report from the TMF Archive view.

2 Locking the TMF

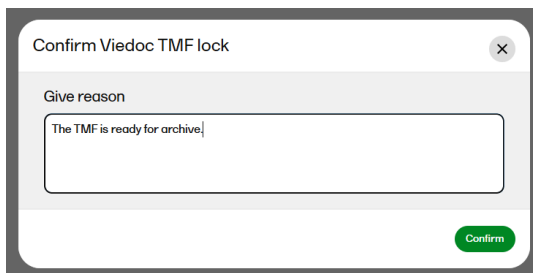
The TMF can only be locked by a **TMF Manager**.

To lock the TMF:

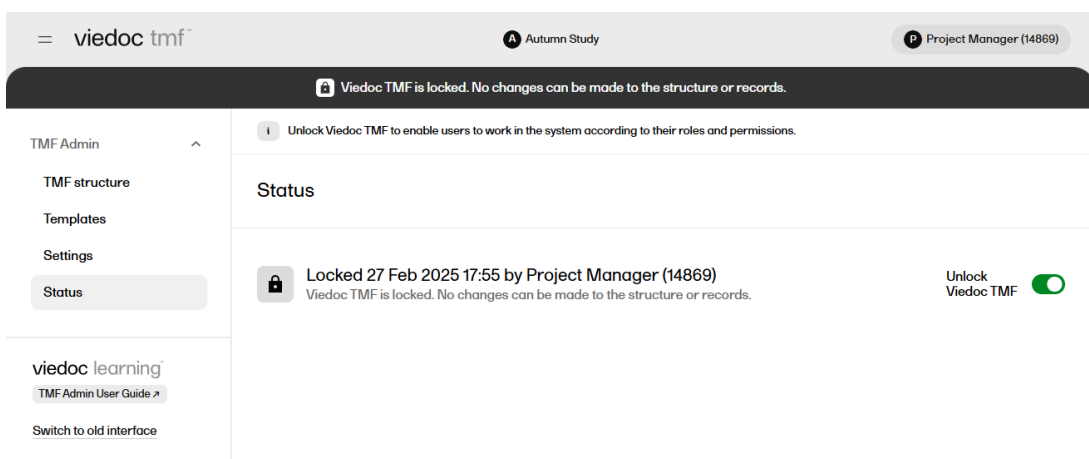
- 1 In the left navigation menu, select to expand **TMF Admin** and select the **Status** page.
- 2 Select **Lock Viedoc TMF**.



- 3 A window opens. Enter a reason for locking the TMF and confirm.



- 4 The status of the TMF changes to **Locked**, and information about when the system was locked and by whom is displayed on the **Status** tab:



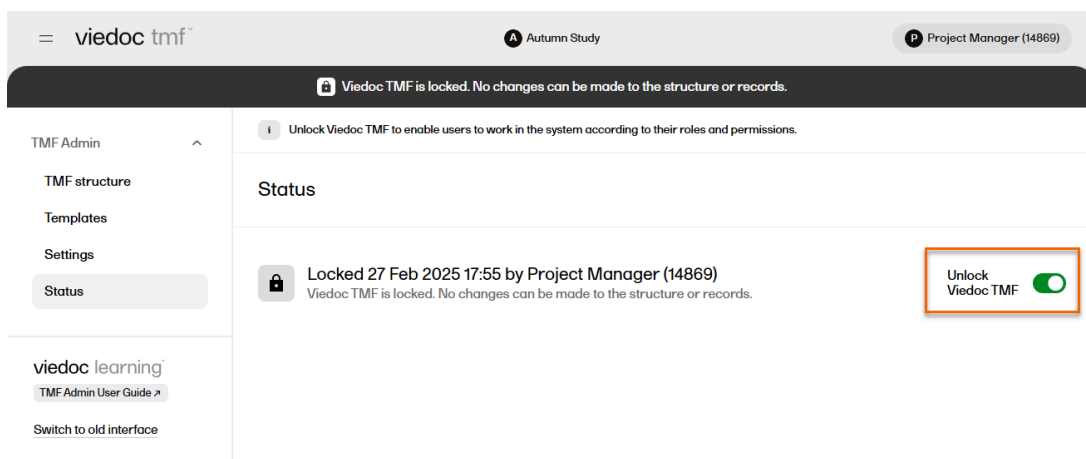
3 Unlocking the TMF

The TMF can only be unlocked by an TMF Manager.

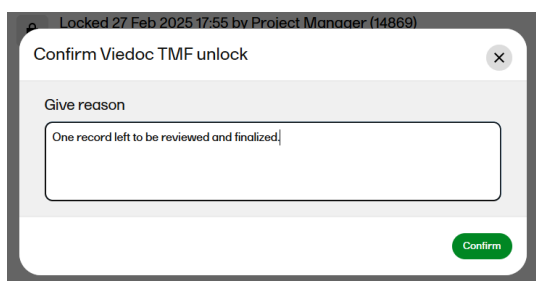
To unlock the TMF:

1 In the left navigation menu, select to expand **TMF Admin**, and select the **Status** page.

2 Select **Unlock Viedoc TMF**.



3 A window opens. Enter a reason for unlocking the TMF and confirm.



4 The status of the TMF changes to the status it had before locking it.

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Enabling record sharing

Enabling record sharing

Published by Viedoc System 2025-03-26

[1. Introduction](#)

[2. Enabling record sharing for an artifact](#)

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

For detailed information, please see [Sharing records with Viedoc Share](#) in the Viedoc TMF User Guide.

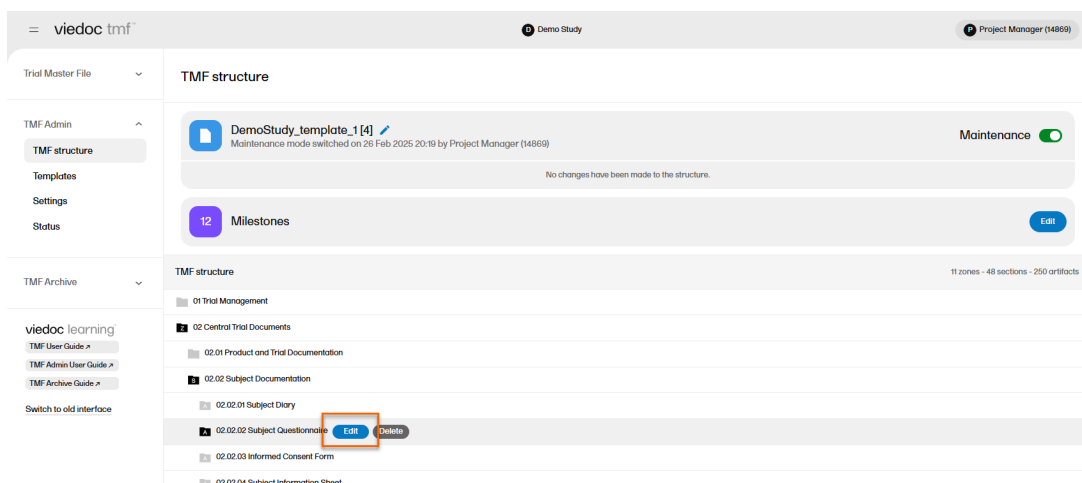
Before a record can be shared, sharing must be enabled at the artifact level in TMF Admin.

2 Enabling record sharing for an artifact

To enable record sharing for an artifact:

- 1 In the left navigation menu, select to expand **TMF Admin**, and select the **TMF Structure** page.
- 2 Switch on **Maintenance mode**.

- 3 Navigate to an artifact and select the **Edit** button that appears when you hover over it:



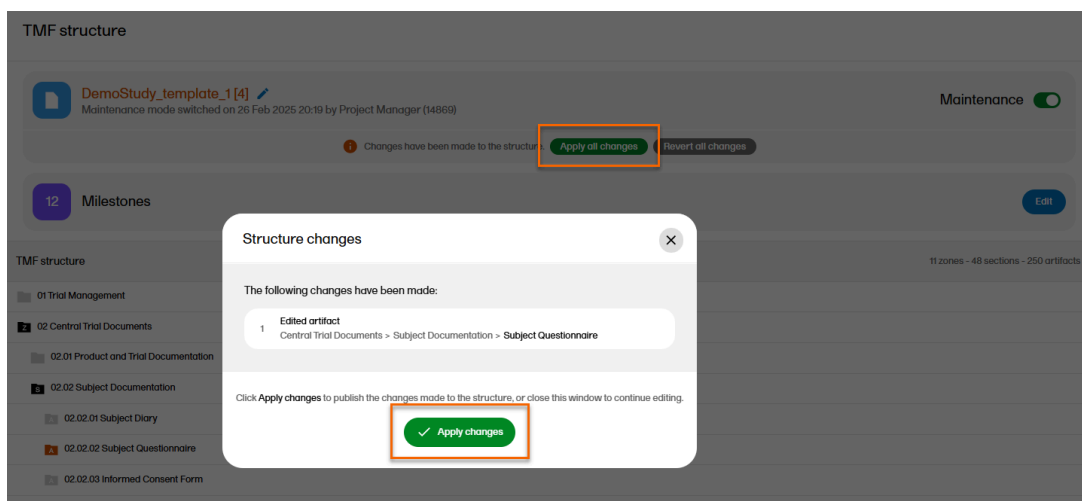
- 3 At the bottom of the **Edit artifact** window in the **Record sharing** section, select the users that records in the artifact can be shared with: Viedoc Clinic users, Viedoc Me users, or both.

Record sharing

Enable for ☐ Viedoc Clinic users ☒ Viedoc Me users

- 4 Select **Save**.

- 5 Select **Apply all changes**, then **Apply changes**.



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Importing and exporting templates

Importing and exporting templates

Published by Viedoc System 2025-04-05

[1. Importing a template](#)

[2. Exporting a template](#)

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:

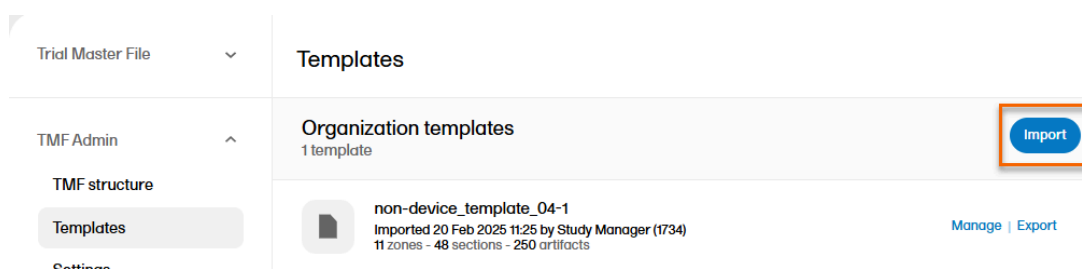
- [Viedoc TMF User Guide](#)
- [Viedoc TMF Admin User Guide](#)

1 Importing a template

To import a TMF template:

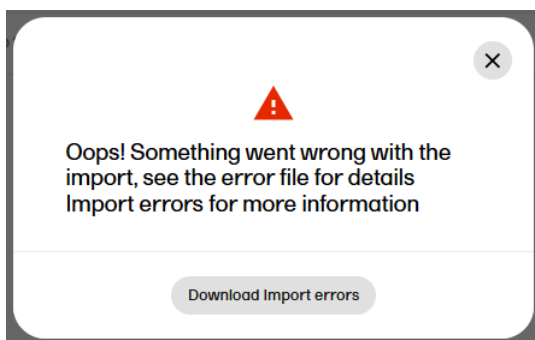
- 1 In the left navigation menu, select to expand **TMF Admin** and select the **Templates** page.

- 2 Select **Import**:



- 3 Browse and select the TMF template you would like to import.

- 4 **Note!** If there are any errors in the imported template, a message will be displayed. To download the file with the error messages for review, select **Download import errors**.

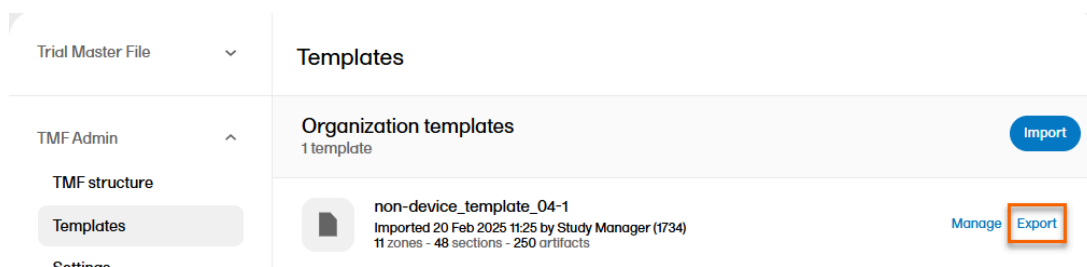


2 Exporting a template

An existing template can be exported in order to make changes to the template Excel file.

To export a TMF template:

- 1 In the left navigation menu, select to expand **TMF Admin** and select the **Templates** page.
- 2 Select **Export** for the template that you want to export:



- 3 The Excel file is then downloaded via your browser.

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Viedoc-provided templates

Viedoc-provided templates

Published by Viedoc System 2025-03-26

[1. Introduction](#)

[1.1 Templates for download](#)

[2. How to use the Viedoc template](#)

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

The Viedoc-provided TMF templates are baseline templates in Excel format that you can download and customize to cover your organization's needs.

The templates are of standard structure based on the TMF Reference Model by CDISC, and are created according to best practices in Viedoc TMF considering artifacts and the roles' permissions to the artifacts.

The templates include artifacts that are meant to be used by the sponsor TMF and Investigator Site File ([ISF](#)). The Site staff role is intended to be assigned to Site personnel so that they can upload records to the ISF. The other roles can be used for different purposes when working on the sponsor TMF.

1.1 Templates for download

The templates currently available for download are for **non-device studies** and **device studies**.

You can download the Viedoc Non-device template [here](#).

You can download the Viedoc Device template [here](#).

2 How to use the Viedoc template

The template can be used off the shelf or with modifications to suit your study needs. Ensure that your approach is properly validated for your study. For further information on how to handle and use the templates, refer to the lessons around templates in the [Viedoc TMF Admin User Guide](#).



Selecting a template

Selecting a template

Published by Viedoc System 2025-03-26

1. [Selecting a template](#)

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 TMF Admin User Guide](#)

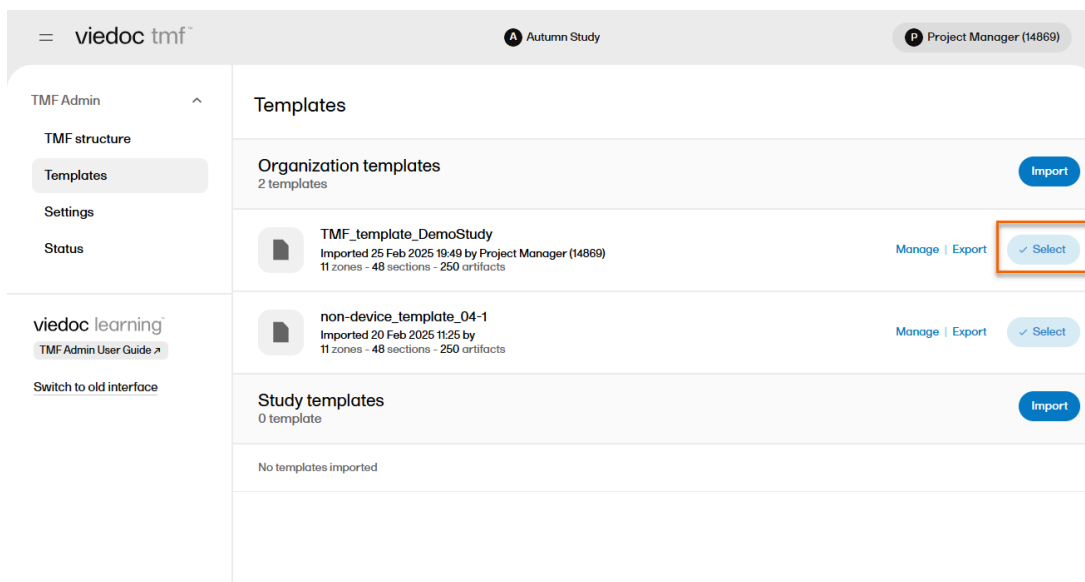
1 Selecting a template

When a TMF template is selected, it is made available on the **TMF structure** tab. There, you can browse through the structure and view the properties of the zones, sections, and artifacts to make sure that the structure corresponds to your needs before you [instantiate](#) it.

Note! Once a template has been instantiated, it is not possible to select a new template. However, you can export a template, edit it, and import a new template to use for other studies within the same organization in Viedoc.

To select a template:

- 1 In the left navigation menu, select to expand **TMF Admin**, and select the **Templates** page.
- 2 Identify which template you need, and select the **Select** button:



- 3** You can now view and browse through the corresponding structure on the **TMF structure** page in **TMF Admin**.

If you need to make changes to the structure, export the template, modify the Excel template file, and import it into Viedoc TMF.

- 4** When you have made sure that the structure corresponds to your needs, you can choose to [instantiate](#) it.

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Customizing a template

Customizing a template

Published by Viedoc System 2025-04-24

1. Introduction

[1.1 Requirements for customizing templates](#)

[1.2 Navigating to templates](#)

[2. The V 3.2.1 sheet](#)

[3. The Viedoc extensions sheet](#)

[4. The Viedoc milestones sheet](#)

[5. Role sheets](#)

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

The TMF template is an Excel file which defines which zones, sections, and artifacts that your TMF will have, as well as the permissions associated with the TMF user roles. The eTMF Manager has permission to **import**, **select**, **instantiate**, **export**, **rename**, and **delete** templates.

In Viedoc TMF, there are two types of templates:

- **Organization template** - available for all studies within your organization
- **Study template** - available only for the specific study

With your Viedoc TMF license, a baseline template is provided (see [Viedoc-provided templates](#)). This template is not intended to be used as it is, but to be adapted to your organization's needs. For example, you can customize, add, or delete zones, sections, and artifacts.

1.1 Requirements for customizing templates

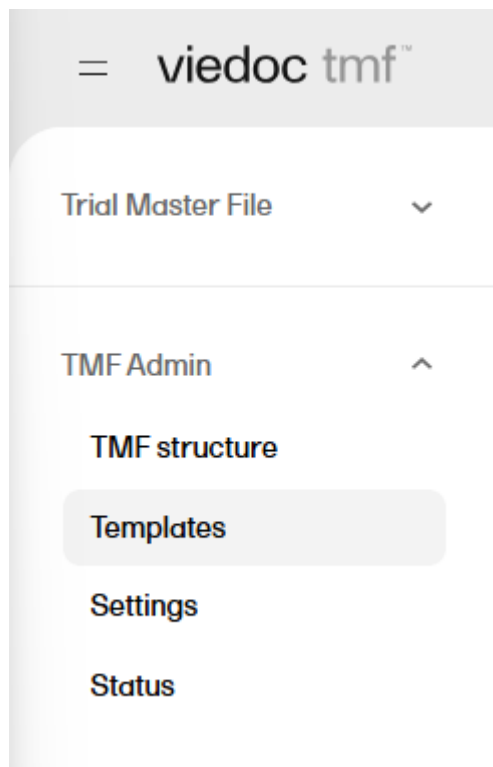
However, the following requirements must be fulfilled for Viedoc TMF to successfully validate the template:

- The template must include nine sheets, in any order.
- The sheet names must not be changed.
- All columns in all sheets are mandatory, which means that they must be present. However, some columns can be left empty. For more information, see the following sub-sections.
- Some columns must include specific values. For more information, see the following sub-sections.
- All sheets must have the same number of rows, that is one row per artifact.

Note! If the following special characters (\ / : * ? < > | " \r \n) are used in the TMF template, they will be replaced by an underscore (_) during archive generation to ensure the archive completes successfully.

1.2 Navigating to templates

To access the templates in Viedoc TMF, in the left navigation menu, select to expand **TMF Admin**, and select the **Templates** page:



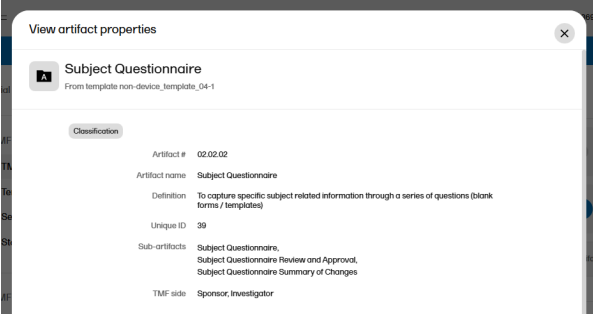
The sections below describe the specific sheets found in the TMF template spreadsheet.

2 The V 3.2.1 sheet

This sheet is based on the TMF Reference Model. Zones, sections, and artifacts can be customized, added, and/or deleted.

These are the requirements for the columns:

Zone #	Must be unique
Zone Name	Must be unique
Section #	Must be unique It consists of two digits that represent the zone number that the section belongs to, followed by a separator and the section number.
Section Name	Must be unique within the zone
Artifact #	Must be unique It consists of two digits that represent the zone number, followed by a period (.), then two digits for the section number, a period (.) and the artifact number. Example: 03.02.01
Artifact name	Must be unique within the section
Alternate names (artifact also commonly known as)	This is an alternative name for the artifact. This column is optional. If it exists, its value can be left empty. Note! This column is not currently mapped to system functionality. It is not currently possible to change it in maintenance mode.

Definition / Purpose	<p>A free-text description of the artifact</p> <p>To view the definition in Viedoc TMF: In the left navigation menu, select to expand TMF Admin, and select the TMF Structure page. Navigate to the artifact, and select View.</p>  <p>This column must have values.</p>
Sub-artifacts	<p>A newline-separated list of sub-artifacts</p> <p>To view the list of sub-artifacts in Viedoc TMF, see above.</p> <p>Sub-artifacts can be used by TMF users to further classify records.</p> <p>This column can be left empty.</p>
Core or Recommended for inclusion ICH Code	<p>These columns are related to GCP.</p> <p>These columns can be left empty.</p> <p>Note! This column is not currently mapped to system functionality. It is not currently possible to change it in maintenance mode.</p>
Unique ID Number	<p>An optional unique ID number for the artifact.</p> <p>This number is validated as follows by Viedoc TMF:</p> <ul style="list-style-type: none"> ▪ If it is available, it must be a valid integer that is unique for the artifact. ▪ If it is not available, that is accepted by the TMF system, and represented as 0 in the exported archive.
Sponsor Document Investigator Document	<p>These columns define what side of the TMF the artifact is: sponsor or investigator (according to GCP).</p> <p>The values can be X (meaning yes) or NO .</p> <p>These columns must have values.</p>
Process Based Metadata - Number Process Based Metadata - Name	<p>These columns define trial processes that artifacts can be linked to. This can be useful for trials where records are filed across multiple zones.</p> <p>Note! These columns are not currently mapped to system functionality. It is not currently possible to change them in maintenance mode.</p>

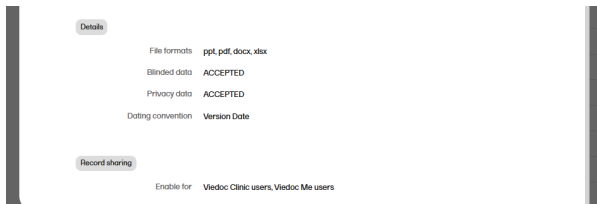
Trial Level Document Trial Level MILESTONE/EVENT Country/ Region Level Document Country Level MILESTONE/EVENT Site Level Document Site Level MILESTONE/EVENT	<p>These columns define which level (Trial/Country/Site) the record should be filed to and which milestones correspond to each.</p> <p>When a Trial/Country/Site level record in the V 3.2.1 sheet in the template is set to:</p> <ul style="list-style-type: none"> ▪ X , then the corresponding Trial/Country/Site level milestone/event should not be empty and must include a valid value from the Viedoc Milestones sheet - Name column. ▪ Empty, then the corresponding Trial/Country/Site level milestone/event should also be empty.
Dating Convention	<p>Defines the dating convention that is used in the metadata of records uploaded to Viedoc TMF</p> <p>This column can be left empty. If it is empty, the default dating convention will be the version date.</p> <p>If you select New in the Dating convention field in the Edit artifact window, you can, for example, enter an expiration date as the dating convention.</p>

3 The Viedoc extensions sheet

This sheet contains Viedoc-specific properties for each artifact.

These are the requirements for the columns:

Artifact #	Unique artifact number as defined on the V 3.2.1 sheet.
Sign	<p>This column is not yet used in Viedoc TMF, but it must have values.</p> <p>The following values are accepted: Required , Optional ,or, Not Permitted .</p>
Applicable in Trial	<p>Defines if the artifact is applicable at trial level.</p> <p>The column must have values.</p> <p>The following values are accepted: Required , Optional ,or, Not Permitted .</p>
Applicable in Country	<p>Defines if the artifact is applicable at country level.</p> <p>The column must have values.</p> <p>The following values are accepted: Required , Optional ,or, Not Permitted .</p>
Applicable at Site	<p>Defines if the artifact is applicable at site level.</p> <p>The column must have values.</p> <p>The following values are accepted: Required , Optional ,or, Not Permitted .</p>

Metadata properties	<p>Additional metadata for the artifact.</p> <p>This column can be left empty.</p> <p>To view the additional metadata in Viedoc TMF: In the left navigation menu, select to expand TMF Admin, and select the TMF Structure page. Navigate to the artifact, and select View.</p> 
File formats	<p>A pipe-separated list of accepted file formats for the artifact. Examples:</p> <ul style="list-style-type: none"> ▪ docx pdf - only docx and pdf files are accepted ▪ * - all file formats are accepted (except for those that are blacklisted for Viedoc)
Accept blinded data	<p>This column is not yet used in Viedoc TMF. It defines if blinded data is accepted for the artifact.</p> <p>The following values are accepted: YES or NO .</p>
Accept privacy data	<p>This column is not yet used in Viedoc TMF. It defines if privacy data is accepted for the artifact.</p> <p>The following values are accepted: YES or NO .</p>

4 The Viedoc milestones sheet

This is an optional sheet. It includes Viedoc-specific properties for each milestone.

If this sheet is not provided, the system will create a list of milestones, under the group **Other**, based on the following specified milestones in the **V 3.2.1 sheet**:

- **Trial Level MILESTONE/EVENT**
- **Country Level MILESTONE/EVENT**
- **Site Level MILESTONE/EVENT**

These are the requirements for the columns:

Id	Unique milestone Id. This column is mandatory.
Name	Unique milestone name. This column is mandatory.
Group	One of the four milestone groups defined in the CDISC Reference Model. This column is mandatory, and the following values are accepted: Start UP, Study Conduct, Close Out, Other
Trial description	Description of trial-level records this milestone includes. This column can be left empty.
Country description	Description of country-level records this milestone includes. This column can be left empty.
Site description	Description of site-level records this milestone includes. This column can be left empty.

5 Role sheets

The role sheets define the permissions associated with each of the TMF roles.

These are the role sheets:

- Role SPONSOR-STUDY
- Role SITESTAFF
- Role SPONSOR-COUNTRY
- Role SPONSOR-SITE
- Role SPONSOR-REVIEW
- Role SPONSOR-DM
- Role SPONSOR-UNBLINDED

These are the requirements for the columns:

Artifact #	Unique artifact number as defined on the V 3.2.1 sheet.
Study	<p>Defines the permission of the role on study/trial level.</p> <p>The following values are accepted:</p> <ul style="list-style-type: none"> ▪ NO ACCESS : the role cannot access or see the records in the corresponding artifact on trial level ▪ READ : the role can see and download the records in the corresponding artifact on trial level ▪ WRITE : the role can see, upload, download, edit, and delete records in the corresponding artifact on trial level. The user needs to be invited on study scope (All production sites) in Viedoc in order to gain WRITE access. Otherwise, the WRITE permission will be translated to READ. ▪ REVIEW : the role can see, download, approve, and give comments on the records published in the corresponding artifact on trial level. The user needs to be invited on study scope (All production sites) in Viedoc in order to gain REVIEW access. Otherwise, the REVIEW permission will be translated to READ. <p>Note! It is possible for users to be invited to 'All sites' for roles and permissions, but we strongly advise against this.</p>
Country	<p>Defines the permission of the role on country level.</p> <p>The following values are accepted:</p> <ul style="list-style-type: none"> ▪ NO ACCESS : the role cannot access or see the records in the corresponding artifact on country level ▪ READ : the role can see and download the records in the corresponding artifact on country level ▪ WRITE : the role can see, upload, download, edit, and delete records in the corresponding artifact on country level. The user needs to be invited on at least country scope in Viedoc in order to gain WRITE access. Otherwise, the WRITE permission will be translated to READ. ▪ REVIEW : the role can see, download, approve, and give comments on the records published in the corresponding artifact on country level. The user needs to be invited on at least country scope in Viedoc in order to gain REVIEW access. Otherwise, the REVIEW permission will be translated to READ.

Site	<p>Defines the permission of the role on site level.</p> <p>The following values are accepted:</p> <ul style="list-style-type: none">▪ NO ACCESS : the role cannot access or see the records in the corresponding artifact on site level▪ READ : the role can see and download the records in the corresponding artifact on site level▪ WRITE : the role can see, upload, download, edit, and delete records in the corresponding artifact on site level▪ REVIEW : the role can see, download, approve, and give comments on the records published in the corresponding artifact on site level
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Editing or deleting templates

Editing or deleting templates

Published by Viedoc System 2025-03-26

[1. Renaming a template](#)

[2. Deleting a template](#)

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)

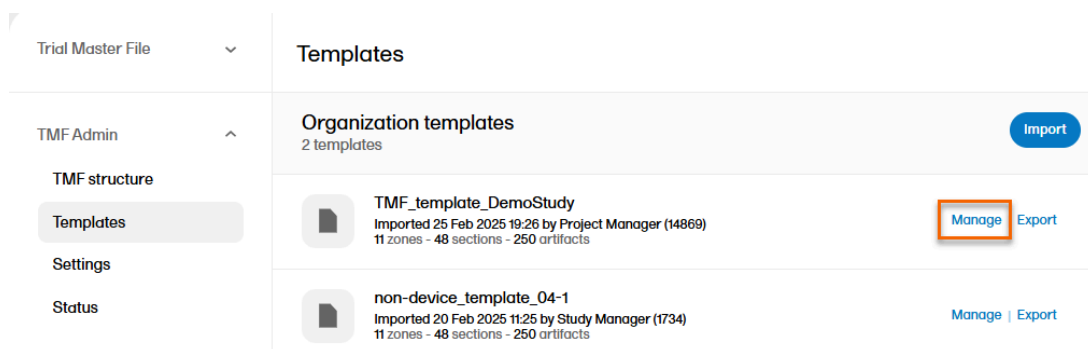
Want to browse more information for the new interface? Please go to the new TMF user guides:

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

1 Renaming a template

To rename a TMF template:

- 1 In the left navigation menu, select to expand **TMF Admin** and select the **Templates** page.
- 2 Select **Manage** for the template that you want to rename:



3 Select **Edit**:

Manage template

Name*

TMF_template_DemoStudy

Category*

Organization template

Delete template

4 Change the template name.

5 Select **Save changes**.

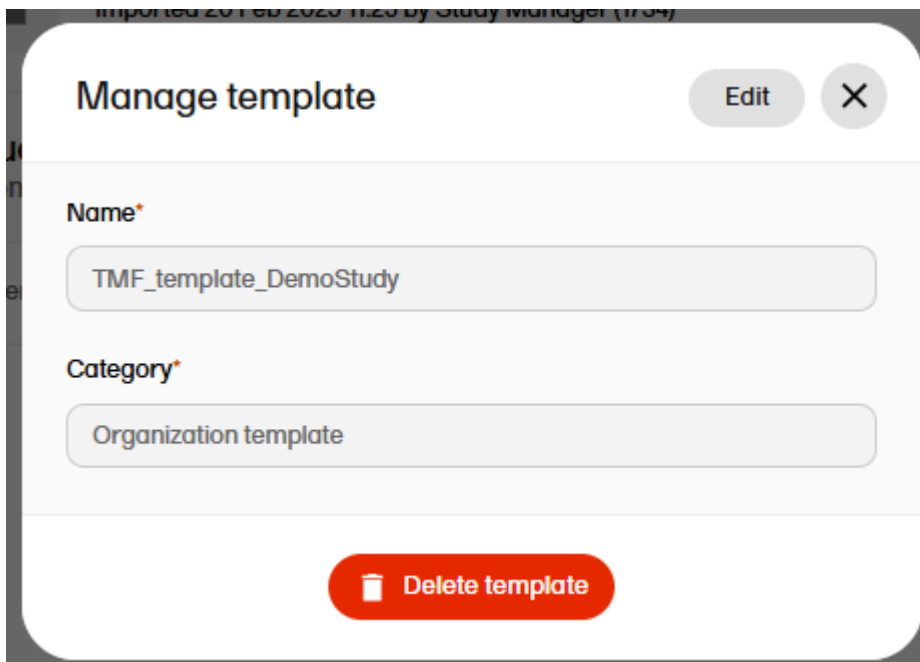
2 Deleting a template

To delete a TMF template:

1 In the left navigation menu, select to expand **TMF Admin** and select the **Templates** page.

2 Select **Manage** for the template that you want to delete:

Trial Master File	Templates
TMF Admin	Organization templates 2 templates
TMF structure	
Templates	<div> <div>TMF_template_DemoStudy</div> <div>Imported 25 Feb 2025 19:26 by Project Manager (14869)</div> <div>11 zones - 48 sections - 250 artifacts</div> <div>Manage Export</div> </div>
Settings	
Status	<div> <div>non-device_template_04-1</div> <div>Imported 20 Feb 2025 11:25 by Study Manager (1734)</div> <div>11 zones - 48 sections - 250 artifacts</div> <div>Manage Export</div> </div>

3 Select **Delete template**:

The screenshot shows a 'Manage template' modal window. At the top, there's a title bar with 'Manage template' and buttons for 'Edit' and a close 'X' icon. Below the title bar, there are two input fields: 'Name*' with the value 'TMF_template_DemoStudy' and 'Category*' with the value 'Organization template'. At the bottom of the modal, there is a prominent red button with a trash icon and the text 'Delete template'.

4 Select **Yes** to confirm.

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Instantiating a structure

Instantiating a structure

Published by Viedoc System 2025-03-26

[1. Introduction](#)

[2. Instantiating a 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:

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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

After a template has been customized and/or imported, and selected, the TMF structure in the template can be instantiated (applied) to the study.

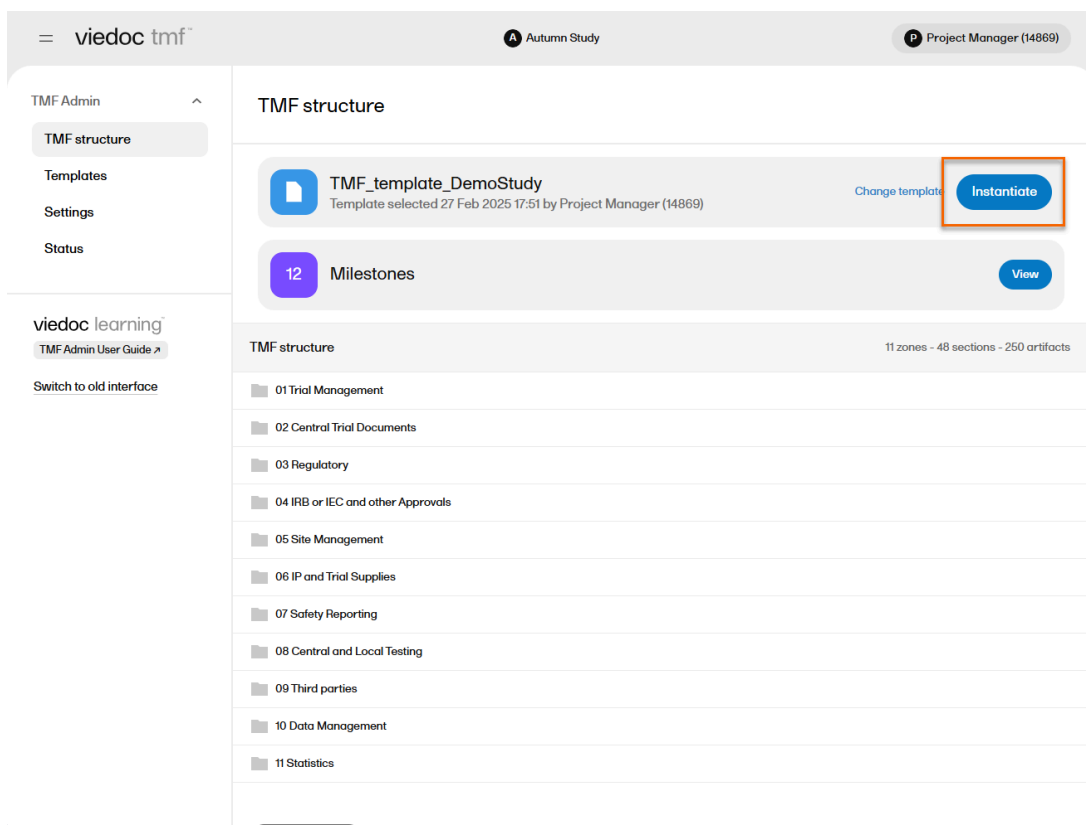
Note! Once a structure has been instantiated for a study, it cannot be un-instantiated. However you can still make changes to an instantiated TMF structure by switching on **Maintenance mode**. For more information, see [Editing a structure](#), [Customizing a template](#), [Importing and exporting templates](#), and [Selecting a template](#).

2 Instantiating a structure

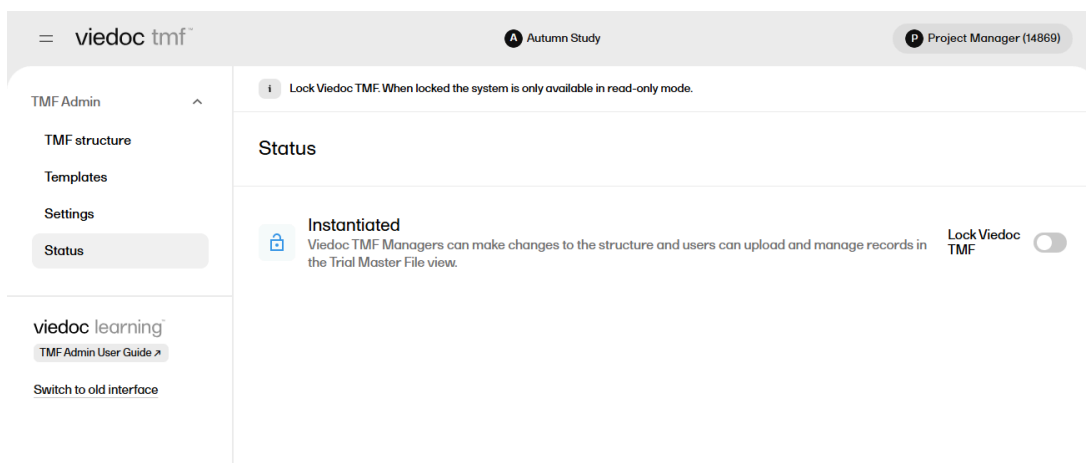
To instantiate a TMF structure:

- 1 In the left navigation menu, select to expand **TMF Admin** and select the **TMF Structure** page.

- 2 Ensure that the correct template is displayed and select **Instantiate**.



- 4 The template is now applied to the study and the structure is available to work with.
- 5 You can confirm that the structure is instantiated by selecting the **Status** page under **TMF Admin**:



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Editing a structure

Editing a structure

Published by Viedoc System 2025-06-10

[1. Introduction](#)

[2. Activating maintenance mode](#)

[3. Editing the structure](#)

[3.1 Editing the structure name](#)

[3.2 Editing the version of the TMF reference model](#)

[4. Editing zones, sections and artifacts](#)

[4.3 Editing zones and sections](#)

[4.4 Editing artifacts](#)

[4.5 Impact of changes to zones, sections and artifacts](#)

[4.6 Adding artifacts](#)

[4.7 Deleting zones, sections or artifacts](#)

[5. Managing milestones](#)

[5.8 Changing the sequence of milestones](#)

[5.9 Editing milestones](#)

[5.10 Adding milestones](#)

[5.11 Deleting milestones](#)

[6. Applying or reverting changes to 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

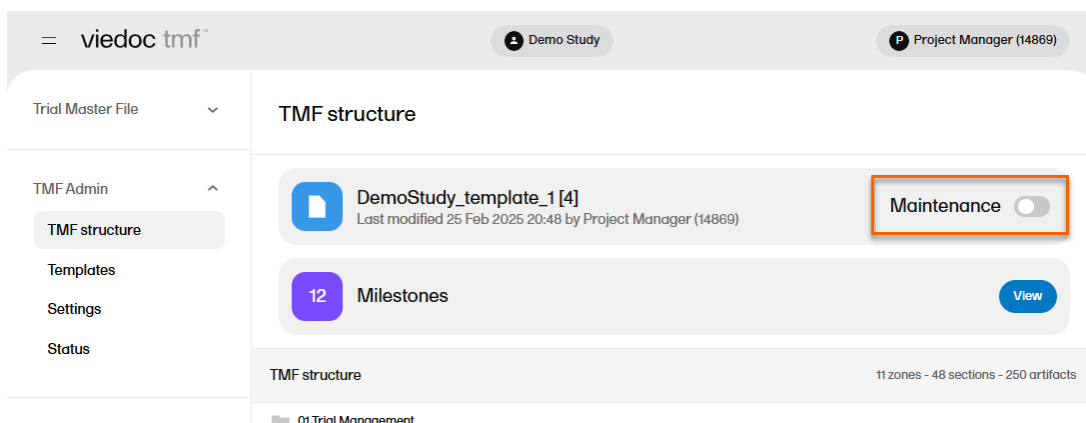
Edits can be made to an instantiated TMF structure by activating **maintenance mode** in TMF Admin (see section below). Edits can be made to the structure name, TMF reference model version number, zone and section names, artifact details and access, and milestones used in the TMF.

2 Activating maintenance mode

To activate maintenance mode:

- 1 In the left navigation menu, select to expand **TMF Admin** and select the **TMF Structure** page.

2 Select the **Maintenance** switch:



When maintenance mode is activated, all non-applied changes to the active structure are shown.

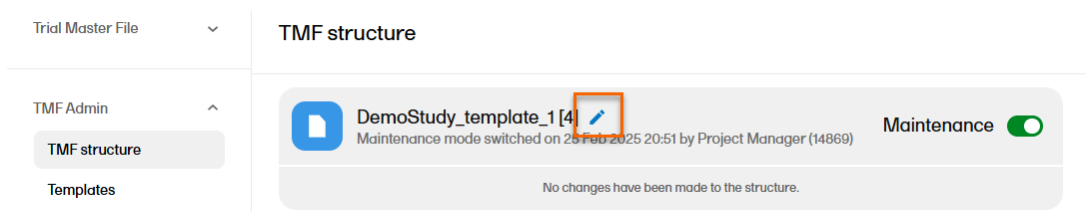
3 Editing the structure

The edits that you can make on the structure level are as described in the following sub-sections.

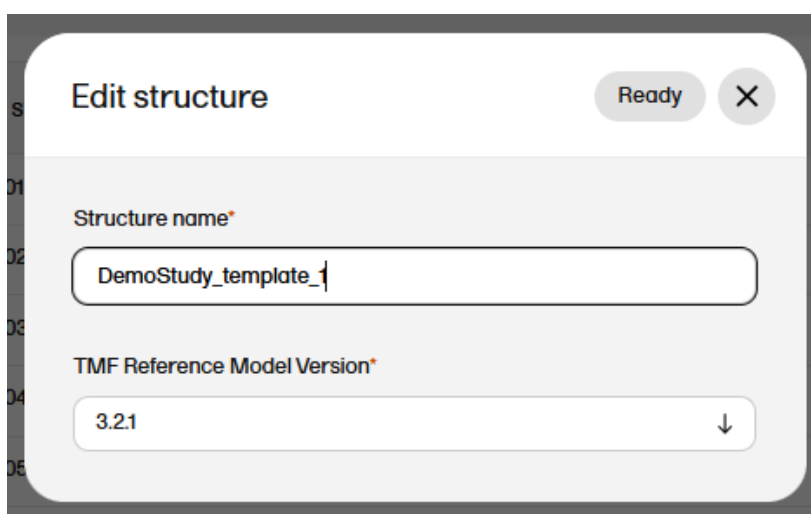
3.1 Editing the structure name

To edit the structure name:

1 In maintenance mode, select **Edit** on the structure level.



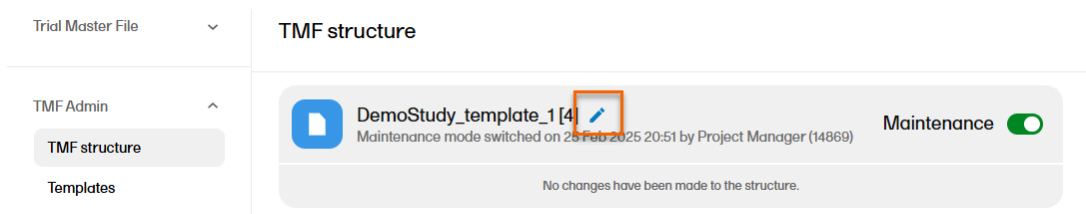
2 In the window that is displayed, edit the structure name and select **Ready**.



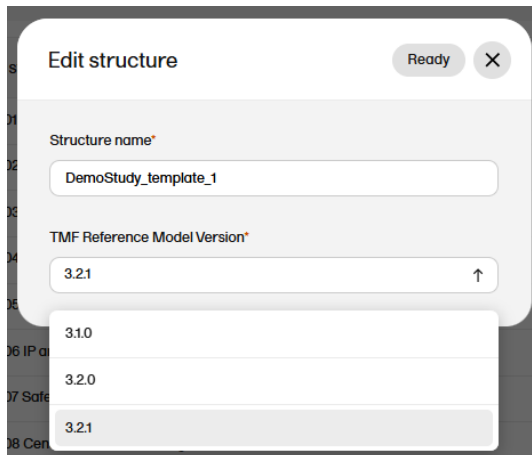
3.2 Editing the version of the TMF reference model

To edit the version of the TMF reference model:

- 1 In maintenance mode, select **Edit** on the structure level.



- 2 In the window that is displayed, select the applicable version of the TMF reference model from the dropdown menu and select **Ready**.



4 Editing zones, sections and artifacts

Changes that can be made to zones, sections and artifacts are described in this section.

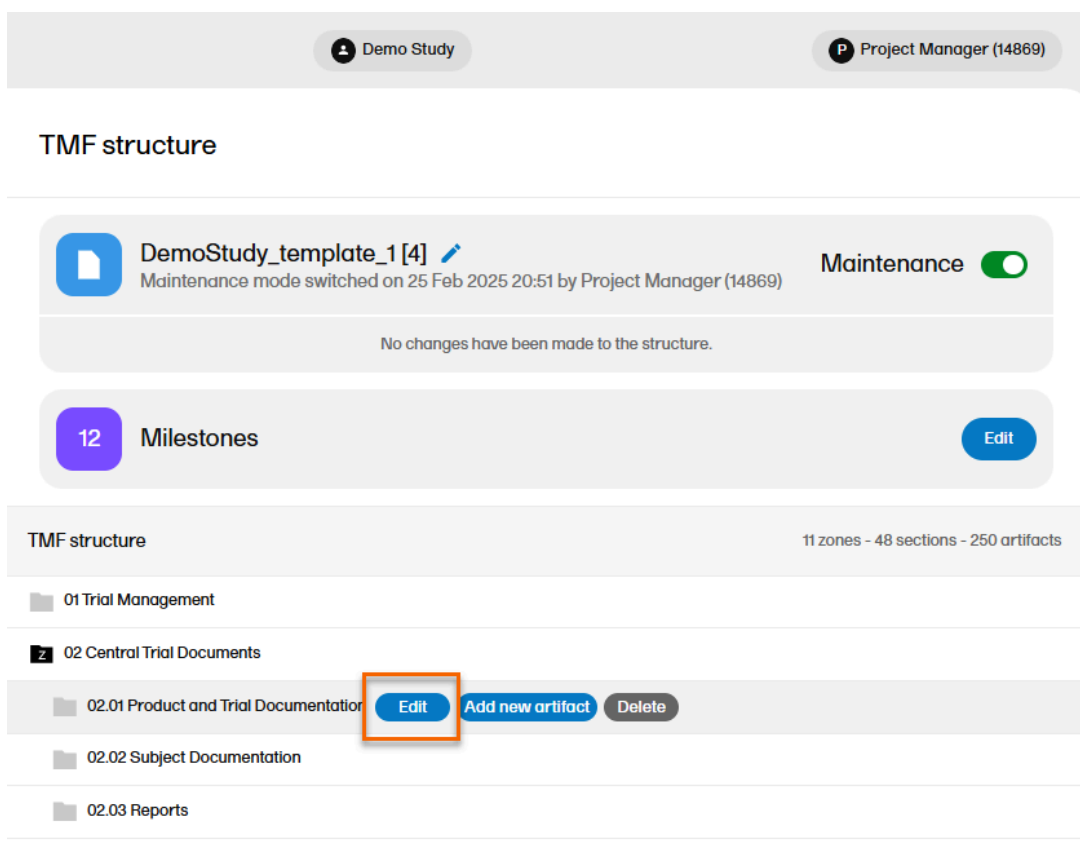
Important! Making changes to any fields (in zones, sections, or artifacts) that are *part of the metadata of a record* may cause some changes to the record statuses. For examples of the impact of these changes, please see the [Impact of changes to zones, sections and artifacts](#) section below.

4.1 Editing zones and sections

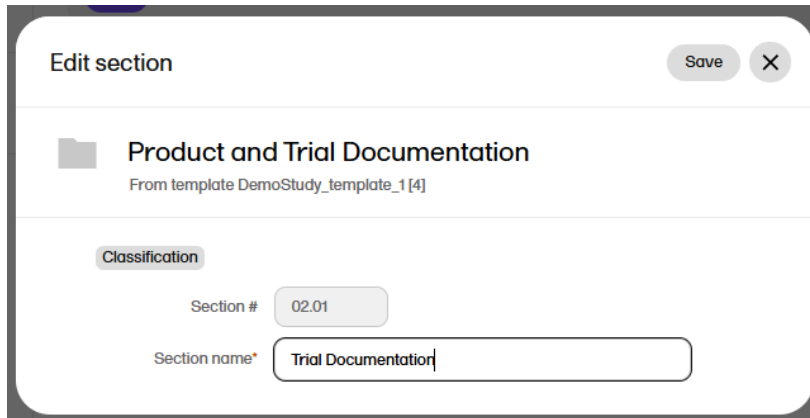
Only the name can be edited for zones and sections in Maintenance mode.

To edit a zone or section:

- 1 When maintenance mode is activated, select the **Edit** button that appears when you hover over a zone or section in the TMF structure.



- 2 In the **Edit section** or **Edit zone** window, make your changes to the zone or section name.

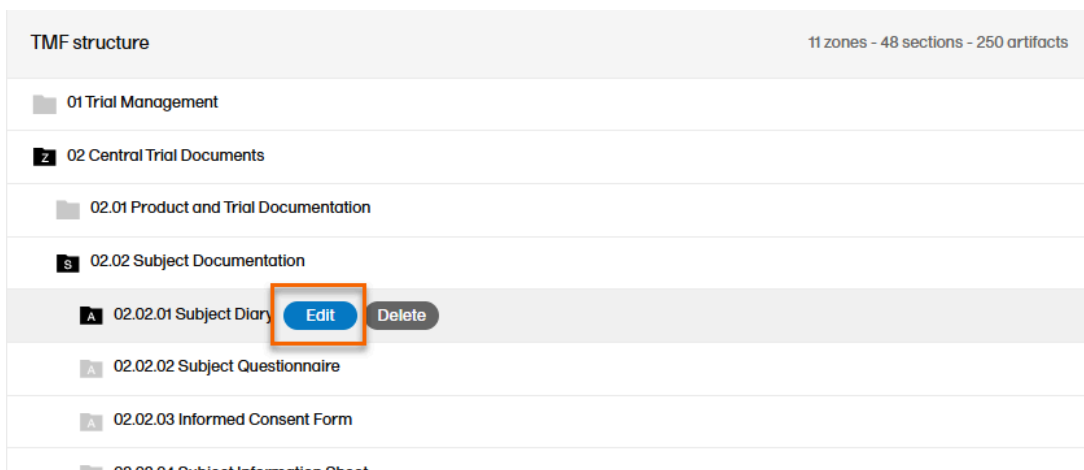


- 3 Select **Save changes**.

4.2 Editing artifacts

To edit an artifact:

- 1 When maintenance mode is activated, select the **Edit** button that appears when you hover over an artifact in the TMF structure.



Select **Edit** and the **Edit artifact** window will display:

- 2 Make your changes in the **Edit artifact** window.

The 'Edit artifact' window is displayed, showing the details for the 'Subject Diary' artifact. The window has a title bar with 'Edit artifact', 'Save', and 'X' buttons. The artifact is titled 'Subject Diary' and is noted as being 'From template DemoStudy_template_1'. The 'Classification' section includes fields for Zone # (02), Zone name* (Central Trial Documents), Section # (02.02), Section name* (Subject Documentation), Artifact # (02.02.01), and Artifact name* (Subject Diary). The 'Definition*' field contains the text: 'To document subject data captured by the subject and external to the CRF (blank forms / templates)'. The 'Unique ID' field is set to 38. The 'Sub-artifacts' section lists three items: 'Subject Diary' (with a green plus icon), 'Subject Diary Review and Approval' (with a red minus icon), and 'Subject Diary Summary of Changes' (with a red minus icon). The 'TMF side' section has checkboxes for 'Sponsor' and 'Investigator', both of which are checked. The 'Trial level settings' section includes a 'Record*' dropdown set to 'Required' (with radio buttons for 'Optional' and 'Not permitted'), and a 'Roles and accesses*' table with three rows: 'SITESTAFF' with 'READ' access, 'SPONSOR-STUDY' with 'WRITE' access, and 'SPONSOR-COUNTRY' with 'READ' access. The background shows a sidebar with navigation options like 'Trial Master', 'TMF Admin', 'TMF str', 'Templat', 'Settings', 'Status', 'TMF Archi', 'viedoc', 'TMF User C', 'TMF Admin', 'TMF Archi', and 'Switch to o'.

The fields available in the **Edit artifact** window are:

Classification

- Zone, Section, and Artifact numbers and names
- Definition
- Unique ID
- Sub-artifacts
- TMF side

Trial, Country, and Site level settings

- Record requirements
- Roles and accesses
- Milestones

Details

- File name extension details
- Blinded data
- Privacy data
- Dating convention

Record sharing

- Enable sharing for Viedoc Clinic and/or Viedoc Me users

For more information about the artifact properties, see [Customizing a template](#), specifically the sections *The V 3.2.1 sheet* and *Role sheets*.

3 Select **Save**.

4.3 Impact of changes to zones, sections and artifacts

When there are uploaded records in a structure, it is important to understand the impact of editing the structure, specifically fields in zones, sections and artifacts that are part of a record's *metadata*. Everything that you see in the record properties window when you open a record is the metadata, except for the file itself.

To show the impact of such changes, please review the example scenario below:

1 An artifact contains multiple uploaded files with the following statuses:

- Flagged by QC
- Awaiting review
- Finalized and locked
- Finalized
- Unpublished

2 A TMF Admin user switches on **Maintenance mode** and makes the following changes:

- Changes the **zone name**
- Changes the **dating convention** in the artifact from "new dating convention" to "last entry date".

The changes are then applied.

Note! These changes were made to fields that are part of the metadata for the records.

3 The following changes can now be observed:

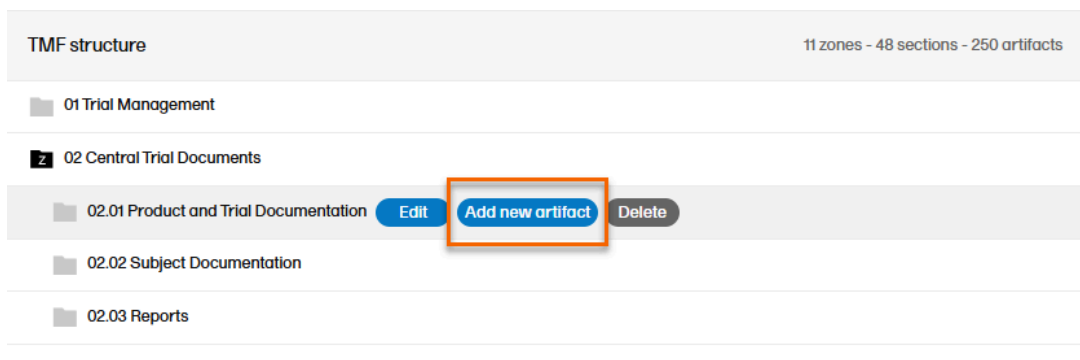
1. In the **Structure page**, the **zone** is displayed with the new name.
2. The record that was **Flagged by QC**:
 - Maintains the same status.
 - Has a comment added to the record by the system with a description of the changes made.
 - In the history section, it states that the record was Flagged by QC by the system (versus by a user taking an action).
3. The record that was **Awaiting review**:
 - Has the status changed to *Flagged by QC* because the changes affected the metadata of this record, therefore a reviewer will need to take action on it.
 - Once a reviewer edits the record, the new zone name and dating convention are shown in the metadata fields. The changes are saved and the record goes back to an *Awaiting review* status.
 - The history states the modifications that were made.
4. The record that was **Finalized and locked**:
 - Nothing has changed. The zone name and dating convention still display the original data. There is nothing noted in the history.
 - To reflect the changes in this record, the user will need to create a new version of the record (copy file from current version) and then the changed zone name and dating convention are shown in the metadata fields of the new version.
 - If a new version is not created, the original metadata will remain in the record. There is no large impact, however in the eTMF-EMS repository there will be "duplicate" zones, one for the old name (with this record in it) and one for the new name (with any records that got the new zone name linked to them).
5. The record that was **Finalized**:
 - Is the same as the *Finalized and locked* record above.
6. The record that was **Unpublished**:
 - Maintains the same status.
 - The changes are reflected in the metadata fields of the record.
 - The changes are also reflected in the record history.

Note! The status changes described above occur because the changes made to fields that are included in the record's metadata. If changes are made to other fields (for example Unique ID, adding a new sub artifact, or selecting Blinded data or privacy data not accepted) then all the statuses for uploaded records will remain the same.

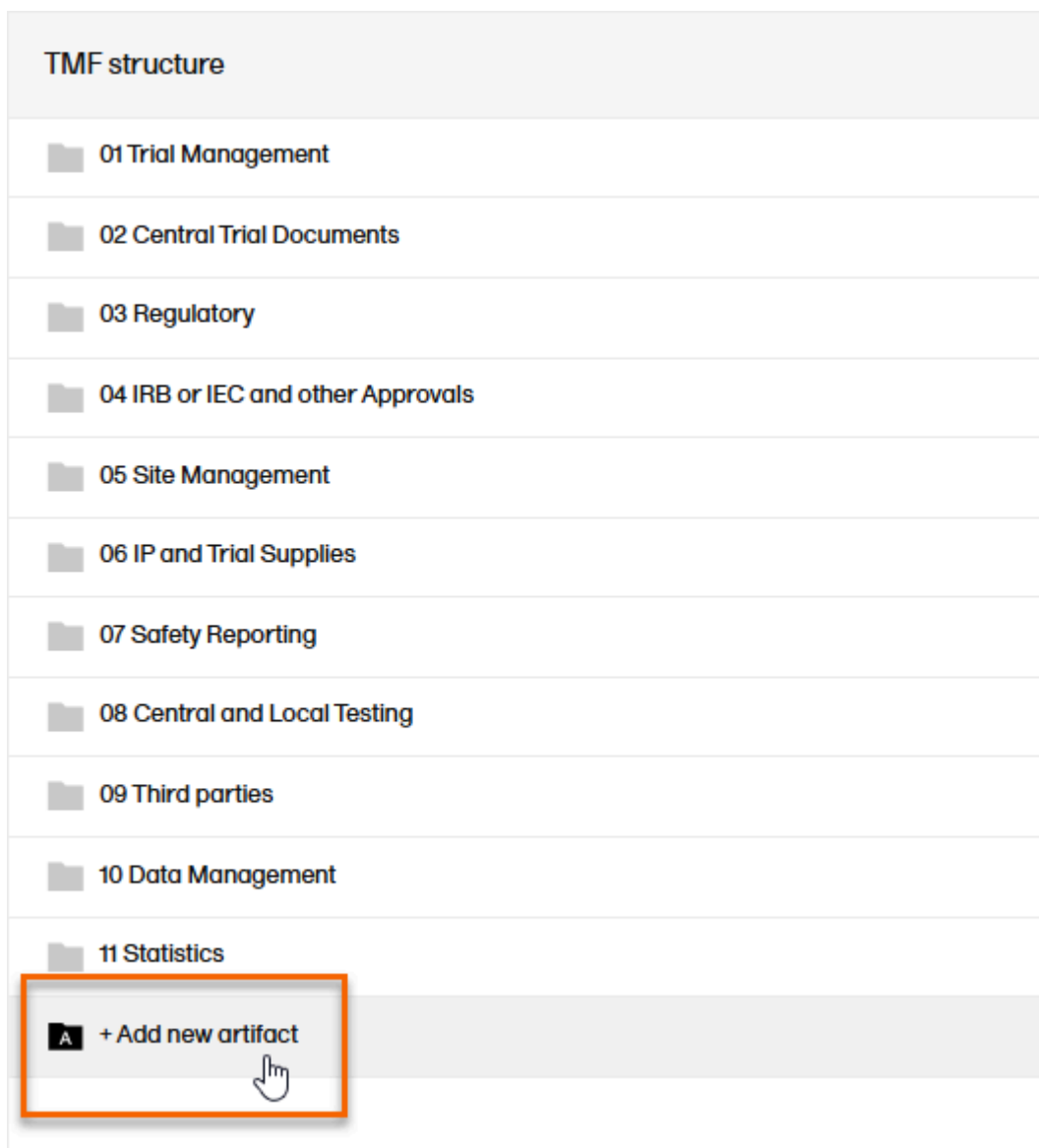
4.4 Adding artifacts

To add an artifact:

- 1 To add a new artifact to a specific zone or section, select the **Add new artifact** button that appears when you hover over a zone or section in the TMF structure.



Alternatively, select **Add new artifact** at the bottom of the structure.



- 2 Fill in the artifact information in the **Add new artifact** window.

If you select **New** in the **Zone name** or **Section name** dropdown menu, you can create a new zone or section where the artifact will be added.

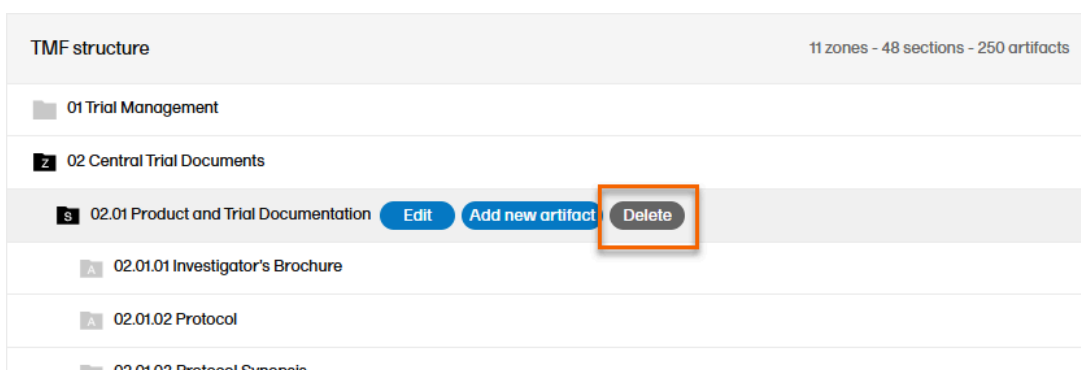
Note! The required fields are marked with red.

- 3 Select **Save**.
















4.5 Deleting zones, sections or artifacts

To delete zones, sections or artifacts:

- 1 Select the **Delete** button that appears when you hover over a zone, section, or artifact.



- 2 The zone or section and all its artifacts are then marked as red strike-through text in the TMF structure.

TMF structure		11 zones - 47 sections - 241 artifacts
	01 Trial Management	
	02 Central Trial Documents	
	02.01 Product and Trial Documentation	
	02.01.01 Investigator's Brochure	
	02.01.02 Protocol	
	02.01.03 Protocol Synopsis	
	02.01.04 Protocol Amendment	
	02.01.05 Financial Disclosure Summary	
	02.01.06 Insurance	
	02.01.07 Sample Case Report Form	
	02.01.10 Report of Prior Investigations	
	02.01.11 Marketed Product Material	
	02.02 Subject Documentation	
	02.03 Reports	
	02.04 General	

- 3 Notes on deletion:

- If you delete on zone or section level, all artifacts in the zone or section are deleted when you apply the changes to the structure.
- If you delete on artifact level, only that specific artifact is deleted when you apply the changes to the structure.
- If you delete the only artifact in a section, the section is also deleted.
- Likewise, if you delete the only section or artifact in a zone, the zone is also deleted.

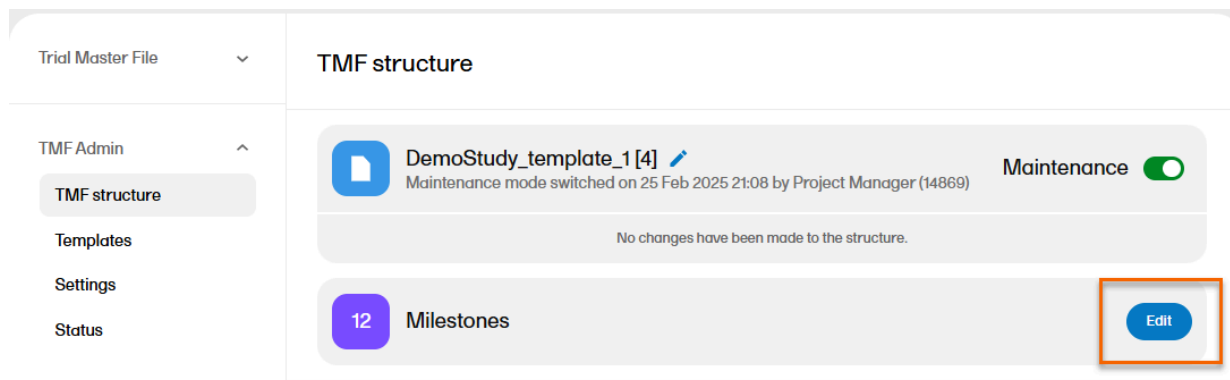
For information about how to apply or revert changes to the structure, see [Applying or reverting changes to the structure](#).

Note! If you delete a zone, section, or artifact, its associated records will **not** be deleted. Instead, the end user view will display the zone, section, and artifact as deleted to indicate that the records in it should be moved.

5 Managing milestones

Milestones are a tool for filtering records. Milestones are defined at the artifact level, and all records within that artifact will have the same milestone. Milestones may be used to search for records, to categorize records within a study timeline, or to filter audit trail reports or EMS repositories.

To manage the milestones defined for the study, select **Edit** in the Milestones section on the **TMF structure** tab.



5.1 Changing the sequence of milestones

The sequence of milestones is how they will appear in the milestones filter in the Trial Master File view, as well as in the milestones dropdown menus in the **View artifact properties** and the **Edit artifact** windows in the TMF Admin view.

To change the sequence of milestones within the group, select the up arrow on a milestone level. The changed sequences will be highlighted in red until the changes are applied to the structure or reverted

Edit milestones

12 Milestones

Add new

Start Up

#	ID	Name	Trial description	Country description	Site description
01	01	01 First Country RA Approval	The first notification (written or silent)	The first notification (written or silent)	The first notification (written or silent)
02	02	02 Clinical Infrastructure Ready	The necessary systems and processes	The necessary systems and processes	-
03	03	03 Site Live / Ready / Open for Enrollment	The first site in the study has been	The first site within the specified country has	The site has been approved / activated,

Study Conduct

#	ID	Name	Trial description	Country description	Site description
04	04	04 First Monitoring Visit	This is the first monitoring visit to	This is the first monitoring visit to	This is the first monitoring visit to
05	05	05 Significant Study Event	Any key event within a study that indicates a	Any key event within a country that indicates	Any key event within a site that indicates a
06	06	06 Annual IRB / IEC Renewal	-	Documentation received from IRB/IEC	Documentation received from IRB/IEC
07	07	07 Last Subject Last Visit	Completion of the last subject's last visit	Completion of the last subject's last visit	Completion of the last subject's last visit at

Close Out

#	ID	Name	Trial description	Country description	Site description
08	08	08 Database Lock	Confirmation that all of the requirements for	-	-
09	09	09 Close-out Monitoring Visit / Site	Completion of the final monitoring visit across	Completion of all final monitoring visits within	Completion of the final monitoring visit for the

5.2 Editing milestones

To edit the properties of a milestone, select **Edit** at that milestone level.

Edit milestones

12 Milestones

Add new

Start Up

#	ID	Name	Trial description	Country description	Site description
01	01	01 First Country RA Approval	The first notification (written or silent)	The first notification (written or silent)	The first notification (written or silent)
02	02	02 Clinical Infrastructure Ready	The necessary systems and processes	The necessary systems and processes	-
03	03	03 Site Live / Ready / Open for Enrollment	The first site in the study has been	The first site within the specified country has	The site has been approved / activated,

Study Conduct

#	ID	Name	Trial description	Country description	Site description
04	04	04 First Monitoring Visit	This is the first monitoring visit to	This is the first monitoring visit to	This is the first monitoring visit to
05	05	05 Significant Study Event	Any key event within a study that indicates a	Any key event within a country that indicates	Any key event within a site that indicates a
06	06	06 Annual IRB / IEC Renewal	-	Documentation received from IRB/IEC	Documentation received from IRB/IEC
07	07	07 Last Subject Last Visit	Completion of the last subject's last visit	Completion of the last subject's last visit	Completion of the last subject's last visit at

Close Out

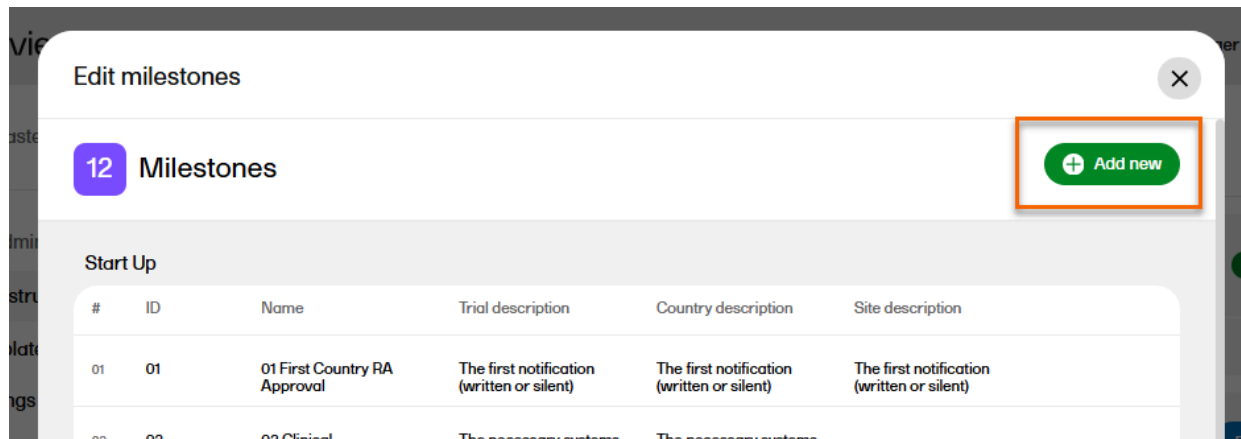
#	ID	Name	Trial description	Country description	Site description
08	08	08 Database Lock	Confirmation that all of the requirements for	-	-
09	09	09 Close-out Monitoring Visit / Site	Completion of the final monitoring visit across	Completion of all final monitoring visits within	Completion of the final monitoring visit for the

The following applies when editing the properties:

- **Group, ID, and Name** are mandatory.
- The description properties are optional.
- **ID and Name** of the milestones must be unique.

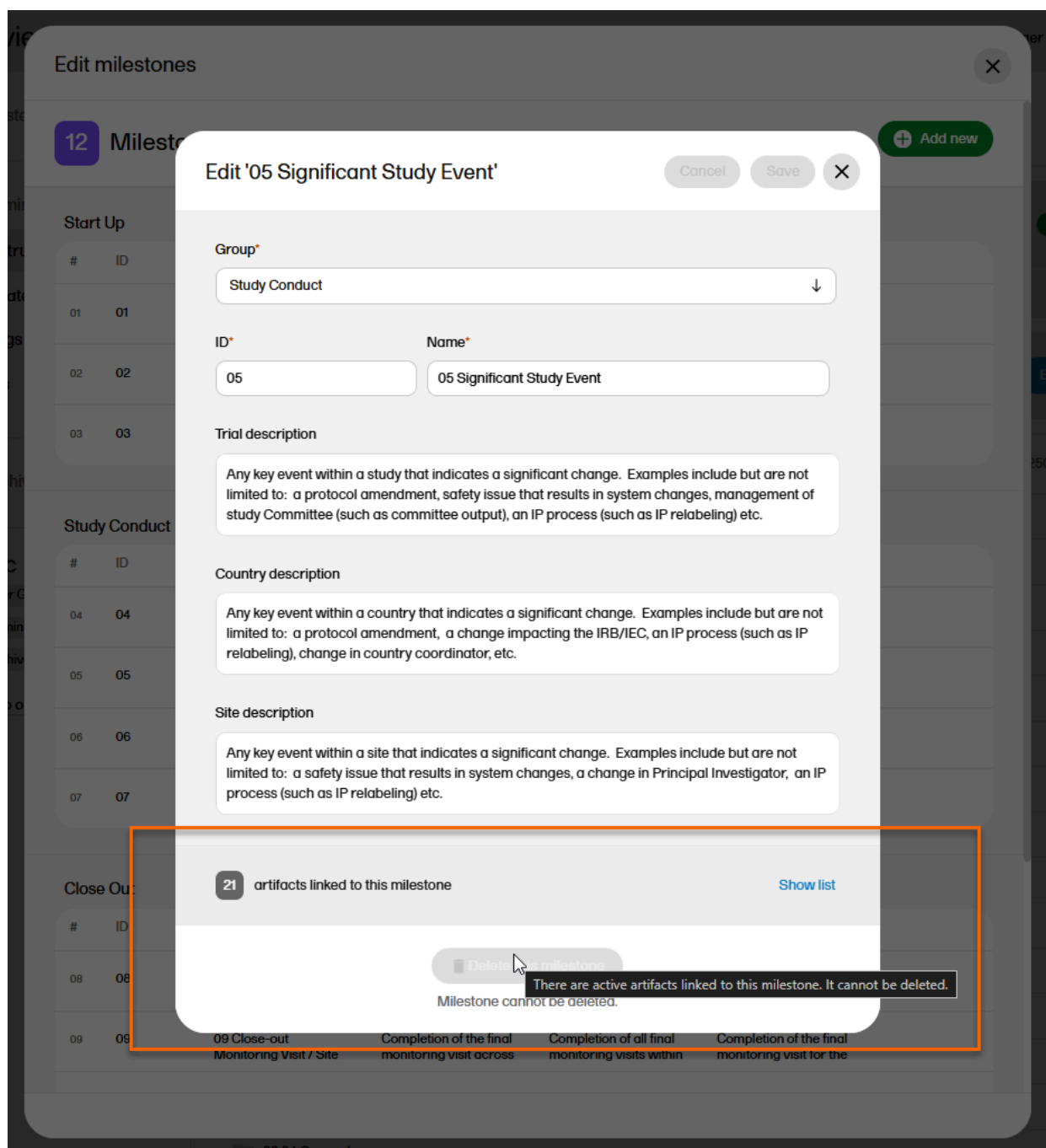
5.3 Adding milestones

To add a new milestone to the list, select **Add new** in the **Edit milestones** window.

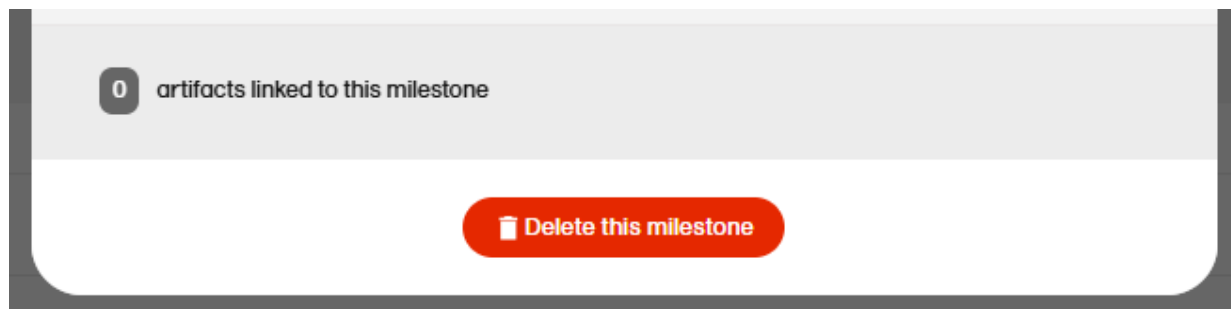


5.4 Deleting milestones

Milestones that are linked to active artifacts cannot be deleted. To delete a milestone, you must remove these links either by deleting the artifact linked to it or by linking the artifact to another milestone.

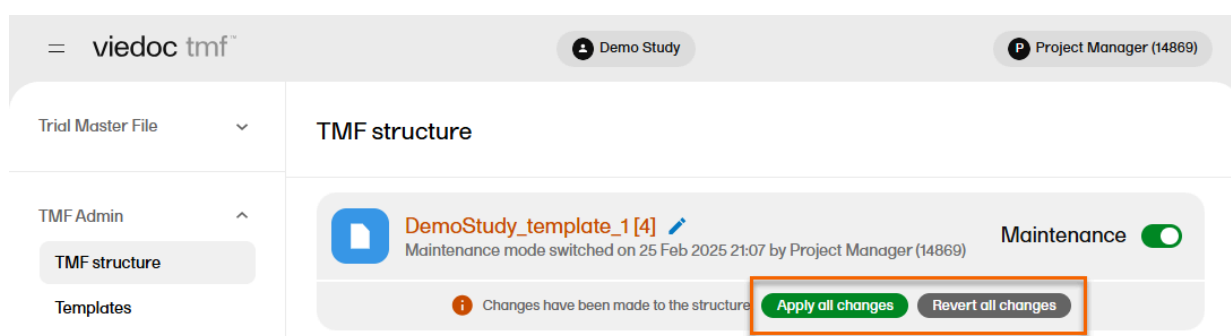


To delete a milestone, select **Delete this milestone** at the bottom of that milestone edit window.




6 Applying or reverting changes to the structure

The Viedoc TMF application automatically recognizes when changes have been made to the TMF structure and displays a message where you can choose to apply or revert all changes that were made during the current maintenance session.



The confirmation window lists the changes that have been made. Select **Apply changes** to apply or select the **X** in the top right to close the window without applying the changes.


Structure changes



The following changes have been made:

- 1 Deleted section
Third parties > General
- 2 Deleted artifact
Third parties > General > Relevant Communications
- 3 Deleted artifact
Third parties > General > Tracking Information
- 4 Deleted artifact
Third parties > General > Meeting Material

Click **Apply changes** to publish the changes made to the structure, or close this window to continue editing.

 **Apply changes**

Note! Any applied changes to the structure will be listed in the complete audit trail report.

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TMF roles and permissions use cases

TMF roles and permissions use cases

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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:

- [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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