viedoc learning™

Viedoc eTMF User Guide

7 Lessons ▪ **7** from Viedoc System

General

1 lessons

| | Introduction to Viedoc eTMF | 1.1 |

Document management

2 lessons

| | Previewing a document | 2.1 |
| | Managing documents | 2.2 |

Document review

1 lessons

| | Reviewing documents | 3.1 |

Viedoc Share

1 lessons

| | Updated Viedoc Share | 4.1 |

TMF Archive

1 lessons

| | TMF Archive | 5.1 |

Use cases

1 lessons

| | eTMF access use cases | 6.1 |

Introduction to Viedoc eTMF

Introduction to Viedoc eTMF

Published by Viedoc System 2024-01-31

1 Overview

Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents for your clinical trial.

Viedoc eTMF is based on the **TMF Reference Model** by the Drug Information Association (DIA). 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 documents 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 documents in zones, sections, and artifacts in a hierarchical structure.
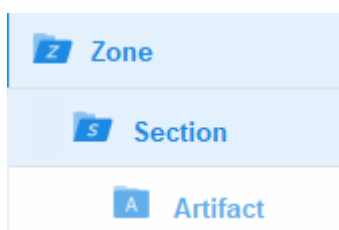
The set of zones, sections, and artifacts included is defined in a template file that is maintained by the **eTMF Manager**.

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

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

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

2 Roles and permissions

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

2.1 eTMF roles

These roles are defined in the template, which is maintained by the eTMF Manager.

Depending on the permission associated with your user role, you can perform different actions on documents. 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 documents 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 document. This is due to the fact that the user does not have write permissions for all sites that the document is linked to.

2.2 eTMF permissions

The permissions are defined in Viedoc Admin and are assigned to you by the eTMF Manager.

The eTMF permissions are:

- **Archive sponsor TMF**
  This permission gives the mapped user role access to the TMF Archive view and the ability to archive artifacts that are listed as Sponsor side (set in the **Edit artifact** window or in the template file on the sheet V 3.1.0, column M Sponsor Document). This is used for creating the main archive of the study documents.
- **Archive investigator TMF**
  This permission gives the mapped user role access to the TMF Archive view and the ability to archive artifacts that are listed as Investigator side (set in the **Edit artifact** window or in the template file on the sheet V 3.1.0, column N Investigator Document). This is used for creating/archiving an Investigator Site File.
- **Read-only TMF Admin**
  This permission gives the mapped user role the ability 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**
  A user role with this permission will gain read access to all the published documents in the Trial Master File view. If this permission is assigned in combination with an eTMF role, the no access permission, set in the template file for that specific role, will be overridden by read access by the system.
- **Download audit trail**
  A user role with this permission will be able to access the TMF Archive view and generate the complete audit trail report from there.
- **Manage drop zone**
  This permission gives the mapped user role access to manage the files in the shared drop zone.

Note! For more information about permissions and accesses, see [eTMF access use cases](#).

3 Document statuses and actions

The following image shows the document version statuses and the actions that change the status of a document version. The initial status of a document when it is uploaded to the eTMF is Unpublished.
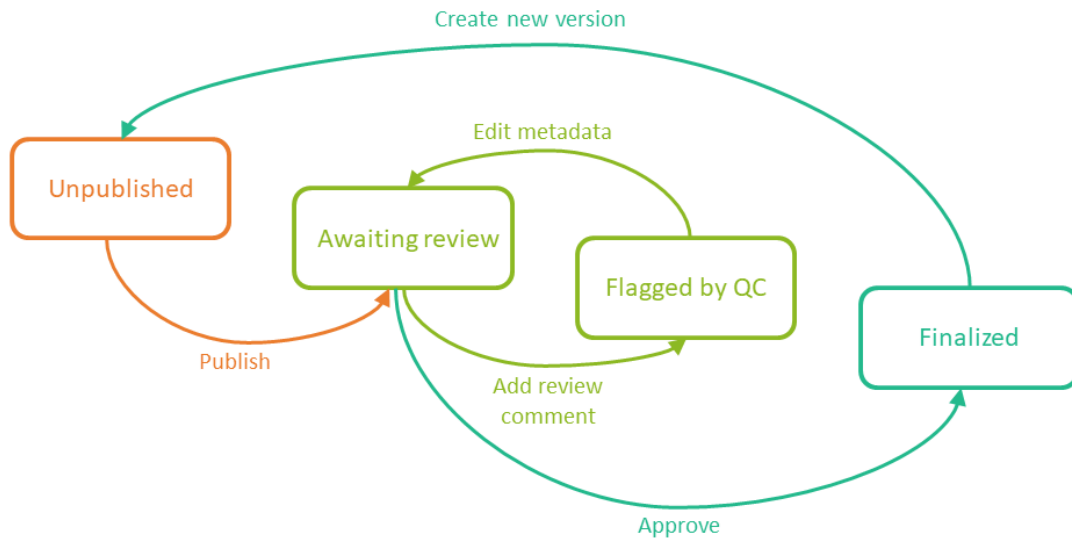
If you edit metadata for a document version that is Unpublished or Awaiting review, the document version status is not changed.

It is not possible to edit the metadata of a Finalized document. 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 user roles.

---

4 eTMF user view

The eTMF user view is your starting point for working with documents:

1. Link to the eLearning curriculum Viedoc eTMF User Guide

2. Use the dropdown menu to filter your view by **Trial level** or **Country level**. You can only select a country that you have permission for.

3. Use the dropdown menu to filter your view by site. You can only select a site that you have permission for.

4. Use the dropdown menu to filter the artifacts by milestones. You can either select a milestone group (**Start Up, Study Conduct, Close Out, Other**) or a specific milestone that is defined in the structure. Selecting a group means filtering the artifacts by all the milestones that belong to that group.

5. The left eTMF metrics area gives an overview of the published documents for the complete trial.

6. The right eTMF metrics area gives an overview of the published documents belonging to the trial artifacts that you have access to.

7. Use the search field to search for words or sub-strings in filenames or within file content.

8. Click the **Details page** button to open the **Details** page, listing <u>all</u> eTMF documents. For more information, see <u>The Details page</u>.

9. Use the **Drop Zone** area to upload files to be managed later either by you or by the drop zone manager.

10. Use the **Zones & sections** area to navigate through the eTMF structure. Click on zones and sections to expand/collapse them.

11. Click the **Details page** button to open the **Details** page, listing the documents in the <u>section</u>. For more information, see <u>The Details page</u>.

12. Click the **Details page** button to open the **Details** page, listing the documents in the <u>artifact</u>. For more information, see <u>The Details</u> page.

13. The **Artifacts & documents** area is where you can view documents and their status. In this area, you can also upload and download documents, delete unpublished documents, as well as open the **Document properties** dialog.

Note! All date and time stamps in the Trial Master File view are according to the user's local time zone.

# Previewing a document

Published by Viedoc System 2023-10-09

1   Previewing a document

The document preview feature lets you view the contents of a file without downloading it. The preview shows the latest version of files in each document version.
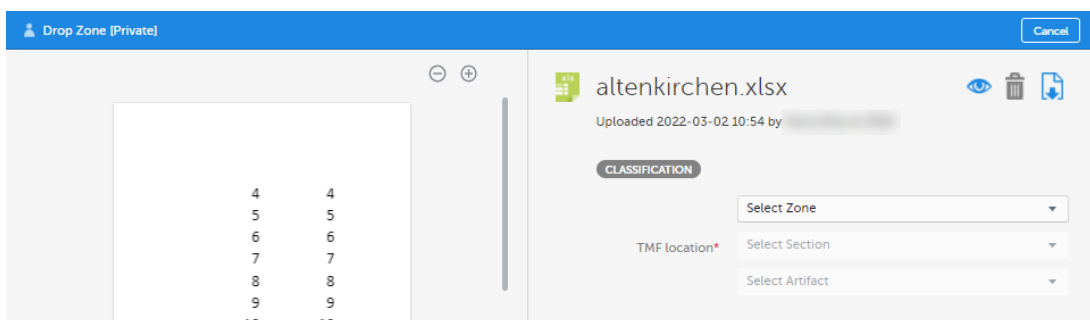
The preview feature is available in the **Document properties** dialog and in the file dialog in drop zones.
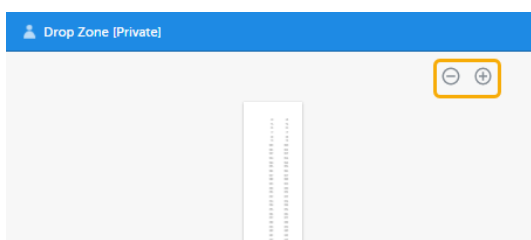
To preview a file:

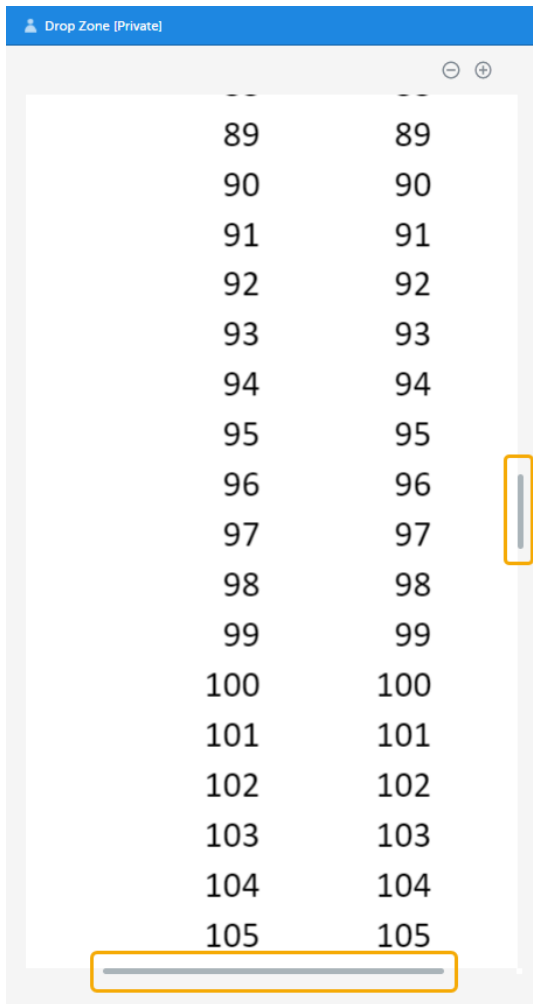1   Click on the **Preview** button at the top right corner of the dialog:
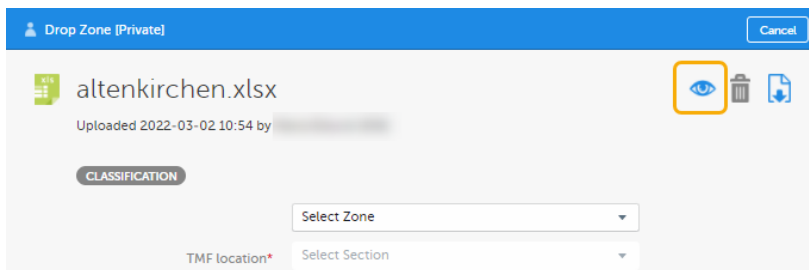
2   The preview opens in the left pane of the dialog.

3   Use the - and + buttons to zoom out or in.

4   If the whole preview does not fit in the pane, you can use the scroll bars to scroll vertically and horizontally.

5   To close the preview, click on the **Preview** button again.

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

1.1   Supported filetypes

The document preview is supported for the following filetypes:

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

Note! For filetypes that are not supported, the following dialog is displayed:
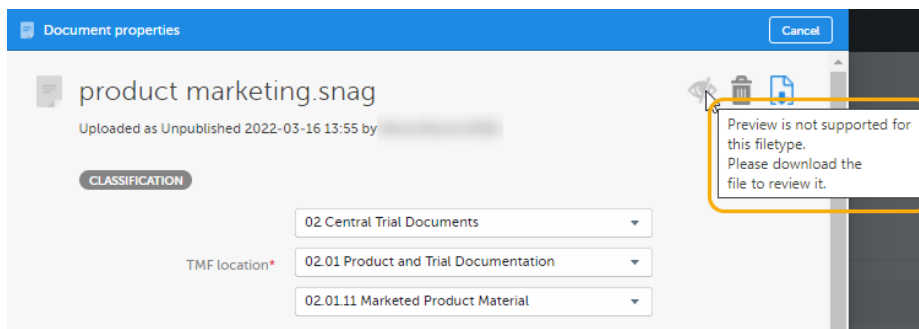
1.2 Audit trail

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

Managing documents

Managing documents

Published by Viedoc System 2024-10-11

---

1 Launching Viedoc TMF

To launch Viedoc TMF, select the **eTMF** icon on the Viedoc landing page.
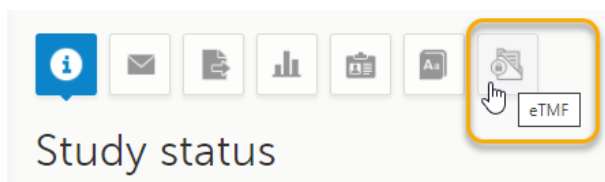
**Note!** The eTMF launch icon is only available in production mode.

Uploading documents to Viedoc TMF requires **write** permission for the artifact on the TMF level that the document is linked to. For more information about eTMF permissions, see [Introduction to Viedoc eTMF](#).

---

2 Uploading a document

To upload a document:

1. In the **Artifacts & documents** area, select the upload button for the artifact:
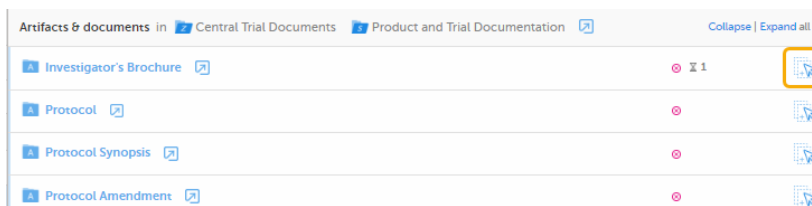
    Note! If you do not know which zone, section, or artifact to place the document in, you can use the drop zones. For more information, see [Working with drop zones](#).

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

    Notes!

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

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

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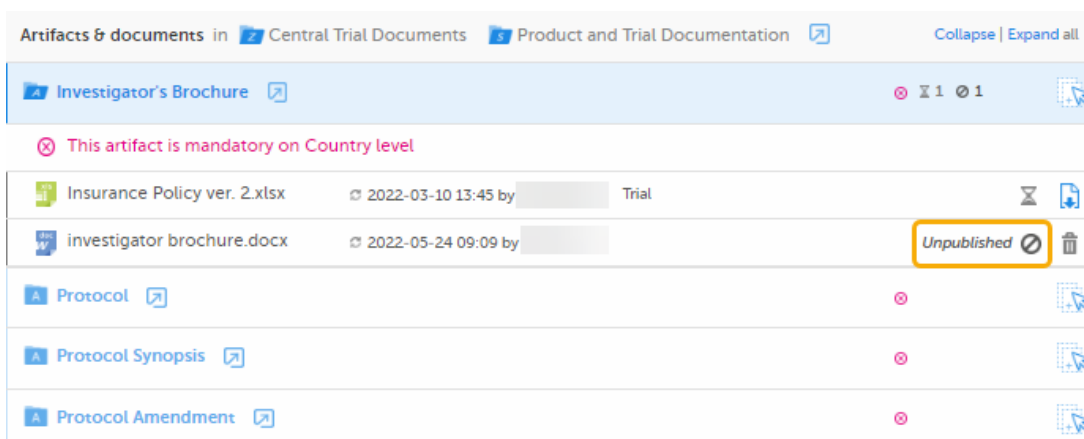
    Notes!

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

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

---

3 Working with drop zones

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

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

- The **Private** drop zone: Files that are uploaded to the private drop zone can only be accessed and managed by the user who uploaded them.

Anyone with access to the study eTMF can upload files to the drop zones. However, moving files from the drop zones to the structure is similar to uploading documents to artifacts within the structure. Both require that the user has **write** permission to the artifact in question.
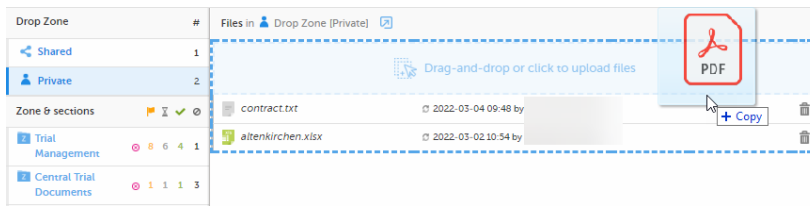
3.1 Uploading a file

To upload a file to a drop zone:

1 Navigate to the desired drop zone, select the **Upload** button.
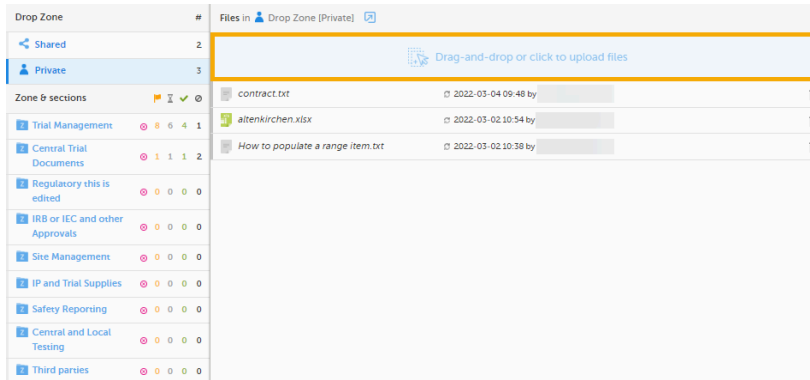
2 Browse to the file(s) that you want to upload, select them, and then select **Open**.

3 Alternatively, to upload file(s), drag them from your file explorer and then drop them in the selected drop zone.

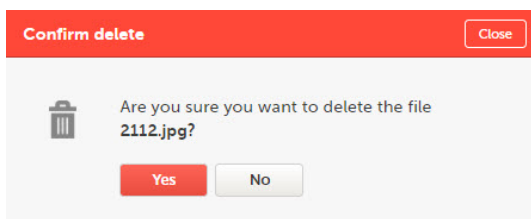
3.2 Deleting a file

To delete a file from a drop zone:

1 Select the trash can button on the level of the file that you want to delete.
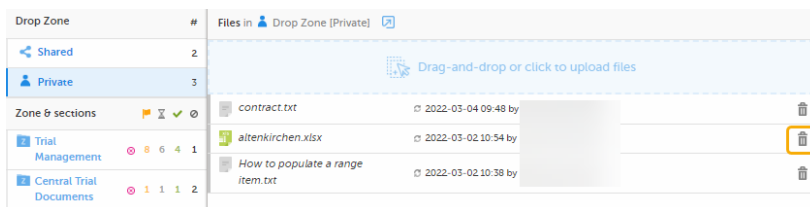
2   Alternatively, open the file by selecting it, and then select the trash can button in the dialog.
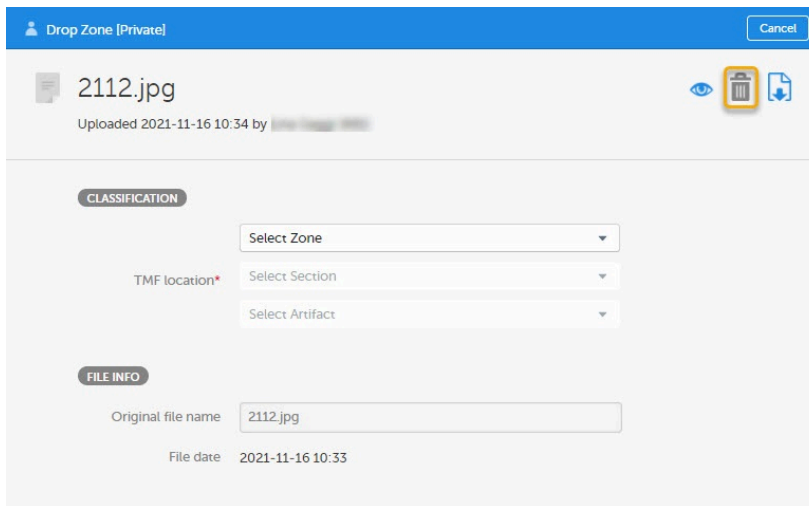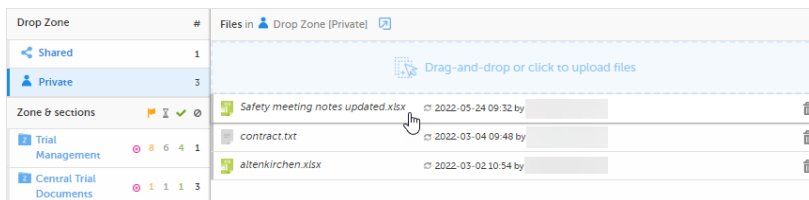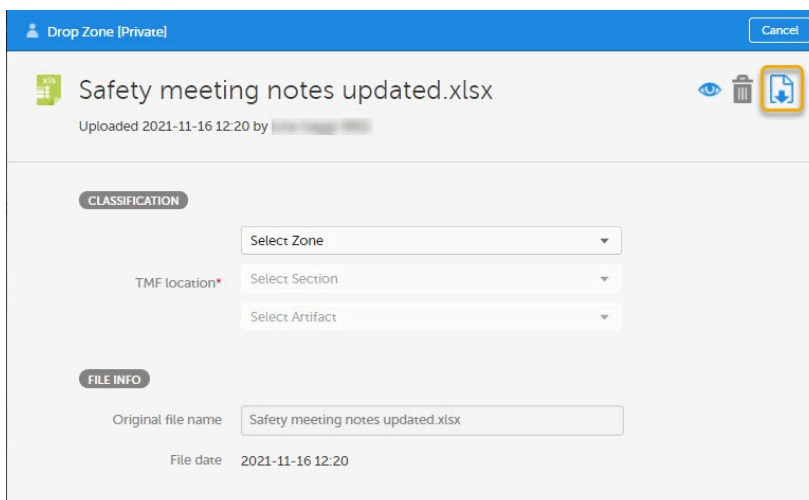

3   Confirm the deletion.

3.3   Downloading a file

To download a file from a drop zone:

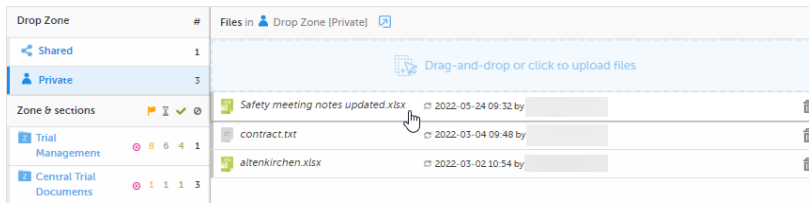**1**   Open the file dialog by selecting the desired file.

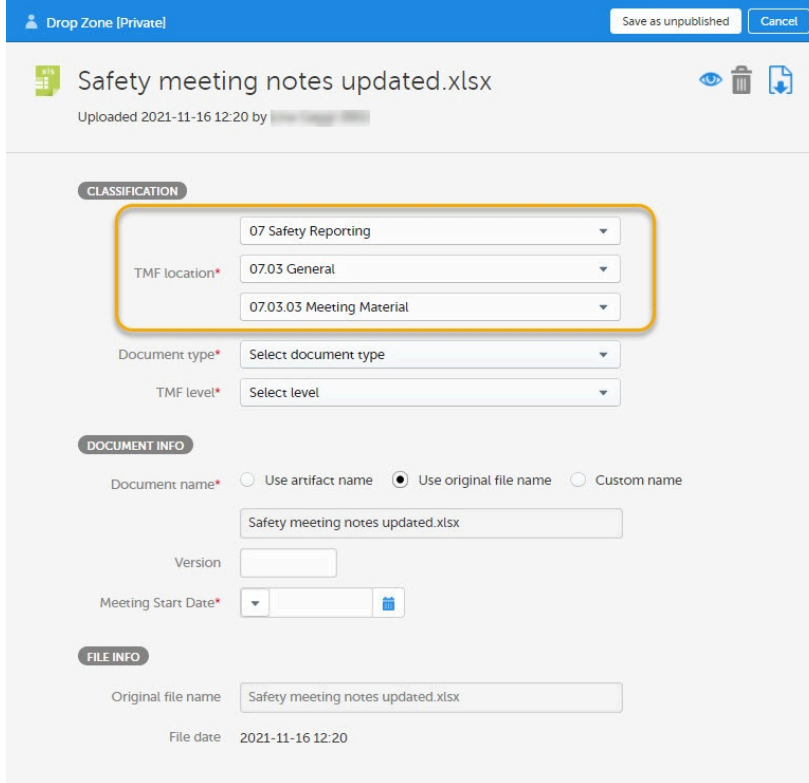**2**   Select the download button in the file dialog.

3.4 Moving a file

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

1   Open the file dialog by selecting the relevant file.

2   Select the TMF location (Zone, Section, and Artifact) where you want to move the file.

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

3 The properties of that artifact will then be populated in the dialog. You can either enter values for the metadata properties or leave them empty. Select **Save as unpublished** to create a new unpublished document in the selected location with the file that was moved from the drop zone.

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

4   Searching for documents

To search for documents in Viedoc TMF:

1   Enter text to search for in the **Search** field.

The text can be a document name or a file name, or a sub-string thereof. It can also be a text or a sub-string of a text in the file contents.

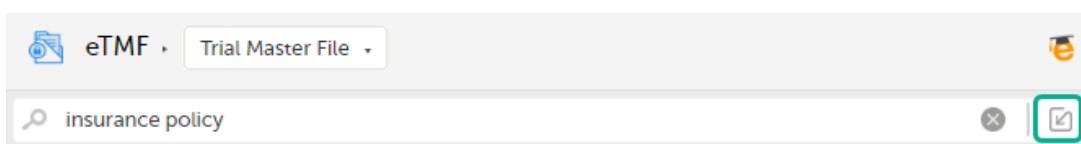2   Press Return (or Enter) or select the magnifying glass.

3   The search results are displayed on the **Details** page, sorted by relevance.

For more information, see The Details page.

≡ ≡ ≡ ≡ Name	≡ Last modified datetime	≡ Last modified by	≡ TMF level	Actions
Insurance Policy.xlsx	2022-03-10 13:46		Country	👁 📥
Insurance Policy ver. 2.xlsx	2022-03-10 13:45		Trial	👁 📥
Demo study template 001.xlsx	2021-12-02 13:37			👁 🗑
abc	2021-08-18 09:18		Country	👁 📥
duplicated zones and section ids.xls	2021-09-14 16:27		Site	👁 📥
This is my cool name	2021-11-01 13:54		Country	👁 📥
Demo study template 001.xlsx	2021-10-04 16:07		Site	👁 📥
Linas CV	2021-12-03 09:27		Site	👁 📥
DemoStudyTemp.xls	2021-09-14 16:17		Site	👁 🗑

Found 9 documents

Tip! If you hover over a zone, section, or artifact icon, its name and artifact number will be displayed.

4   To return to the structure view, select the **Structure page** button.

eTMF › Trial Master File ▾

🔍 insurance policy

---

5   The Details page

To open the **Details** page, press Return (or Enter) or select the magnifying glass in the search field. You can also open it by selecting the **Details page** button in any location in the user view:

The **Details** page provides an overview of the documents that you have access to together with their metadata in a table or grid. The **Details** page lets you:

- Choose the metadata to display in the columns
- Sort and filter by the visible columns
- Take actions on the documents from the **Actions** column (that is always pinned to the right), or by clicking anywhere on a row to open the **Document properties** dialog for a specific document

1. The search field

2. Select to delete the entered search string.

3. Select to return to the structure view.

4. The number of search results.

5. The **View** menu. For more information, see [The View menu](#).

6. The column menu. For more information, see the following sub-sections.

7. An arrow indicates that the search results are sorted by the column contents. For more information, see the following sub-sections

8. A funnel icon indicates that the search results are filtered. For more information, see the following sub-sections

9. The actions that you can perform on the documents. The possible actions are **Preview**, **Download**, and **Delete**. The actions available for you depend on your permissions.

10. Icons showing the status of the zones, sections, and artifacts. The fourth column from the left contains icons for the filetypes.

These are the icons that can occur:

Icon	Description
	A zone that is expanded in the tree view
	A deleted zone that is expanded in the tree view
	A zone that is collapsed in the tree view
	A deleted zone that is collapsed in the tree view
	A section that is expanded in the tree view
	A deleted section that is expanded in the tree view
	A section that is collapsed in the tree view
	A deleted section that is collapsed in the tree view
	An artifact that is expanded in the tree view
	A deleted artifact that is expanded in the tree view
	An artifact that is collapsed in the tree view
	A deleted artifact that is collapsed in the tree view
	The private drop zone, when enabled
	The private drop zone, when disabled

Icon	Description
	The shared drop zone, when enabled
	The shared drop zone, when disabled
	A file
	A deleted file

5.1 The View menu

The **View** menu lets you save and display a customized view of the **Details** page. This can be useful if you have filtered, sorted, or sized the columns and want to be able to re-use your viewing preferences.

These are the available menu options:

Menu option	Description
Default	Displays the default view, as provided by the system. When you perform a search on the **Structure** page, this view is displayed. When you perform a search on the **Details** page, and you haven't made or saved any customization, this view is displayed.
Default+	Indicates that changes have been made to the default view, but the changes have not been saved as a customization. To save the changes, select **Save as customized**.
Customized	Displays the saved customized view. This option is not available if you haven't saved a customization. **Tip!** This view is retained between login sessions.
Customized+	Indicates that changes have been made to the customized view, but the changes have not been saved as a customization. To save the changes, select **Save as customized**.
Reset columns	Resets the view to the latest used of the default or the customized views.
Save as customized	Saves the current view as a user-specific customization. Each user can save their own tailored viewing preferences. This option is not available when the eTMF is locked.

Note! If you perform any further search on the **Details** page, the system displays the latest used view.

5.2 Sorting the column contents

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

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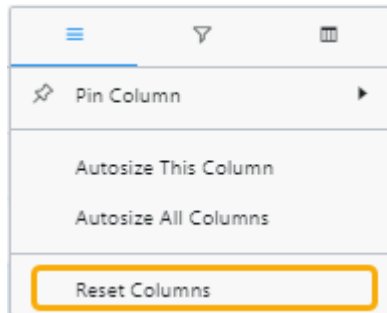
5.3   Pinning a column to the left or the right

To pin a column to the left or the right:

1   Select the menu button in the column header to open the column menu.

2   In the leftmost group, select **Pin Column** and then **Pin Left** or **Pin Right**.
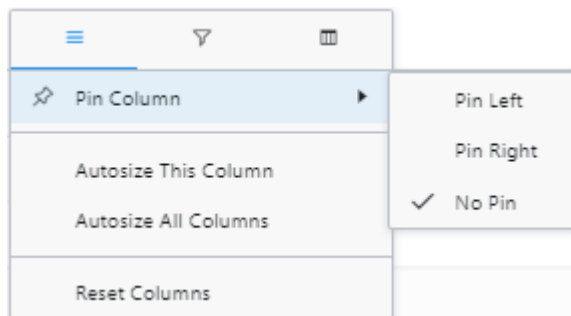
Tips!

- The **No Pin** option unpins the column.
- To reset all pinning, select **Reset Columns**.

5.4   Autosizing columns

To adjust the width of columns to the width of the text in them:

1   Select the menu button in the column header to open the column menu.

2   Select the leftmost button in the header, then select **Autosize This Column** or **Autosize All Columns**.
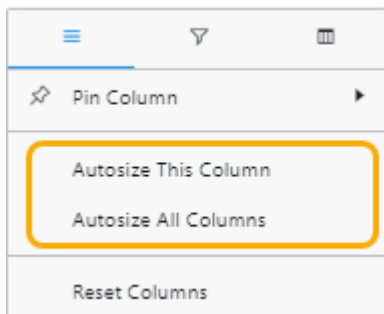
Tip! To reset all autosizing, select **Reset Columns**.

5.5   Filtering out data

To filter out data to be displayed on the **Details** page:

1   Select the menu button in the column header to open the column menu.

2   Select the filter button.
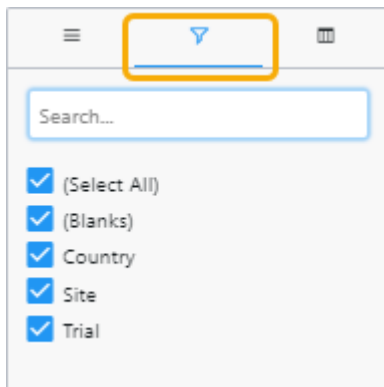
3   Select the column contents that you want to filter out, and deselect the ones that you don't want to filter out.

4   Use the search field to search for column contents to filter by.

5   When a filter has been applied to a column, a filter icon is visible in the column header.

Tip! To reset all filtering, open the column menu, select the filter button and select (**Select All**).

5.6   Selecting which columns to display

To select which columns to display on the **Details** page:

1	Select the button in the column header to open the column menu.

2	Select to open the column selector.
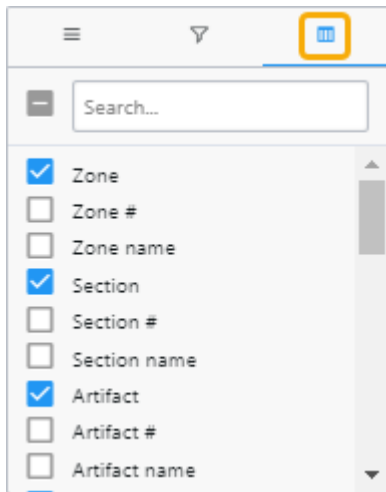
3	Select the columns that you want to display.
4	Use the search field to search for columns.

Tip! To reset to the initial state, select **Reset Columns**.

5.7   Copying data

To copy the data in a table cell on the **Details** page, right-click in the cell and select one of these:

- **Copy** - copies the contents of the table cell to your clipboard
- **Copy with Headers** - copies the contents of the table cell and the column header to your clipboard

5.8   Exporting data

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

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

5.9   The columns on the Details page

These are the columns that are available to show or hide on the **Details** page:

Column	Description
Zone	This column shows the zone or drop zone icon. When you hover over the icon, a tooltip shows the zone number and the zone name. For drop zones, the tooltip shows the drop zone name.
Zone #	The zone number.
Zone name	The name of the zone as set in the structure.
Section	This column shows the section icon. When you hover over the icon, a tooltip shows the section number and the section name.

| Column	Description
Section #	The section number
Section name	The name of the section as set in the structure.
Artifact	This column shows the artifact icon. When you hover over the icon, a tooltip shows the artifact number and the artifact name.
Artifact #	The artifact number
Artifact name	The name of the artifact as set in the structure.
Filetype	The filetype icon. When you hover over the icon a tooltip text shows the filetype.
Filetype name	The filetype name in text, for example pdf or xlsx.
Name	This column shows: - Display label. - If Display label is not applicable, then it shows the Document name. - If neither Display label nor Document name are applicable, then it shows the Original file name.
Display label	This label represents how the document is displayed on the Trial Master File view.
Document name	The name of the document as set by the user in the corresponding **Document properties** window.
Download label	The name of the latest version of the document when downloaded.
Archive label	The name of the document in the archive.
Dating convention	The dating convention label that is applicable to the document.
Dating convention value	The date value of the dating convention metadata in the format YYYY-mm-DD.
Last modified datetime	The date and time when the document was last modified, in the format YYYY-mm-DD HH:MM.
Last modified by	The user name of the user who last modified the document
Last reviewed datetime	The date and time when the document moved to the status Flagged by QC, in the format YYYY-mm-DD HH:MM.
Last reviewed by	The user name of the user who last commented on the document.
Uploaded to drop zone datetime	The date and time when the file was uploaded to a drop zone, in the format YYYY-mm-DD HH:MM.
Uploaded to eTMF datetime	The date and time when the file was moved to the eTMF structure, in the format YYYY-mm-DD HH:MM.
TMF level	One of Trial, Country, or Site.
Document type	For main artifacts, the column shows the artifact name. For sub-artifacts, the column shows the sub-artifact name. For other types, the column shows the customized name.
Countries	The names of the countries that the document is linked to.

Column	Description
Country codes	The country codes of the countries that the document is linked to.
Sites	The names of the sites that the document is linked to.
Site codes	The site codes of the sites that the document is linked to.
Document version	The document version number as set by the user in the **Document properties** window.
Document system version	The system version of the document.
Document Id	The document's unique Id within the study eTMF.
Original file name	The original name of the file when it was uploaded.
File size	The size of the file.
File date	The date and time when the latest version of the file was uploaded to the eTMF structure, in the format YYYY-mm-DD HH:MM.
Milestone group	The milestone group that the milestone which the artifact is linked to on the level that the document is filed to in that artifact.
Milestone	The milestone that the artifact is linked to on the level that the document is filed to in that artifact.
Document status	This column shows the document status icon. It can be one of the following: - Unpublished - Awaiting review - Flagged by QC - Finalized - Finalized and locked - Finalized, locked, and shared
Actions	This column is pinned to the right and cannot be removed. It shows the action buttons according to the actions that can be performed on the document according to the user permissions. The actions can be: - Delete, if the document is unpublished - Download - Preview, if the preview is supported for the filetype. Click the button to open the **Document properties** window in the preview mode.
ICH code	The code according to the International Council for Harmonisation
Unresolved notes count	The number of unresolved notes for a document

6   Downloading a document
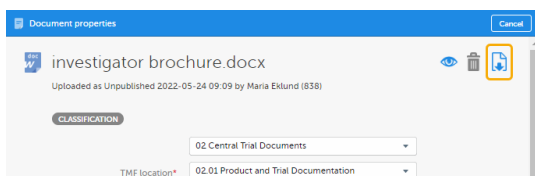
Downloading a document from Viedoc TMF requires read, review, or write permission for the artifact on the TMF level that the document is linked to. For more information about permissions, see Introduction to Viedoc eTMF.
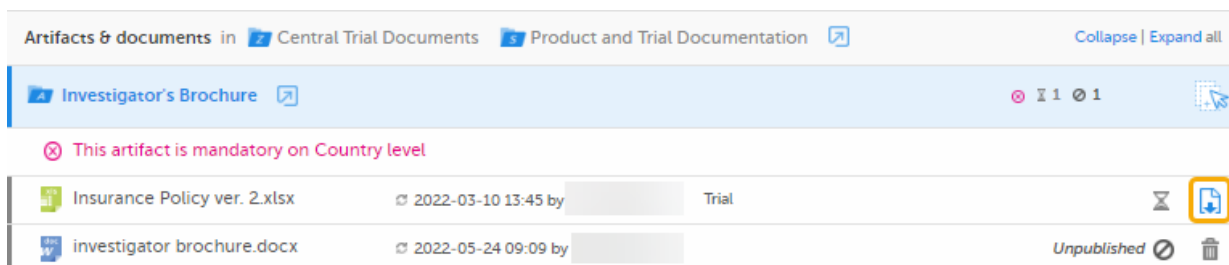
To download a document:

1   Open the **Document properties** dialog by selecting a document in the **Artifacts & documents** area.
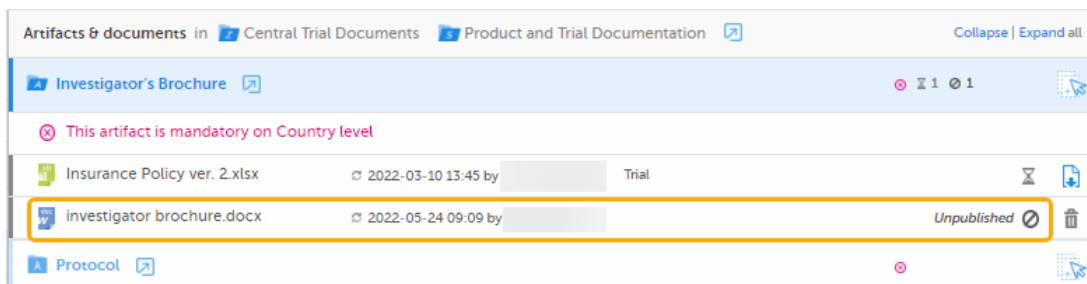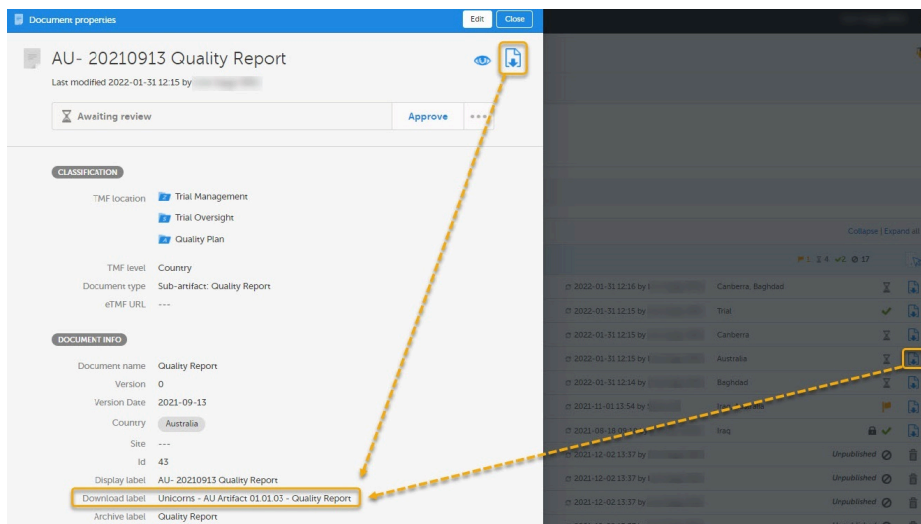

2   In the **Document properties** dialog, select the download button.

You can download published documents by selecting the download button in the **Artifacts & documents** area:

Note! The name of the latest version of the document, when downloaded, will be according to the download label in the **Document properties** dialog:

To navigate between versions of a document, use the version menu at the top of the **Document properties** dialog.
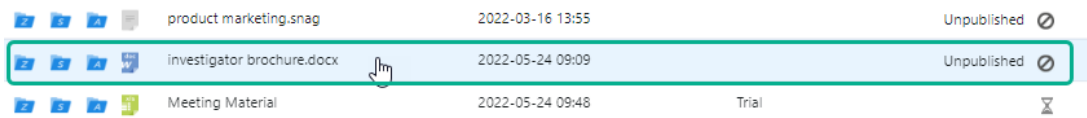
7   Editing document properties

Editing document properties in Viedoc TMF requires **write** permission for the artifact on the TMF level that the document is linked to. For more information about permissions, see Introduction to Viedoc eTMF.

Note! it is not possible to edit a finalized document. To make changes, a new document version must be created. For more information, see Creating a new version of a document.
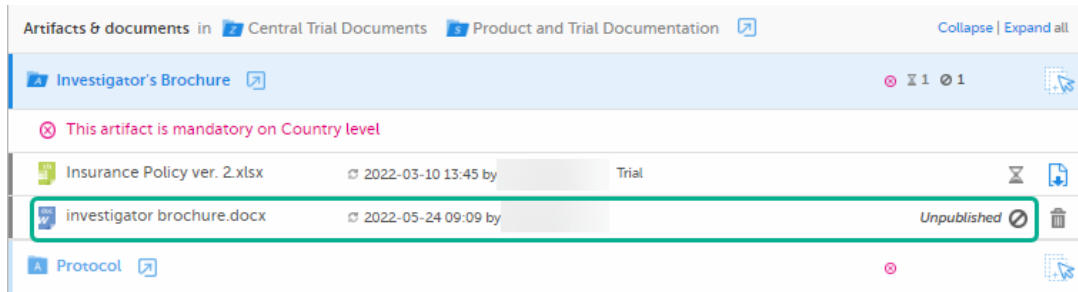
To edit the document properties:

1   Open the **Document properties** dialog by selecting a document on the **Details** page.
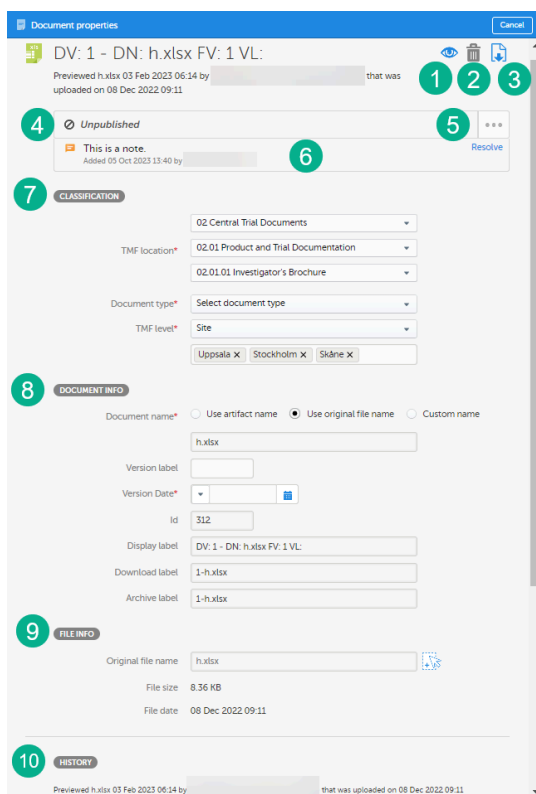

2   Alternatively, open the **Document properties** dialog by selecting a document in the **Artifacts & documents** area.

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

3   The **Document properties** dialog is displayed:

1. **Preview** button. For more information, see Previewing a document.

2. **Delete** button

3. **Download** button

4. The document status, one of Unpublished, Awaiting review, Flagged by QC, and Finalized.

5. The **Actions** menu. Note that the available menu options depend on the document status and your permissions.

6. Document notes section.

7. CLASSIFICATION

- TMF location: The zone, section, and artifact of the document
- Document type: The available document types are Main Artifact, Sub-artifacts (if any), and Other. If you select Other, you can enter a customized document type.
- TMF level: Choose between Site, Trial, and Country. If you choose Country or Site, you will be prompted to also choose which country or site to link the document to. You can only choose a country or site that you have access to. A document can be linked to more than one site or to more than one country. When a document is linked to a TMF level, users with at least read permissions on that level can access the document, even when the document is Unpublished.
The TMF Manager can make a setting to automatically populate this field (when there is only one TMF level option available for the user for the selected document).

8. DOCUMENT INFO

- The name or title of the document is displayed at the top of the dialog and in the **Artifacts & Documents** area. The available options are:
  - **Use sub-artifact name** - as specified in the eTMF template
  - **Use original file name** - the file name including the file name extension
  - **Custom name** - Select this option to enter a customized document name.

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

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

9. **FILE INFO** File date is the date and time when the file was uploaded. If the document is in edit mode, you can click the upload button to browse for a new version of the file. If you upload a new file, the document status will be changed to **Awaiting review**.

10. The **HISTORY** section is the audit trail for the selected document version. Changes to the document version are logged here together with information about the date and time when it was done and by which user. Note that, in this section, you will not see the name of a site that you do not have access to, but instead the site ID. Note also that document note actions are not included in the history.

4   Make your settings, and then select **Publish** or **Save as unpublished**.

When a document is published, it is available for all eTMF users with at least **read** permission for that artifact, and the document status is changed to **Awaiting review**.

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

---

8 Creating a new version of a document

To create a new version of a finalized document:

1   Open the **Document properties** dialog according to the instructions in the section [Editing document properties](#).

2   At the top of the dialog, select **. . .** to open the **Actions** menu.

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

4   Select whether you want to copy the file from the previous version or upload a new file.
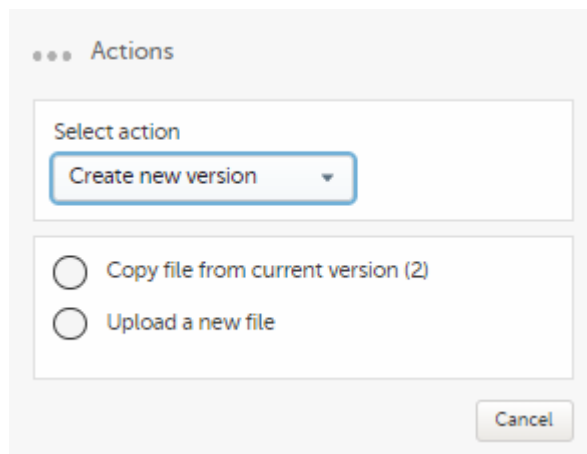
5   If applicable, edit the metadata of the new document version.

6   Select **Ready**.

The new document version is saved in an unpublished status.

9 Navigating between document versions

When you open the **Document properties** dialog, the latest version of the document is displayed by default.

To navigate between document versions, use the version dropdown menu at the top of the **Document properties** dialog.


---
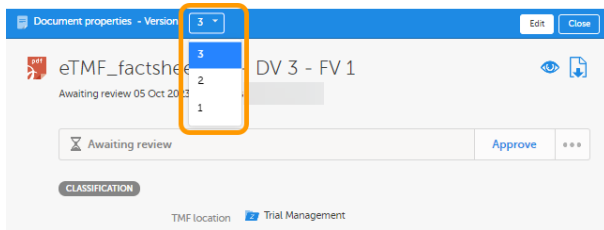
10 Adding notes to a document version

Document notes are a way to communicate with other users about documents without affecting the document status. The notes actions are not recorded in the document history.

These are the permissions needed for adding or resolving notes:
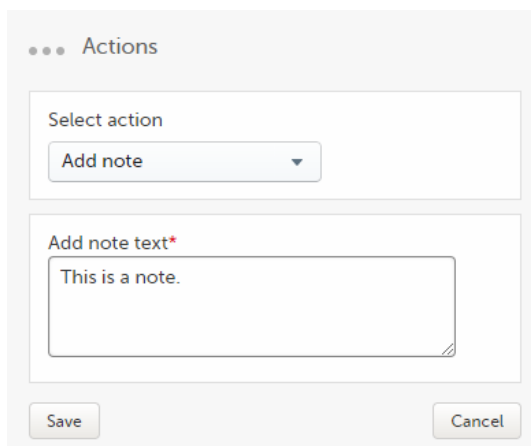
- For a document in the TMF structure, you need WRITE or REVIEW permission for the document.
- For a document in a drop zone, you need to have access to the document.

To add a note to a document:

1   Open the **Document properties** dialog according to the instructions in the section Editing document properties.

2   At the top of the dialog, select . . . to open the **Actions** menu.
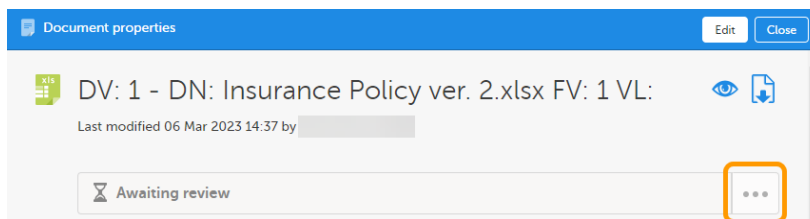
3   Select **Add note** from the menu.

4   Enter your note text and select **Save**.

5   The note is then displayed like this:
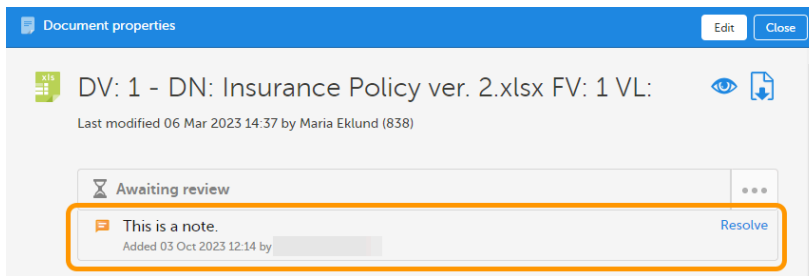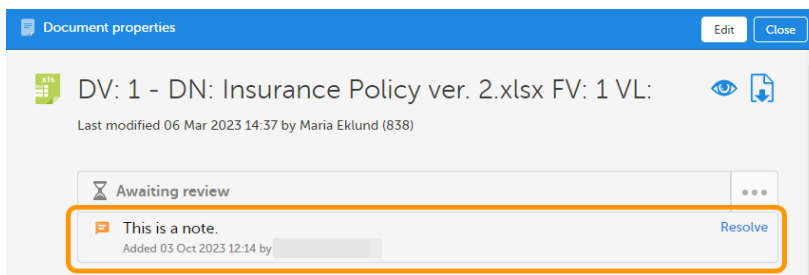

The note is associated with the selected document version.

---

11   Resolving notes

To resolve a note in a document:

1   Open the **Document properties** dialog according to the instructions in the section [Editing document properties](#).

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


The note is then immediately removed.

---

12   Publishing a document

Publishing a document in Viedoc TMF requires write permission for the artifact on the TMF level that the document is linked to. For more information about permissions, see [Introduction to Viedoc eTMF](#).

To publish a document:

1   Open the **Document properties** dialog according to the instructions in the section [Editing document properties](#).

2   Make sure all mandatory fields (marked with red) are filled in.

3 Select **Publish** at the top of the dialog:
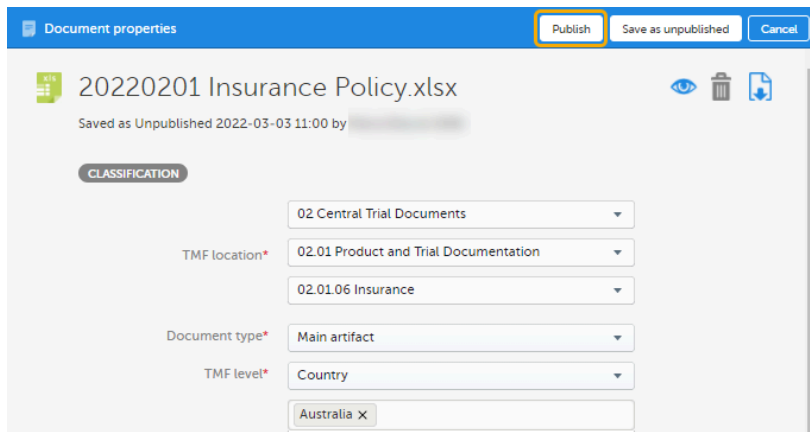
4 When the document is published, it is available for all eTMF users with at least read permissions for that artifact and with access to the TMF level that the document is linked to.

The document status is now Awaiting review:
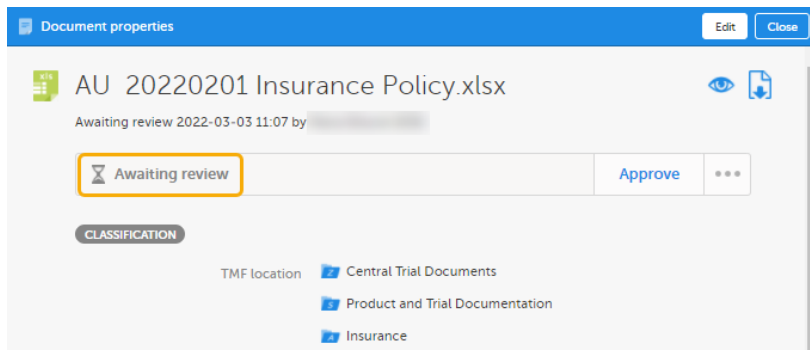
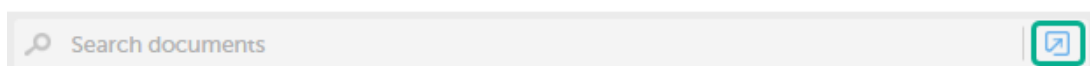
13 Resolving issues for documents that are flagged by QC

In the metrics area at the top of the page, the orange flags indicate if there are any documents that are flagged by QC.
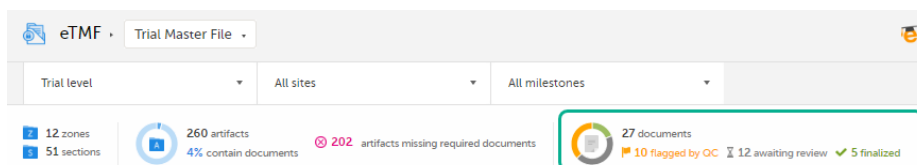
13.1 Locating the documents that are flagged by QC

To locate the documents that are flagged by QC:

1 In the search field, select the **Details page** button.

2 On the **Details** page, locate the column **Document status**, and select to open the column menu.
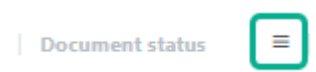
3   Select the filter button, and then deselect all statuses except **Flagged by QC**.
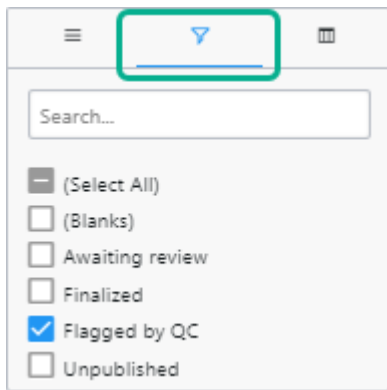

4   The **Details** page now shows a list of all the documents that are flagged by QC.

13.2   Resolving issues

To resolve issues for documents that are flagged by QC, you need to edit the document metadata.

To edit the document metadata:

1   Open the **Document properties** dialog according to the instructions in the section Editing document properties.

2   If there is a review comment, you can see it at the top of the dialog.
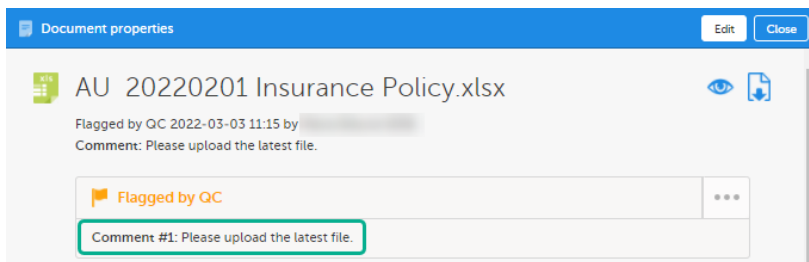
3   Select **Edit** in the top right corner of the dialog.
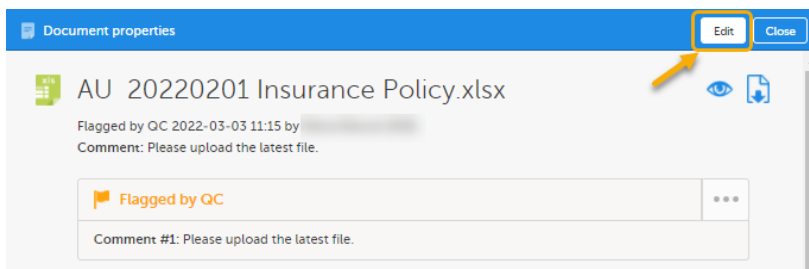
4   In the **Document properties** dialog, edit the applicable document metadata.

To upload another file, select the upload button in the **FILE INFO** area.

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

When the changes have been saved, the document status is changed to Awaiting review.
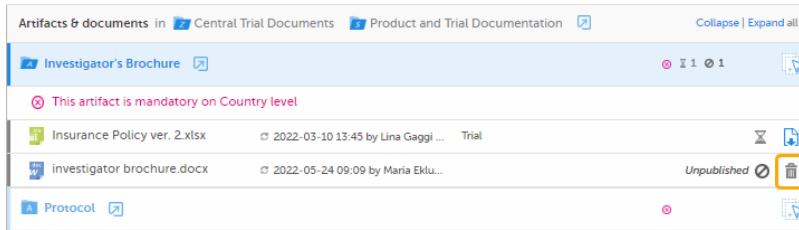
14   Deleting a document

14.1   Deleting an unpublished document

Deleting a document in Viedoc TMF requires write permission for the artifact on the TMF level that the document is linked to. For more information about permissions, see Introduction to Viedoc eTMF.
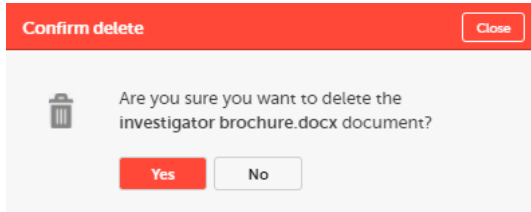
To delete an unpublished document:

1   Select the delete button in the **Artifacts & documents** area or in the **Document properties** dialog.


2   Select **Yes.**

14.2   Deleting a published document

Deleting a document in Viedoc TMF requires write permission for the respective trial, country, or site. For more information about permissions, see Introduction to Viedoc eTMF.
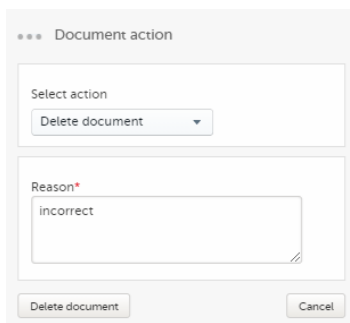
To delete a published document:

1   Open the **Document properties** dialog by selecting a document in the **Artifacts & documents** area.

2   Select to open the **Document action** dialog.
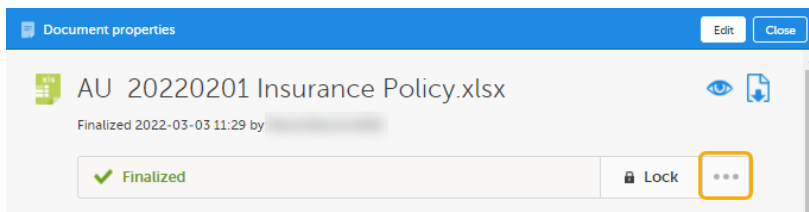
3   In the dropdown menu, select **Delete document**.

           Note! If the document has been shared and has at least one active binder, it cannot be deleted.

4   Enter a reason (mandatory).
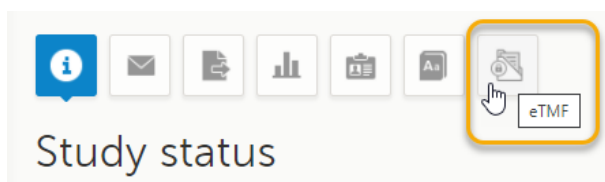
5   Select **Delete document.**

Reviewing documents

Published by Viedoc System 2023-10-09

1   Launching Viedoc eTMF

To launch Viedoc eTMF, click on the **eTMF** icon on the Viedoc landing page.

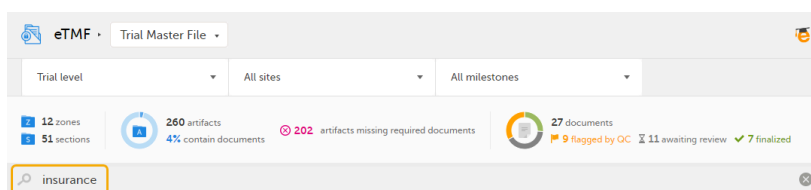**Note!** The eTMF launch icon is only available in production mode.

Reviewing a document in Viedoc eTMF requires **review** permission for the artifact on the TMF level that the document is linked to. For more information about permissions, see [Introduction to Viedoc eTMF](#).

2   Searching for documents

To search for documents in Viedoc eTMF:

1   Enter a text to search for in the **Search** field.

     The text can be an document name or a file name, or a sub-string thereof. It can also be a text or a sub-string of a text in the file contents.

2   Press Return (or Enter) or click on the magnifying glass.

3   The search results are displayed on the **Details** page, sorted by relevance.

Tip! If you hover over a zone, section, or artifact icon, its name will be displayed.

3 Reviewing a document

To review a document with the status Awaiting review:

1   Click on a document on the **Details** page to open the **Document properties** window in read-only mode.

2   Make sure that all document metadata is correct.

3   To view the the latest version of the uploaded file, click the **Preview** button in the top right corner of the window.

For more information, see [Previewing a document](#).
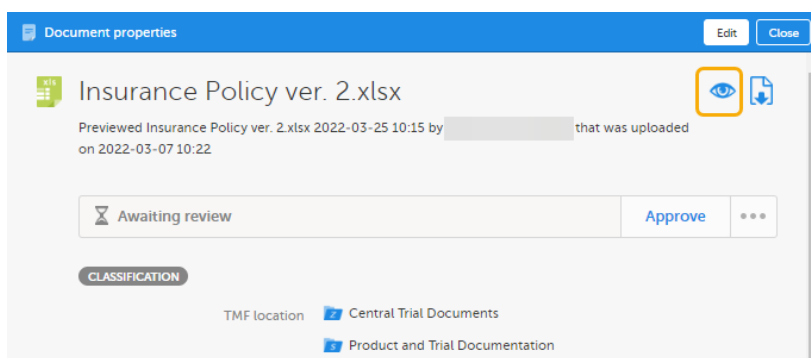
Alternatively, click the download button to download the file.
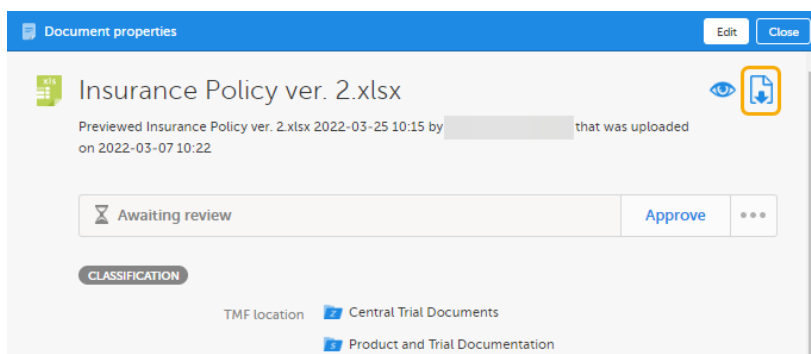
4   Review the file contents.

5   To navigate between versions of the document, use the version dropdown menu at the top of the **Document properties** dialog.

6   If you need to add a review comment, open the **Document action** window by clicking on the **Document action** button in the **Document properties** dialog:
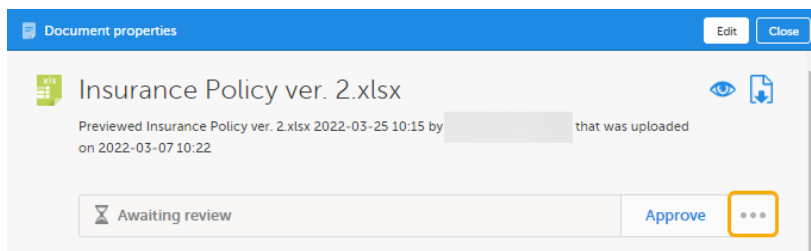
7   Select **Add review comment**.
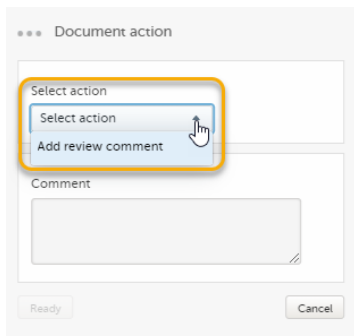
8   Add your review comment in the **Comment** field.

9   Click **Ready** to save your review comment.

Note! If you add a review comment, the document status is changed to Flagged by QC. To change the status back to Awaiting review, a user with write permission needs to edit to the document metadata or upload another file.

10   If there is no need for a review comment, the document is ready to be approved.

---

4   Approving a document

Approving a document in Viedoc eTMF requires review permission for the respective trial, country, or site. For more information about permissions, see Introduction to Viedoc eTMF.

To approve a document with the status Awaiting review:

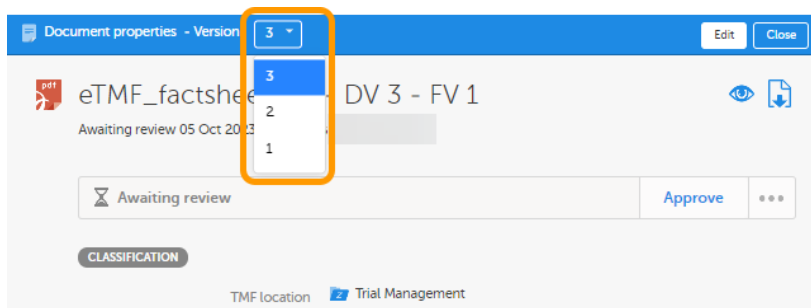**1**   Open the **Document properties** window by clicking on a document on the **Details** page.
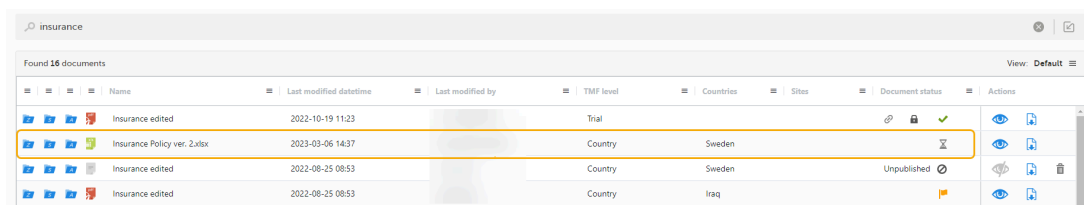
2   In the **Document properties** window, click **Approve**.
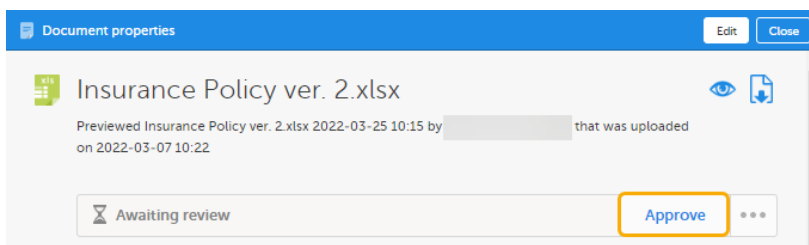
3   The document status is now Finalized.

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

5 Locking a document

To make sure no changes can be made to a Finalized document, it needs to be locked. If the eTMF is configured to *Automatically lock documents on approve*, the document will automatically be locked when it is approved. Otherwise you can lock it.

To lock a document:

1   Open the **Document properties** window by clicking on a document on the **Details** page.
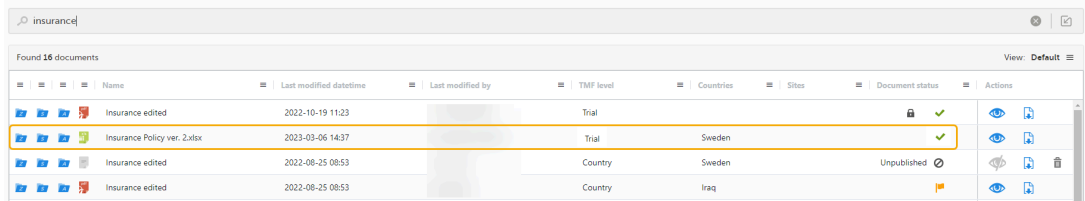
2   In the **Document properties** window, select **Lock**.
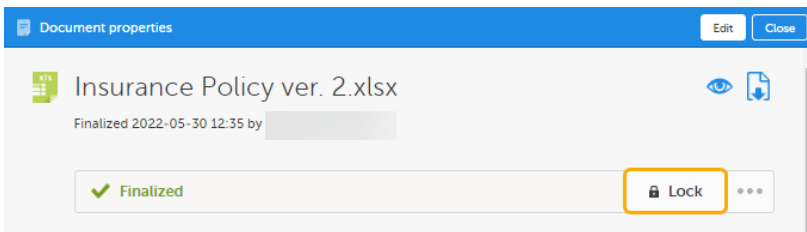
3   The **Lock** button is now changed into an **Unlock** button.

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

---

6 Unlocking a document

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

To unlock a document:

1   Open the **Document properties** window by clicking on a document on the **Details** page.
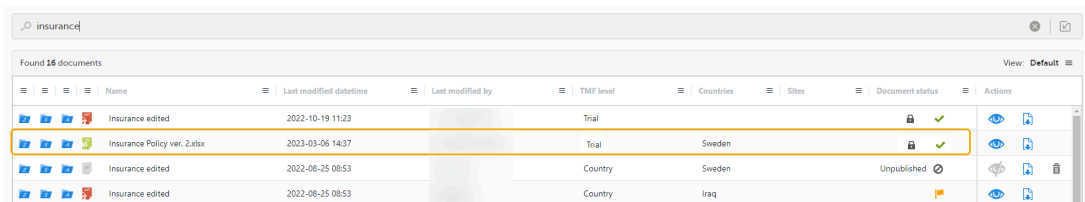
2   In the **Document properties** window, click **Unlock**.
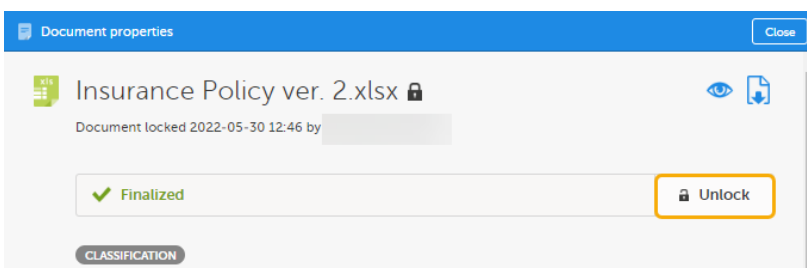
3   If the eTMF is configured such that a reason must be given to unlock the document, click the Document action button in the **Document properties** window:
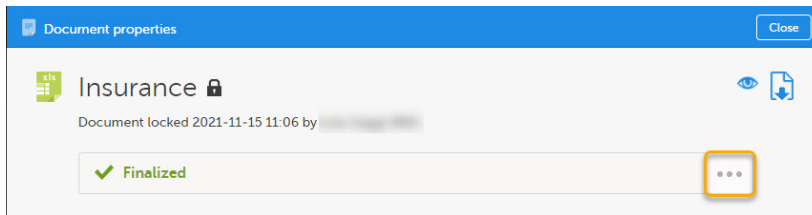
  ■ Select **Unlock**:
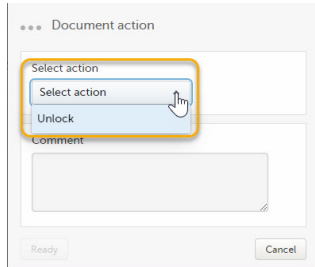
  ■ Add your reason in the **Reason** field:
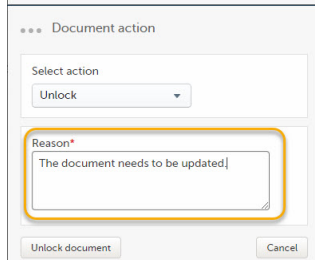
  ■ Click **Unlock document** to unlock the document:
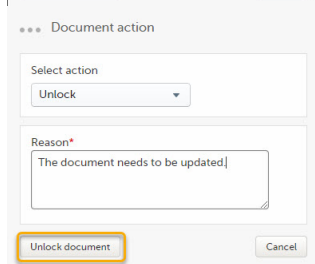
4   The document is now unlocked.

Viedoc Share

Viedoc Share

Published by Viedoc System 2025-01-14

1 Introduction

The Viedoc Share feature is available to eTMF users for sharing documents with Viedoc Me users or Viedoc Clinic users for information sharing or for collecting signatures.

2 Definitions

These concepts are used in the following text:

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

3 Prerequisites

An eTMF user can share documents if the eTMF manager assigns one of the following permissions to their role:

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

A document can only be shared if:

- the corresponding artifact has been configured for sharing (done by the eTMF Manager)
- the document is **finalized**
- the Sharer has permissions for the same scope (trial, country, site) as the Viedoc Me user or the Viedoc Clinic user

4 Workflow

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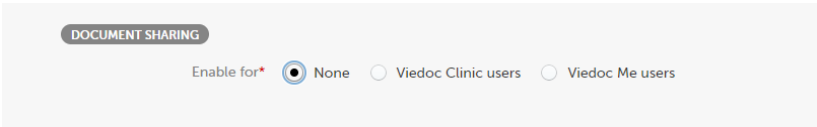   - Creates binder(s) and shares them with recipients and co-signatories
4. Recipients receive a an email with a link to Viedoc Share where they can read, complete fields, and/or and sign the document using a one-time code.
5. For Viedoc Me users, a link to Viedoc Share is also available under **Documents**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

---

5 Configuring a document for sharing

An eTMF user with WRITE access to a document must enable the sharing before other TMF end users can share the document.

To configure a document for sharing:

1	In the **Trial Master File** view, navigate to the *unpublished* document in the TMF structure.
2	Select the document to open the **Document properties** window.
3	In the **DOCUMENT SHARING** section, select the users that the document can be shared with - Viedoc Clinic users or Viedoc Me users.
4	Select **Publish** or **Save as unpublished**, depending on your needs.

Note! Only an unpublished document can be configured for sharing or have document fields added (see next section below). If a document has already been published and/or finalized, you can create a new version of the document, configure for sharing and/or add document fields, then publish and finalize again.

---
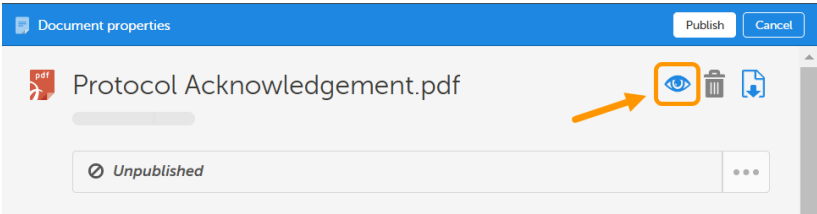
6 Adding document fields

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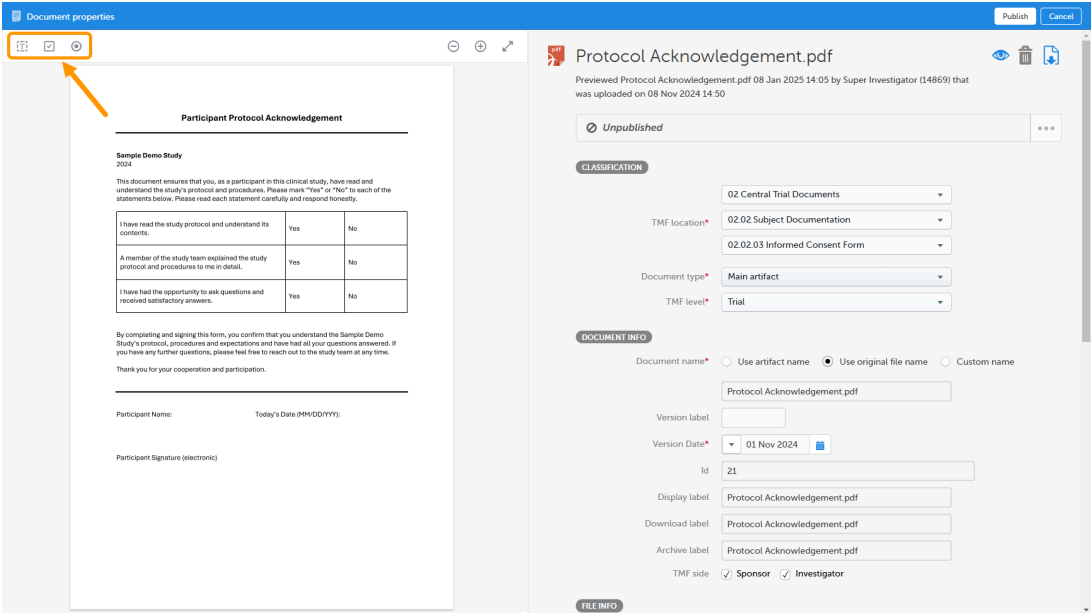
To add fields to a document:

1	In the **Trial Master File** view, navigate to the *unpublished* document in the TMF structure.

2	Select the document to open the **Document properties** window. Select the eye icon to open a preview of the document.

3	On the far left of the document, the options for adding/editing fields are displayed:
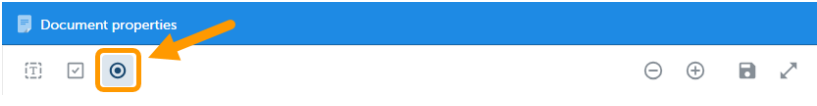
Types of document fields available:
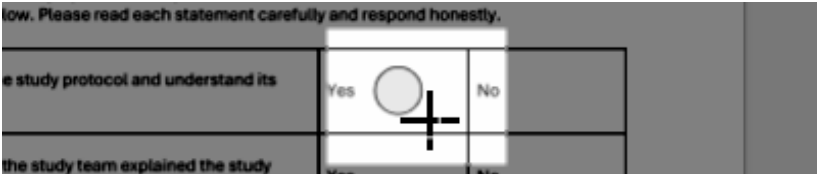
- **Radio buttons** allow recipients to select a single option from a predefined set of choices, ensuring only one selection is made.

- **Checkboxes** allow recipients to select multiple options independently from a list, allowing for one, several, or all choices to be selected.

- **Open text fields** provide recipients with a space to input free-form text, accommodating responses that require personalized or detailed information.

6.1 To create a **Radio Button**:

1	Select **Radio Button**:

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

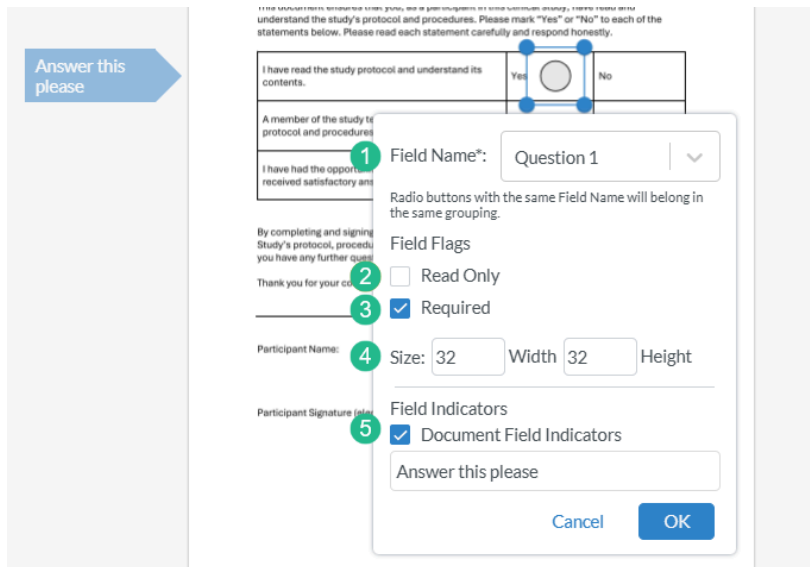| 3	Once the shape is created, an edit window is displayed:
	1. To name the radio button, click inside the text box to the right of **Field Name** and type the name (for example "Question 1". Then select the option that appears below to create the field name.
	Note! For radio buttons to function properly, options belonging to the same question must have the same field name. For example, both "yes" and "no" radio buttons belonging to the first question must both be named "Question 1", and the next set of "yes" and "no" radio buttons belonging to the second question must both be named "Question 2".
	2. Setting the field as **Read Only** will not allow the recipient to select or deselect the button
	3. Setting the field as **Required** will prevent the recipient from signing the document until all required fields have been completed.
	4. Setting the **Size** controls the size of the radio button
	5. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. Note! This may not be visible if the recipient is viewing the document on a mobile device.
4	Once all of the desired fields and settings have been completed, select **save**.

6.2   To create a checkbox:

1	Select **Checkbox**:

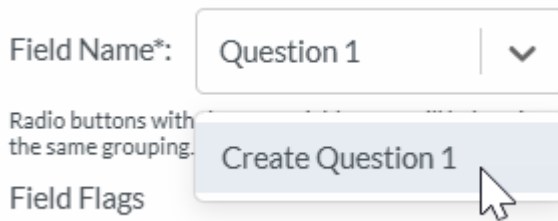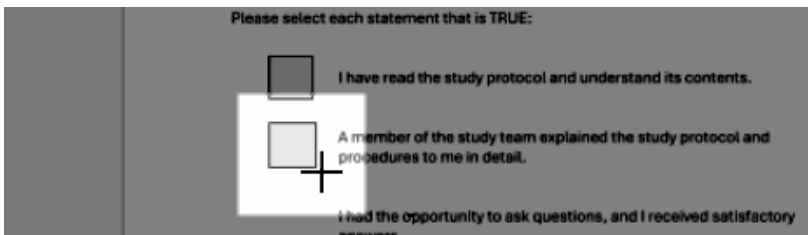|	
2	Drag the cursor to create the field shape (size and position can be edited later).
3	Once the shape is created, an edit window is displayed: **1.** To name the checkbox, click inside the text box to the right of **Field Name** and type the name (for example "CheckBox1". Note! Checkboxes must have unique field names. If you give a checkbox the same name as another checkbox in the same document, you will not be able to save the checkbox. 2. Setting the field as **Read Only** will not allow the recipient to select or deselect the checkbox. 3. Setting the field as **Required** will prevent the recipient from signing the document until all required fields have been completed. Note! If a required checkbox if left blank, the recipient will not be able to sign the document. 4. Setting the **Size** controls the size of the checkbox 5. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. Note! This may not be visible if the recipient is viewing the document on a mobile device.
4	Once all of the desired fields and settings have been completed, select **save**.

6.3 To create a **Text Field:**
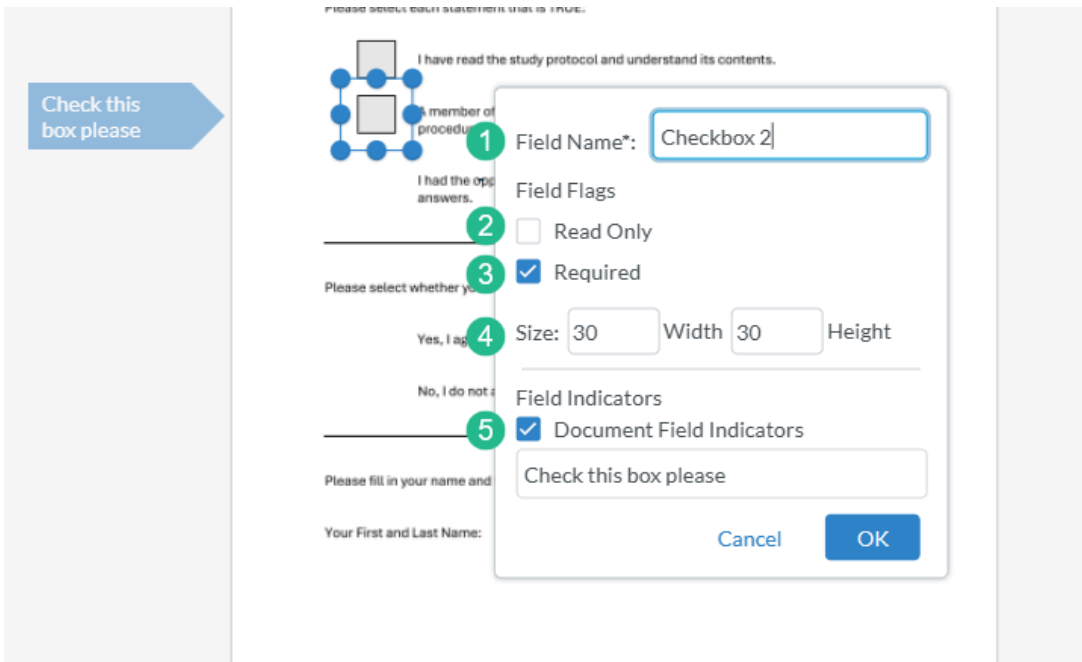
1	Select **Text Field**:
2	Drag the cursor to create the field shape (size and position can be edited later).
3	Once the shape is created, an edit window is displayed:

Edit options for the text field as needed:

1. To name the text field, click inside the text box to the right of **Field Name** and type the name (for example "TextFormField 1"). Note! Text field names do not affect the functionality as the radio button names do.

2. Entering a **Default Value** will autofill the text field with any text you enter here.

3. Setting the field as **Read Only** will not allow the recipient to type any text in the text field.

4. Setting the field as **Multiline** will allow for multiple lines of text to be entered.

5. Setting the field as **Required** will prevent the recipient from signing the document until all required fields have been completed.

6. Setting the **size** controls the size of the text field

7. Selecting **Document Field Indicators** and typing in a label creates a flag to the left of the field that the recipient will see. Note! This may not be visible if the recipient is viewing the document on a mobile device. |
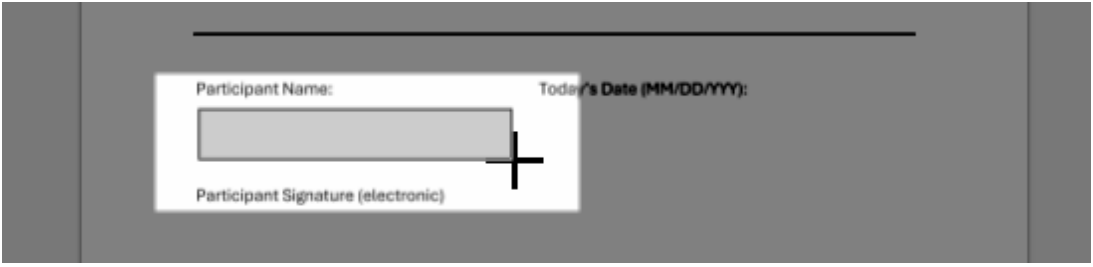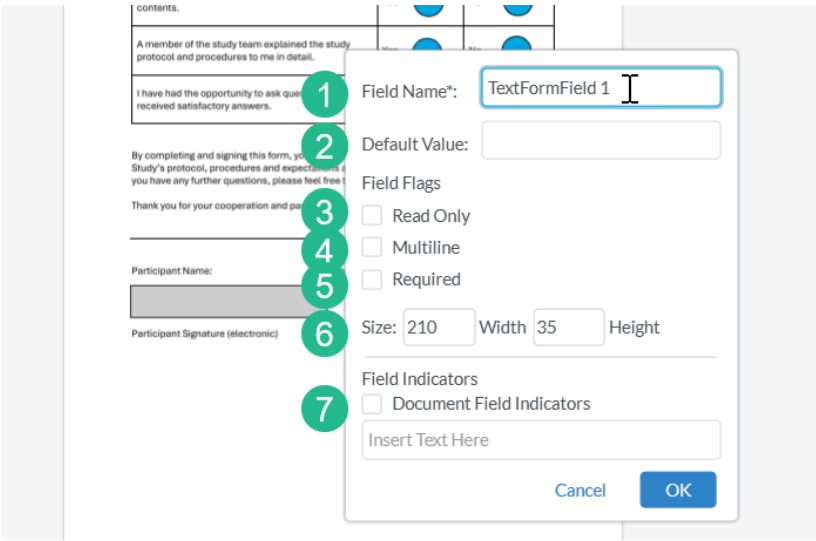| **4** | Once all of the desired fields and settings have been completed, select **save**. |

Note! Document fields and settings may be changed while a document remains unpublished. Once a document is published, fields may not be edited or added.

7 Sharing a document

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

1 In the **Trial Master File** view, navigate to the *finalized* document in the TMF structure.

2 Select the document to open the **Document properties** window.

3 In the **Sharing** section at the top of the window, select **. . .** to open the **Sharing** window.
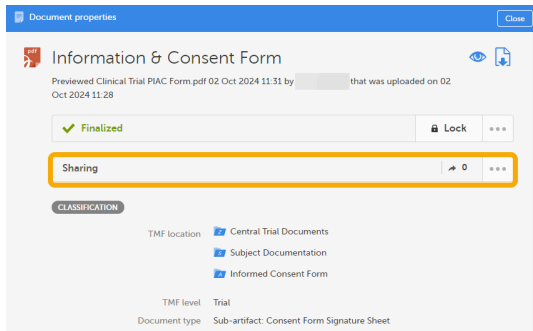
4 Select **Create a new binder**.

5 Select **Recipients > Viedoc Me users** or **Viedoc Clinic users**.
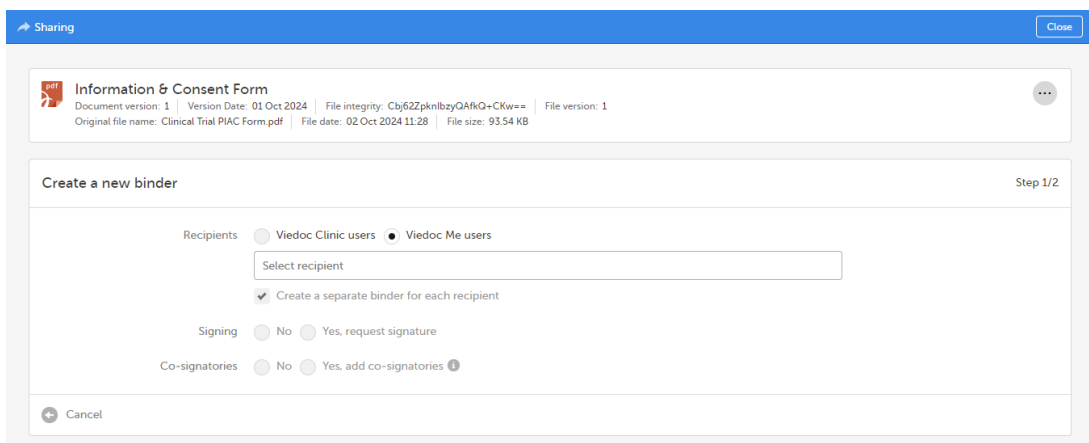
6 In the field just below, select the users that you want to share the document with.

Note! If you select more than one user, the option **Create a separate binder for each recipient** will be automatically selected and non-editable. This is because the recipients should not share any study information with each other.

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

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

7 For the **Signing** option, select whether or not to request a signature.

8 If you selected **Yes** in the previous step, select a signature reason.

9 Select whether or not a co-signatory is required.

Note! The co-signatory cannot sign the document if you selected **No** in step 7.

10	Select the co-signatory or co-signatories.
	Note! You can only select users within the same scope as yourself.

11	Select a signature reason for the co-signatory.

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

13	If the sharing details are correct, select **Confirm**.
	Otherwise, you can select **Back** and edit.

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

8   Viewing the binder properties

1	In the **Trial Master File** view, navigate to the document.

2	Select the document to open the **Document properties** window.

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

4	Select the arrow icon to open the **Binder properties** window.

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

9 Downloading the document

To download the shared document from the binder:

1   In the **Trial Master File** view, navigate to the document.

2   Select the document to open the **Document properties** window.

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

4   Select the arrow icon to open the **Binder properties** window.

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

6
- The menu item **Download original file** downloads the original file to your computer.
- The menu item **Download with sharing details** downloads a zipped folder to your computer. The zipped folder contains the original file and a PDF with the sharing details.
- The menu item **Download with signatures** downloads a PDF file to your computer. This menu item is only available if all recipients and co-signatories have signed the document. The PDF contains the original file and a cover page with the signatures. This is an example of such a cover page:

10 Revoking a binder

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

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

To revoke a binder:

1   In the **Trial Master File** view, navigate to the document.

2   Select the document to open the **Document properties** window.

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

4   Select the arrow icon to open the **Binder properties** window.
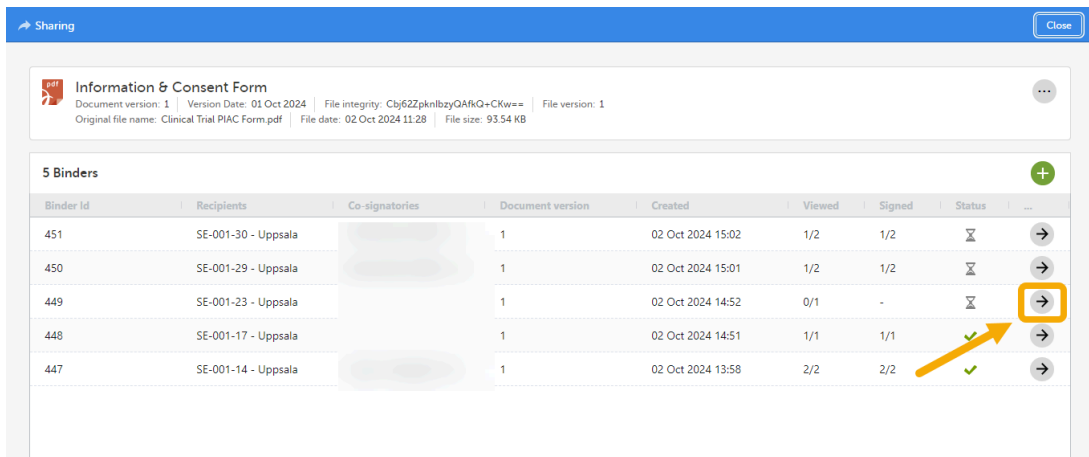
5   In the top right corner, select **. . .** to open the binder menu.
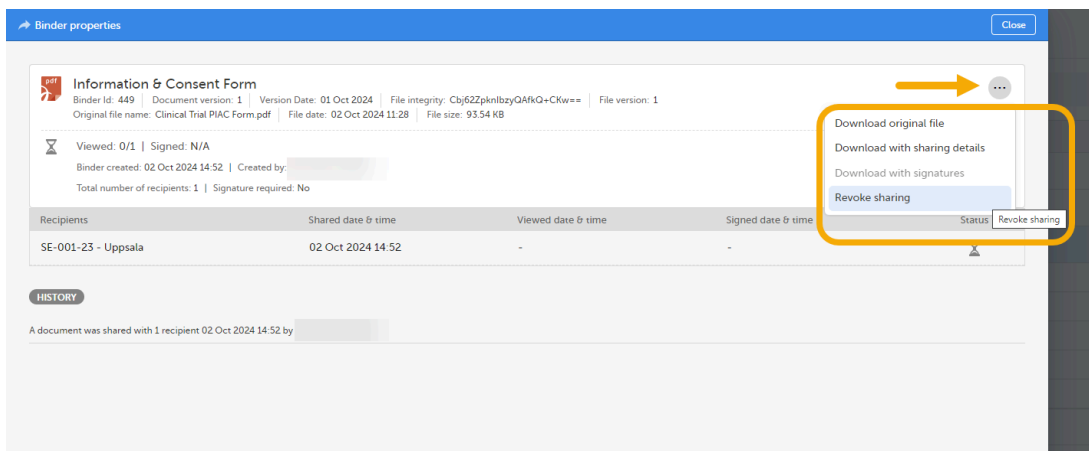
6   Select **Revoke sharing**.

7   The binder properties are displayed, and you can now see that the binder is revoked.
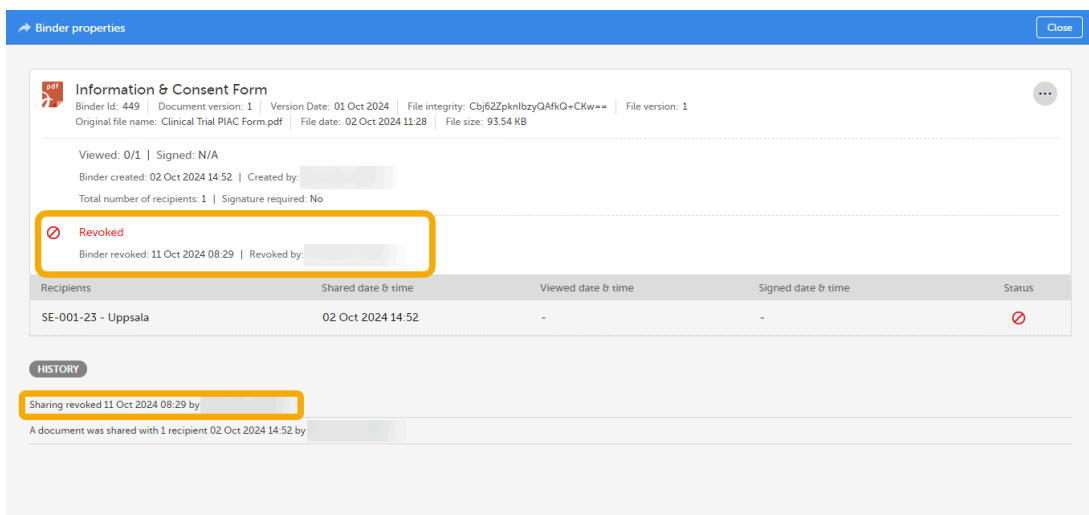
11   The Sharing section in the Document properties window

An eTMF user with Manage sharing permission will see a **Sharing** section at the top of the **Document properties** window.
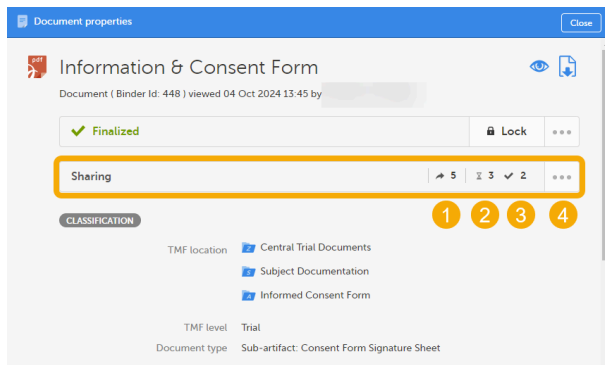
1. The number of active shared binders accessible by the Sharer.

2. The number of pending actions for binders accessible by the Sharer (only displayed if the number is greater than 0).

3. The number of actions done for binders accessible by the Sharer (only displayed if the number is greater than 0).

4. Select ... to open the Sharing window with an overview of the existing binders. This is also where new binders can be created.

TMF Archive

TMF Archive

Published by Viedoc System 2024-10-11

---

1   Complete audit trail report

1.1   Introduction

The complete audit trail report is in Excel format. It includes a complete list of actions done on:

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

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

1.2   Generating and downloading the report

To generate the complete audit trail report:

1   Set the options (a) for the documents' audit trails to be included. You can choose to include documents that are filed on trial/country/site levels according to your permissions to those.

2   Set the milestones/milestone groups (b) you would like to filter by.

3   Click **Generate**.

4   Click on the generated document link to download the report (c).

1.3   Included sheets

Each sheet in the complete audit trail report corresponds to the actions done by users on a certain view or section, as shown in the following table:

Templates Management

eTMF ▸ TMF Admin ▾

TMF structure | **Templates** | Settings

Organization templates 2 templates

NoneDevice
Imported 2021-08-05 14:19 by
11 zones - 50 sections - 262 artifacts
Manage | Export   ✓ Select

new org template
Renamed 2021-08-04 15:03 by
2 zones - 3 sections - 6 artifacts
Manage | Export   ✓ Select

Study templates 1 template

NoneDevice
Imported 2021-08-06 10:45 by
11 zones - 50 sections - 262 artifacts
Manage | Export   ✓ Select

© Viedoc Technologies AB 2021 Terms of Use · Privacy Policy
Viedoc™ version 4.67.2108.150 [2021-08-06T11:39 UTC]

Structure Management

eTMF ▸ TMF Admin ▾

TMF structure | Templates | Settings

NoneDevice [customized]
Last modified 2021-08-06 10:53 by
MAINTENANCE ⬤

10 **Milestones**   View

TMF structure 11 zones - 50 sections - 262 artifacts

Z **Trial Management**
Z **Central Trial Documents**
Z **Regulatory**
Z **IRB or IEC and other Approvals**
Z **Site Management**
Z **IP and Trial Supplies**
Z **Safety Reporting**
Z **Central and Local Testing**
Z **Third parties**
Z **Data Management**
Z **Statistics**

Export structure

Archive Management

eTMF ▸ **TMF Archive** ▾	

ℹ The file is available for download until a new file is generated. Make sure to download the existing file if you need it. Generating a new file will replace the existing one.

Generate a new file

⦿ Audit trail report

Include

Trial level documents:	Trial level ✕
Country level documents:	All countries ✕
Site level documents:	All sites ✕
Filter by milestones:	All milestones ✕

Generate

Settings Management

eTMF ▸ **TMF Admin** ▾

TMF structure	Templates	Settings	Status

Filters

☑ Enable milestones filter

Review process

☐ Automatically lock documents on approve   ☐ Give reason for unlocking documents

Drop zone

☑ Enable shared drop zone   ☑ Enable private drop zone

Document name templates

Display template:	{CountryCode} {SiteCode} {DatingCo	ℹ
Download template:	{StudyName} - {CountryCode}{SiteCc	ℹ
Archive template:	{DocumentName}	ℹ

Status Management

The report is self-explanatory, but in the following sections you can find detailed information about each sheet in the file:

1.3.1 Report Info

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

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

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

1.3.2 Trial Master File

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

- Published documents only.
- Documents that are linked to a level (Trial/Country/Site) that the user chose to include and are filed to an artifact that is linked to a milestone that the user has filtered by.
- Documents that the user has at least READ access to.

1.3.3 Sharing

This sheet includes information about all user actions on binders in Viedoc Share and Viedoc TMF.

Note! The sheet only include actions on the binders that the archivist has access to.

1.3.4 Templates Management

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

1.3.5 Structure Management

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

Structure Management sheet

Action	Structure Version	Date/time	Identifier	Old Value	New Value	Done By
				User Actions on Structure		
Delete artifact	2	2021-08-17 11:21:50	01.01.01	Trial Master File Plan		
Delete artifact	2	2021-08-17 11:21:50	01.01.02	Trial Management Plan		
Apply changes	2	2021-08-17 11:21:50		None Device	None Device [customized]	
Add zone	1	2021-08-16 11:29:23	01		Zone name = Trial Management	
Add section	1	2021-08-16 11:29:23	01.01		Zone name = Trial Management Section name = Trial Oversight	
Add artifact	1	2021-08-16 11:29:23	01.01.01		Zone name = Trial Management Section name = Trial Oversight Artifact name = Trial Master File Plan Definition = To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc. Sub artifacts = Core Document List, TMF Report, TMF Transmittal Form, TMF Setup Request Sponsor document = X Investigator document = NO Trail level document = YES Country level document = NO Site level document = NO Dating convention = Version Date	

Tabs: Report Info | Trial Master File | Templates Management | Structure Management | Archive Management | Settings Management

1.3.6 Archive Management

This sheet includes this user actions done on the TMF Archive page.

Archive Management sheet

Action	Date/time	Included Documents	Filtered By	TMF Side	Done By	User Roles	User Permissions
			User Actions				
Create audit trail report	2021-08-06 09:20:54	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail
Download audit trail report	2021-08-06 06:25:39	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail
Create audit trail report	2021-08-06 06:24:52	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail
Download audit trail report	2021-08-05 09:45:04	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail
Download audit trail report	2021-08-05 09:44:57	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail
Create audit trail report	2021-08-05 09:44:25	Trial level, All countries, All sites	All milestones			Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail

User log on TMF Archive.

Tabs: Report Info | Trial Master File | Templates Management | Structure Management | Archive Management | Settings Management

1.3.7 Settings Management

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

1.3.8 Status management

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

2 eTMF-EMS repository

2.1 Introduction

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

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

2.2 Generating and downloading the EMS repository

To generate the repository:

1	Set the options (1) for the documents you want to include in the archive. You can choose to include documents that are filed to the investigator or sponsor side of the eTMF, and documents that are filed on trial/country/site levels according to your permissions to those.
2	Set the milestones-milestone groups (2) you would like to filter by.
3	Click **Generate** (3).
4	Click the generated document link to download the zipped folder (4).
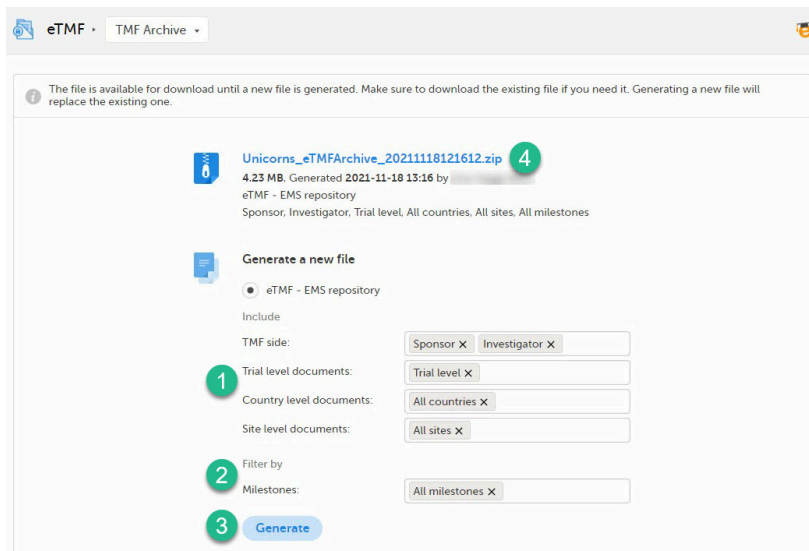
2.3   The zipped folder structure and content

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

- **Level 1** – this level includes:
    - The main zipped folder with a name in the format:
      `StudyName_eTMFArchive_DatetimeStamp`
        - `StudyName` - the study name
        - `eTMFArchive` - static text
        - `DatetimeStamp` - the UTC date and time of generating the eTMF-EMS repository in the format `YYYYmmDDHHMMss`

- **Level 2** – this level includes:
    - A subfolder that has the name TransferID (datetime stamp of generating the eTMF-EMS repository) in the format `YYYYmmDDHHMMss`
    - An exchange.xml file for each chosen milestone. You can read about the content of the xml files and find an example [here](#)
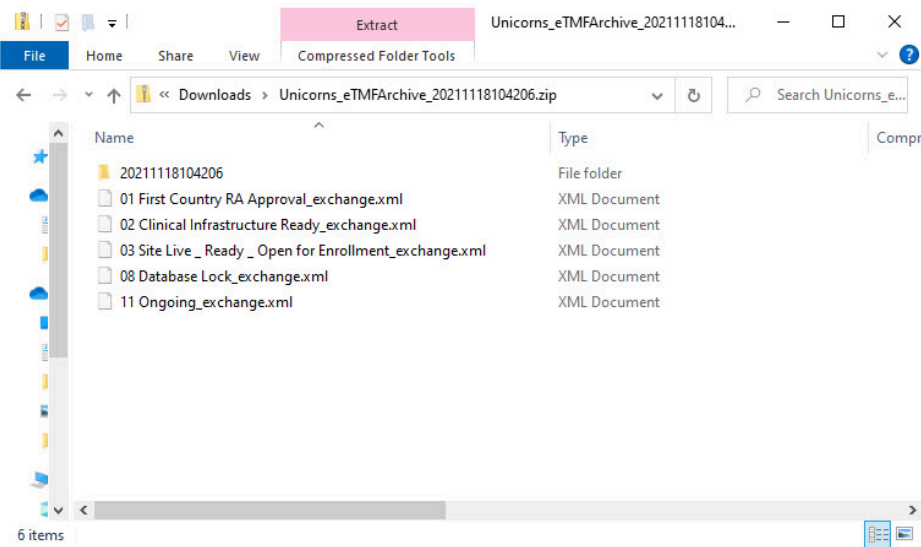
- **Level 3** – this level includes:
  - A folder with `ZoneID.ZoneName` for each included zone from the structure
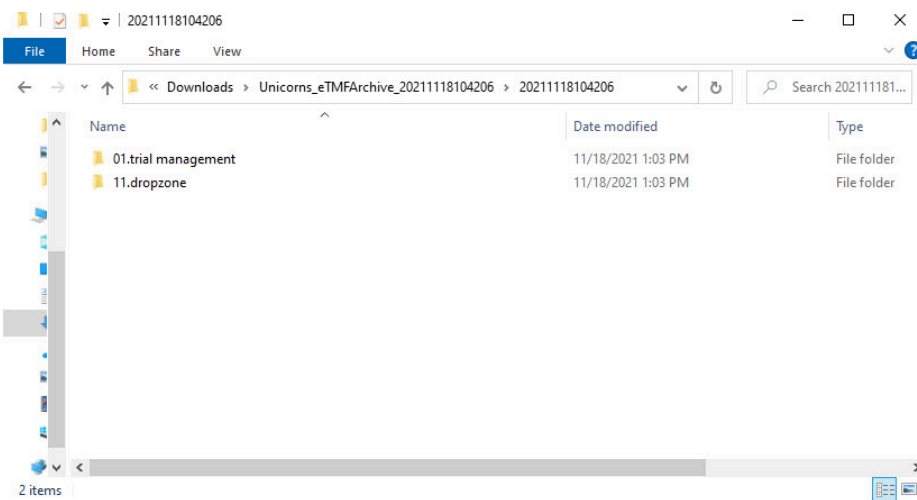
- **Level 4** – this level includes:
  - A folder with `ZoneID.SectionID.SectionName` for each included section from the structure
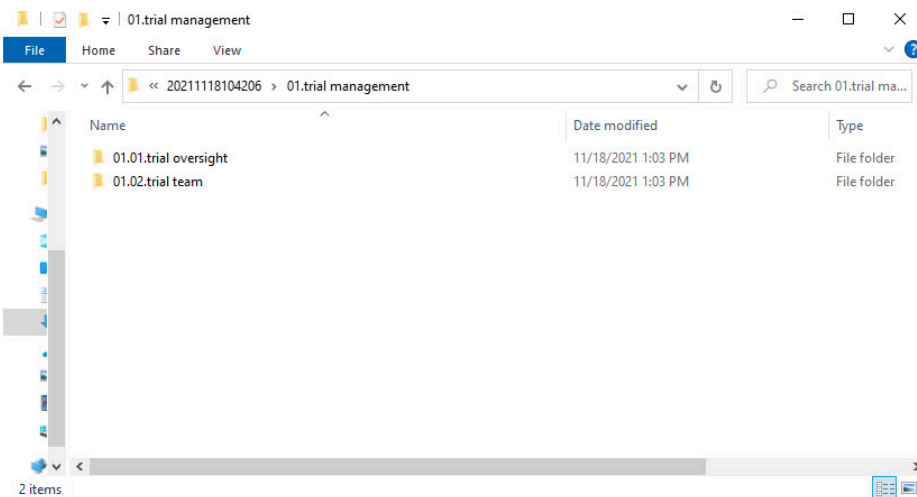
- **Level 5** – this level includes:
  - A folder with `ZoneID.SectionID.ArtifactID.ArtifactName` for each included artifact from the structure
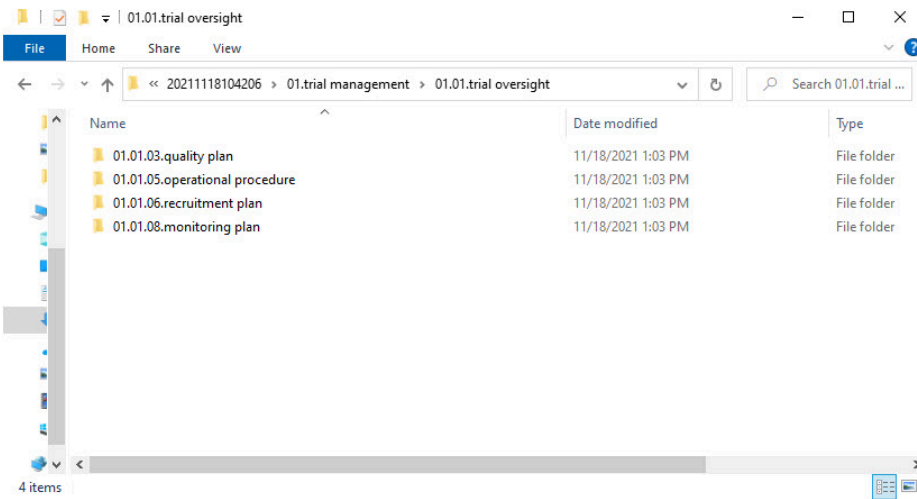
- **Level 6** – this level includes:
    - Documents filed to this artifact on trial level
    - A subfolder for signed documents*
    - Subfolders for included countries with country code as their names
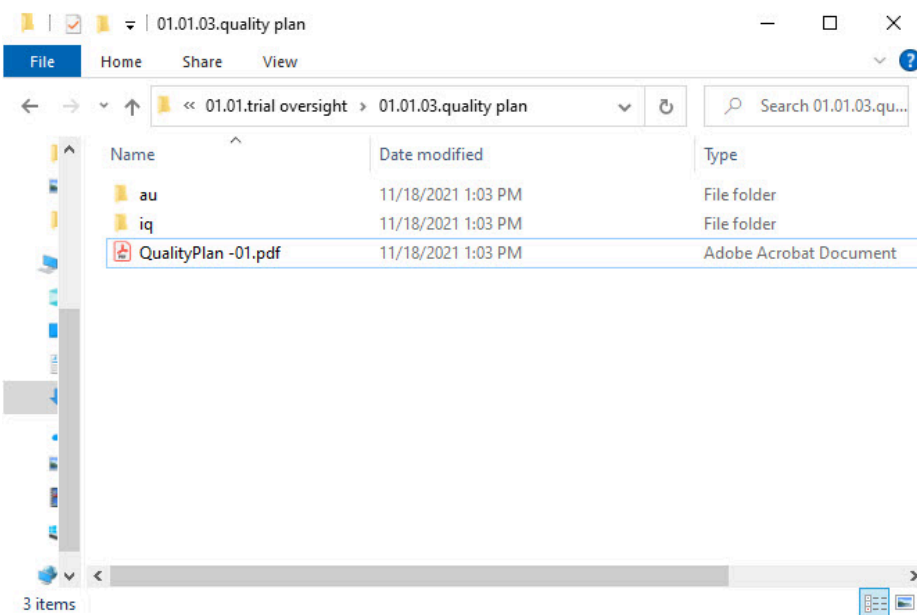
- **Level 7** – this level includes:
    - Documents filed to the artifact and linked to this specific country
    - A subfolder for signed documents*
    - Subfolders for sites in this country with site names as their names
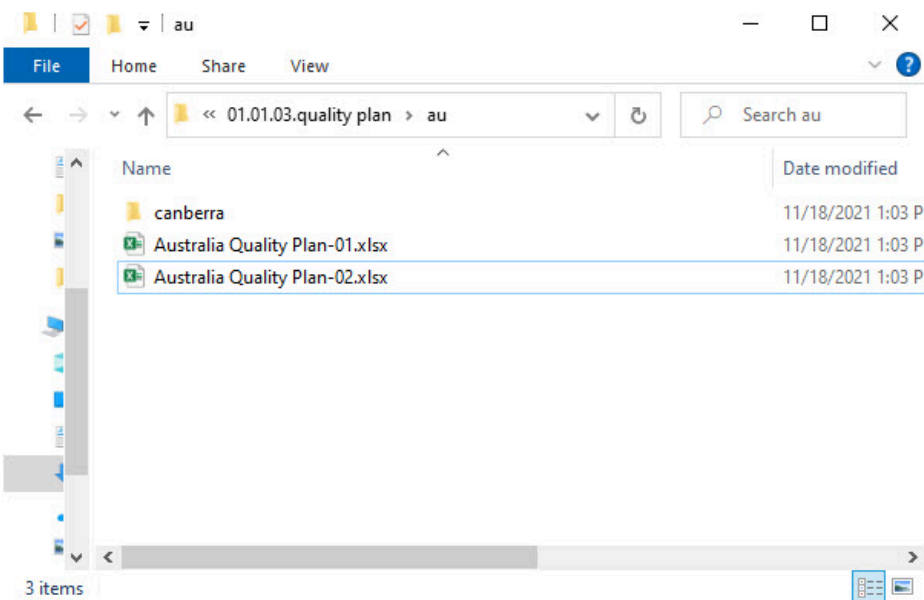
- **Level 8** – this level includes:

- A subfolder for signed documents*
- Documents filed to the artifact and linked to this specific site
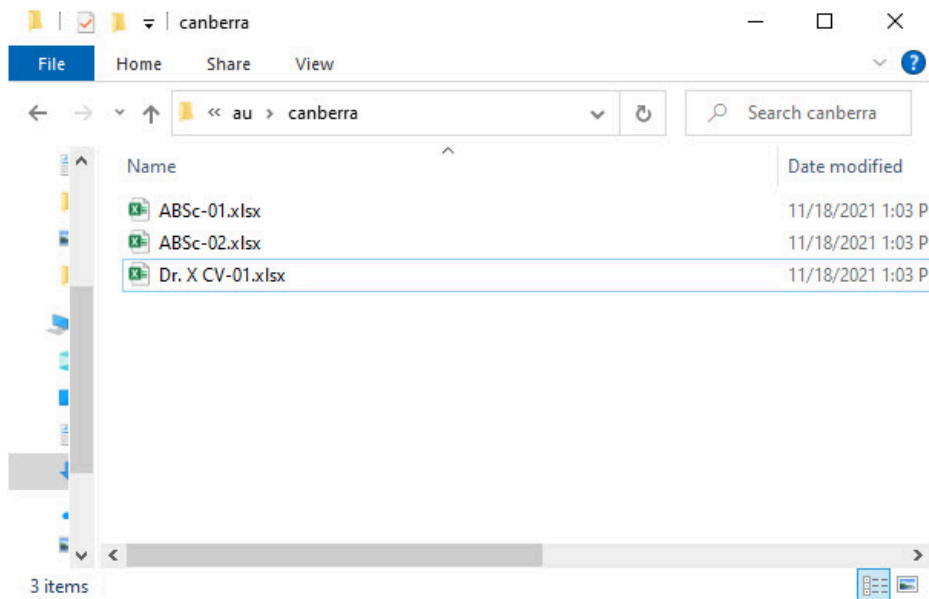
*The files that are signed by Viedoc Me users are only included when archiving the Investigator side of the TMF.

The zipped folder includes all the versions of documents included in the structure. The name of the files will be as follows:
`CurrentDocumentName-SystemVersion.extension` , where:

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

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

eTMF access use cases

Published by Viedoc System 2023-03-07

1   Study roles, eTMF roles, and permissions

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

For more information about site groups, see [Managing users](#) and [Managing study sites](#).

Study role	Task	eTMF role	Viedoc Clinic site group	eTMF level access	Permissions	Comments
Study coordinator General site user	Drop documents 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 documents, 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	

Study role	Task	eTMF role	Viedoc Clinic site group	eTMF level access	Permissions	Comments
Project manager	File study-level documents, view all sponsor-side documents, 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.
Monitor	File site-level documents, view all documents for the study, my country, and my site, manage drop zone documents, review site level documents	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 documents too, the end user will only have read rights to those documents, 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 documents, view all sponsor-side documents at all levels and review all documents	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	eTMF role	Viedoc Clinic site group	eTMF level access	Permissions	Comments
Read-only role Regulatory inspector	Read-only access to all documents* 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 documents only on all levels	Sponsor unblinded	All production sites*	Write access to blinded documents on study level and site level (when applicable) No access to non-applicable documents 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.

2 Scenarios

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 documents in the drop zone.	- The user is invited to a clinic role for a specific site. - The eTMF role mapped has NO ACCESS for all levels and artifacts.
eISF: As a **General site user**, I want to be able to file pre-defined documents on site level, view some artifacts on study and country levels and archive the Investigator site TMF/eISF.	- The user is invited to a clinic role for a specific site. - The eTMF 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 eTMF 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.
As a **Project manager**, I want to be able to file documents at study level, view all sponsor-side documents at all levels in the study, archive the TMF (sponsor side), download the audit trail, and see the TMF settings and structure.	- The user is invited to a clinic role that has a mapped eTMF 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 eTMF 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.
As a **Monitor**, I do not have access to patient information documents on site level. I file site-level documents that belong on the sponsor-side TMF, view documents for my country and the study, manage drop zone documents, and review site-level documents.	- The user is invited to a clinic role that has a mapped eTMF 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 an eTMF 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 eTMF 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 documents at country level, view all sponsor-side documents at all levels in the study, and review all sponsor-side documents.	■ The user is invited to a clinic role that has a mapped eTMF 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 an eTMF 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 documents 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 documents (sponsor side and investigator side), TMF settings, and access to the audit trail.	■ The user is invited to a clinic role that has the mapped eTMF 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 documents only on all levels.	■ The user is invited to a clinic role that has a mapped eTMF 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 documents 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 eTMF role with at least Read to the artifact at the expected level.	Invite the user to a clinic role with a mapped eTMF 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 documents 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 eTMF role with Write access to the artifact at the expected level.	Invite the user to a clinic role with a mapped eTMF 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 documents) or Study level, All production sites (for write permission to Study level documents), 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 documents) or Study level, All production sites (for write permission to Study level documents).

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 eTMF role with Review access to the artifact at the expected level.	Invite the user to a clinic role with a mapped eTMF 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 documents) or Study level, All production sites (for review permission to Study level documents, 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 documents) or Study level, All production sites (for write permission to Study level documents).

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

Check	To resolve
Check that the user is invited to a clinic role with a mapped eTMF 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 documents but not see applicable artifacts or not choose the wanted TMF level when classifying the document?

Check	To resolve
Check that the user is invited to a clinic role with a mapped eTMF role with Write access to the artifact at the expected level.	Invite the user to a clinic role with a mapped eTMF 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 documents) or Study level, All production sites (for write permission to Study level documents, 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 documents) or Study level, All production sites (for write permission to Study level documents).