viedoc learning"

Viedoc eTMF User Guide

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Introduction to Viedoc eTMF

Introduction to Viedoc eTMF

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 1. Overview

 2. Roles and permissions

 2.1 eTMF roles

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Viedoc <u>eTMF</u> 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 (<u>DIA</u>). 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

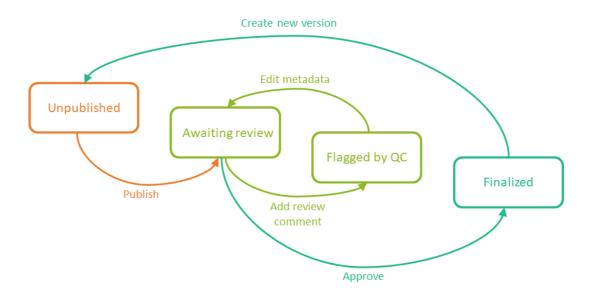
This permission gives the mapped user role access to manage the files in the shared drop zone.

Notel For more information about permissions and accesses, see eTMF access use cases.



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.

Notel 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:

eTMF ► Trial Maste	er File 🔹			1
All documents	▼ All s	ites 3	_	
2 12 zones 5 51 sections	260 artifacts 4% contain docume	② 202 artifacts missing required documents 28 documents P 9 flagged by OC I 12 awaiting review ✓ 7 finalized	6	
Search documents			8	0
Drop Zone 9	#	Artifacts & documents in ಶ Central Trial Documents 📑 Product and Trial Documentation 🗵 🚺	Collapse	Expand a
< Shared	2	Investigator's Brochure 🕞 12	⊗ ✔1 ⊘1	ų.
👗 Private	2	Protocol 🗵	8	
Zone & sections 10	P 🛛 🗸 Ø			
Z Trial Management	⊗ 8 7 4 1	N Protocol Synopsis 🗩	8	4
🔁 Central Trial Documents	⊗ 0 0 3 3	🚺 Protocol Amendment 🛛	8	1
Product and Trial Documentation	⊗ 0 0 3 3	Financial Disclosure Summary 🗩		
s Subject	⊗ 0 0 0 0	Insurance 🗩	⊗ ✔ 2 Ø 1	ļ
Documentation		Sample Case Report Form	8	ų.
	⊗ 0 0 0 0			
Documentation	⊗ 0 0 0 0⊗ 0 0 00 0 0	Report of Prior Investigations (7)	8	

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</u> <u>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.

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



Previewing a document

Previewing a document

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<u>1. Previewing a document</u> <u>1.1 Supported filetypes</u> <u>1.2 Audit trail</u>



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:

Lop Zone (Private)			Cancel
altenkirchen.xlsx Uploaded 2022-03-02 10:54 by CLASSIFICATION		٢	
	Select Zone	•	
TMF location*	Select Section		

2 The preview opens in the left pane of the dialog.

🎽 Drop Zone	[Private]					Cancel
	4	4	⊝ ⊕	altenkirchen Uploaded 2022-03-02 :	10:54 by	o 🏛 🖡
	5	5			Select Zone	•
	7	7		TMF location*	Select Section	·
	8	8			Select Artifact	*
	10	10				

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

🛓 Drop Zone [Private]		
		\bigcirc \oplus

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

👗 Drop Zone [Private]		
		\ominus \oplus
89	9 89	
90	0 90	
9:	1 91	
92	2 92	
93	3 93	
94	4 94	
9	5 95	_
90	5 96	
9	7 97	
98	8 98	
99	9 99	
100	0 100	
10	1 101	
102	2 102	
103	3 103	
104		
10	5 105	- I

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
- pdfpng
- ppt
- pptx
- tif
- tiff
- txt
- xls
- xlsx
- xmlzip

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

Document properties			Cancel
Uploaded as Unpublished 2022-0	5 5		Preview is not supported for this filetype. Please download the file to review it.
TMF location*	02 Central Trial Documents 02.01 Product and Trial Documentation	• •	
	02.01.11 Marketed Product Material	•	

1.2 Audit trail

All preview actions are logged in the audit trail. For more information, see $\underline{\mathsf{TMF}}$ Archive.



Managing documents

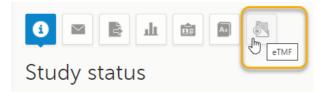
Managing documents

Published by Viedoc System 2024-10-11

1. Launching Viedoc TMF 2. Uploading a document 3. Working with drop zones 3.1 Uploading a file 3.2 Deleting a file 3.3 Downloading a file 3.4 Moving a file 4. Searching for documents 5. The Details page 5.5 The View menu 5.6 Sorting the column contents 5.7 Pinning a column to the left or the right 5.8 Autosizing columns 5.9 Filtering out data 5.10 Selecting which columns to display 5.11 Copying data 5.12 Exporting data 5.13 The columns on the Details page 6. Downloading a document 7. Editing document properties 8. Creating a new version of a document 9. Navigating between document versions 10. Adding notes to a document version **11. Resolving notes** 12. Publishing a document 13. Resolving issues for documents that are flagged by QC 13.14 Locating the documents that are flagged by QC 13.15 Resolving issues 14. Deleting a document 14.16 Deleting an unpublished document 14.17 Deleting a published document

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 <u>Introduction to Viedoc eTMF</u>.

2 Uploading a document

To upload a document:

1 In the Artifacts & documents area, select the upload button for the artifact:

Artifacts & documents in 📷 Central Trial Documents 👔 Product and Trial Documentation 🧔	Collaps	e Expand all
Investigator's Brochure	⊗ ⊻1	A +
Protocol 🗵	0	-53
Protocol Synopsis 🔊	۲	-53
Protocol Amendment	۲	.5

Notel 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 <u>Working with drop zones</u>.

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 <u>blacklisted</u>.
- 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.

Artifacts & documents in 🝺 Central Trial Documents 👔 Product and Trial Documentation 🦻	Collapse	e Expand all
🗾 Investigator's Brochure 🛛	⊗ ∑1 ⊘1	5
⊗ This artifact is mandatory on Country level		
Insurance Policy ver. 2.xlsx @ 2022-03-10 13:45 by Trial		X 🕽
investigator brochure.docx C 2022-05-24 09:09 by	Unpublish	hed Ø 💼
A Protocol 3	0	±2+
Reveal Synopsis 3	۲	- L
A Protocol Amendment 🕢	0	-
lotes!		

- 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.

Drop Zone	#	Files in 👗 Drop Zone [Private] 🛛 🦻		
< Shared	2		Drag-and-drop or click to upload files	
👗 Private	3		14.96 bing and alop of ellen to aprove mes	
Zone & sections	⊨ I ✓ Ø	contract.txt	© 2022-03-04 09:48 by	俞
7 Trial Management	⊗ 8 6 4 1	altenkirchen.xlsx	☐ 2022-03-02 10:54 by	â
Z Central Trial Documents	◎ 1 1 1 2	How to populate a range item.txt	@ 2022-03-0210:38 by	â
Regulatory this is edited	◎ 0 0 0 0			
IRB or IEC and other Approvals	◎ 0 0 0 0			
2 Site Management	⊗ 0 0 0 0			
IP and Trial Supplies	◎ 0 0 0 0			
Z Safety Reporting	◎ 0 0 0 0			
Central and Local Testing	◎ 0 0 0 0			
Z Third parties	00000			

- 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.

Drop Zone	#	Files in 👗 Drop Zone (Private) 🗵	
< Shared	1	Desc and deep as slighted uplead files	PDF
👗 Private	2	Drag-and-drop or click to upload files	PDF
Zone & sections	P I 🗸 Ø	Contract.txt C 2022-03-04 09:48 by	+ Copy
Trial Management	⊗ 8 6 4 1	altenkirchen.xlsx Ø 2022-03-02 10:54 by	â
Central Trial Documents	⊗ 1 1 1 3		

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.

		#	F	iles in 👗 Drop Zone [Private]	Л	
		2			Drag and drap or click to uply	and files
		3			High Drag-and-drop of click to upin	Jau mes
P	X	~ e	,	contract.txt	© 2022-03-04 09:48 by	â
۰ ه	6	4 1	Ŀ	altenkirchen.xlsx	© 2022-03-02 10:54 by	
0 1	1	1 2		How to populate a range item.txt	© 2022-03-02 10:38 by	D
	08	⊗ 8 6	2 3 ► X ✔ @ ⊗ 8 6 4 1	# F 2 3 ▶ X ✓ Ø 0 8 6 4 1 0 1 1 2	2 3 ♥ ∑ ♥ Ø 0 8 6 4 1 1 40w to populate a range item txt	2 3 Contract.kt □ 2022-03-04 09-48 by ○ 8 6 4 1 W to populate a range item kirchen xisx □ 2022-03-02 10.58 by

2 Alternatively, open the file by selecting it, and then select the trash can button in the dialog.

👗 Drop Zone [Private]			Cancel
2112.jpg Uploaded 2021-11-16 10:	34 by		• 📋 ᠺ
CLASSIFICATION			
	Select Zone	•	
TMF location*	Select Section	•	
	Select Artifact		
FILE INFO			
Original file name	2112.jpg		
File date	2021-11-16 10:33		

3 Confirm the deletion.

Confirm o	delete			Close
Î	Are you sure 2112.jpg? Yes	e you want t No	to delete the file	

3.3 Downloading a file

To download a file from a drop zone:

1 Open the file dialog by selecting the desired file.

Drop Zone	#	Files in 👗 Drop Zone (Private) 🛛 🗵	
< Shared	1	Drag-and-drop or click to upload files	
👗 Private	3	et grand-and or click to upload lites	
Zone & sections	⊨ ⊻ ✔ Ø	Safety meeting notes updated.xlsx a 2022-05-24 09:32 by	₿
Z Trial	08641	Contract.txt	Ê
Management Central Trial	-	3 altenkirchen.xlsx C 2022-03-02.10:54 by	Ê
Documents	◎ 1 1 1 3		

2 Select the download button in the file dialog.

👗 Dro	op Zone [Private]			Cancel
	Safety meetin Uploaded 2021-11-16 12:	ng notes updated.xlsx 20 by		• 🖬 💽
	CLASSIFICATION			
		Select Zone	•	
	TMF location*	Select Section	*	
		Select Artifact	•	
	FILE INFO			
	Original file name	Safety meeting notes updated.xlsx		
	File date	2021-11-16 12:20		

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.

Drop Zone				#	Files in 👗 Drop Zone [Private] 🛛 🗵	
< Shared				1	The Drag and drag or click to upload files	
👗 Private				3	Drag-and-drop or click to upload files	
Zone & sections		X	~	0	Safety meeting notes updated.xlsx @ 2022-05-24 09:32 by	會
Z Trial	0.8	6	4	1	contract.txt	â
Management					altenkirchen:xlsx @ 2022-03-02.10:54 by	俞
Central Trial Documents	⊚ 1	1	1	3		

2

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

Lop Zone [Private]		Save as unpublished	Cancel
Safety meeti Uploaded 2021-11-16 12	ng notes updated.xlsx	•	i
CLASSIFICATION			
	07 Safety Reporting	·]	
TMF location*	07.03 General	•	
	07.03.03 Meeting Material	•	
Document type*	Select document type	•	
TMF level*	Select level	•	
DOCUMENT INFO	O Use artifact name O Use original file name O C	Custom name	
	Safety meeting notes updated.xlsx		
Version			
Meeting Start Date*	× ii		
FILE INFO			
Original file name	Safety meeting notes updated.xlsx		
File date	2021-11-16 12:20		

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

The properties of that artifact will then be populated in the 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.

👗 Drop Zone [P	Private]			[Save as unpublished	:
				ing notes updated.xlsx 220 by	• 💼 🖡	
CLASSI	FICATIO	N				
				07 Safety Reporting		
	TMFI	locati	ion	07.03 General		
				07.03.03 Meeting Material		
D	ocume	ent ty	/pe	Select document type		
	TI	MF le	vel	Select level		
DOCUM	MENTIN	FO				
	ocumer		me	Use artifact name 💿 Use original file name 🕓 Cu:	stom name	
				Safety meeting notes updated.xlsx		
		Vers	sior			
Mee	ting Sta	art Da	ate	v iii		
	Ē					
FILE INI	FO					
Or	riginal f	file na	ame	Safety meeting notes updated.xlsx		
		File o	date	2021-11-16 12:20		
Drop Zone		#		Artifacts & documents in 波 Safety Reporting 📑 General 🗔	Collapse Expan	d all
< Shared		1		Relevant Communications 🕞	0	E
👗 Private		2	2	Tracking Information		<u>حا</u>
Zone & sections	M 3	e 🗸 (0	Meeting Material	Ø Ø 1	
Z Trial Management	⊗ 8 (54	1	This artifact is mandatory on Trial level		4772
Z Central Trial Documents	⊗ 1 1	1 1	3	Safety meeting notes upda g	Unpublished Ø	â
 Regulatory this is edited 	000	D O (0	Tilenote 🗩	0	
IRB or IEC and other Approvals	⊗ 0 ¢	D O (0			
Z Site Management	000	000	0			
IP and Trial Supplies	000	D O (0			
Safety Reporting	000	D O :	1			
Safety Documentation						
Trial Status Reporting	000	D 0 0	0			
🛐 General	000	D O :	1			

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.

🛓 Drop Zone [Private]	Publish Save as u	unpublished Cancel
Safety meeti Uploaded 2021-11-16 12	ng notes updated.xlsx 2:41 by	• 📋 🕽
CLASSIFICATION		
	07 Safety Reporting 👻	
TMF location*	07.03 General 👻	
	07.03.03 Meeting Material	
Document type*	Main artifact 🔹	
TMF level*	Site 🔹	
	Rainbow city ×	
Document name* Version Meeting Start Date* FILE INFO Original file name File date	 Use artifact name Use original file name Custom name Meeting Material 1 16 Nov 2021 Safety meeting notes updated xlsx 2021-11-16 12:41 	ne
Drop Zone # #	trifacts & documents in 📷 Safety Reporting 📷 General 🗵	Collapse Expand all
Shared 1	Relevant Communications	₹
Zone θ sections Z 🗸 Ø	Tracking Information	1
Trial Management 💿 8 6 4 1	27 Meeting Material 🕞	II 🔊
Central Trial Documents © 1 1 1 3	Meeting Material © 2022-05-24 09-48 by Trial	
Regulatory this is edited O O O O	Filenote	0
IRB or IEC and other Approvals		
Site Management 💿 0 0 0 0		
IP and Trial Supplies © 0 0 0 0		
Safety Reporting O 1 0 0		
Documentation		
Initial status © 0 0 0 0 Reporting © 0 1 0 0 1 0		

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 substring of a text in the file contents.

🛃 eTMF ·	Trial Master File 🔹					ē
Trial level	•	All sites	•	All milestones	•	
Z 12 zones S 51 sections	260 artifacts 4% contain do	⊗ 202 artif	acts missing required d	ocuments	27 documents 9 flagged by QC	∑ 11 awaiting review ✓ 7 finalized
🔎 insurance						8

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

4

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

For more information, see <u>The Details page</u>.

Fou	nd 9	docui	ments						
=	=	=	=	Name	■ Last modified datetime	■ Last modified by	■ TMF level	Actions	
z	5	A	ар. 1	Insurance Policy.xlsx	2022-03-10 13:46		Country		
Z	s	A	Ĩ,	Insurance Policy ver. 2.xlsx	2022-03-10 13:45		Trial		
Z	s		Ĩ.	Demo study template 001.xlsx	2021-12-02 13:37				₿
Z	5	A	i,	abc	2021-08-18 09:18		Country		
Z	5	A	í,	duplicated zones and section ids.xls	2021-09-14 16:27		Site		G.
Z	s	A	Ĩ.	This is my cool name	2021-11-01 13:54		Country		D.
2	s	A	5	Demo study template 001.xlsx	2021-10-04 16:07		Site		F.
Z	\$	A	i)	Linas CV	2021-12-03 09:27		Site		
z	5	A	÷,	DemoStudyTemp.xis	2021-09-14 16:17		Site		尙

Tipl 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.

6 eTMF → Trial Master File →	<u>s</u>
insurance policy	8 E

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:

Þ

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

Found 7 documents				(View: Default+
= = = Name	$6 \equiv \text{ Last modified datetime } \sqrt{7} \equiv \text{ Last modified by}$	TMF level	≡ Countries ⊽ 8 Sites	■ Document status ■	
😰 📴 🚺 🔋 Insurance edited	2022-11-18 15:06	Country	Sweden	₽ ✓	•
🔁 📴 🐹 📄 Insurance edited	2022-08-25 08:53	Country	Sweden	Unpublished 🖉	۵
😰 📴 🐹 👭 🛛 Insurance Certificate	2022-08-25 08:53	Country	Sweden	Unpublished 🖉	•
🛛 📴 🕅 🌹 Insurance edited	2022-08-25 08:53	Country	Sweden	P	•
🛛 📴 🕅 🌹 Insurance edited	2022-08-25 08:53	Country	Sweden, United	P*	•
🛛 📷 📜 Insurance Certificate	2022-08-25 08:53	Country	Sweden, Iraq		•
🔽 📴 🛅 📕 Insurance Certificate	2022-08-25 08:53	Country	Sweden	Unpublished Ø	•

- 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 <u>The View menu</u>.

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:

lcon	Description
Z	A zone that is expanded in the tree view
	A deleted zone that is expanded in the tree view
Ζ	A zone that is collapsed in the tree view
8	A deleted zone that is collapsed in the tree view
S	A section that is expanded in the tree view
	A deleted section that is expanded in the tree view
S	A section that is collapsed in the tree view
	A deleted section that is collapsed in the tree view
A	An artifact that is expanded in the tree view
	A deleted artifact that is expanded in the tree view
Α	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

lcon	Description
<	The shared drop zone, when enabled
<u> </u>	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:

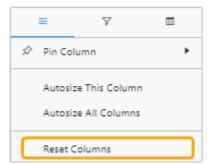
Menu option	Description
Default	Displays the default view, as provided by the system. When you perform a search on the Structure page, this view is displayed. When you perform a search on the Details page, and you haven't made or saved any customization, this view is displayed.
Default+	Indicates that 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.



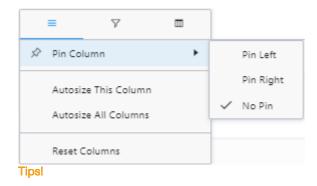
5.3 Pinning a column to the left or the right

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**.

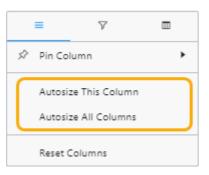


- The No Pin option unpins the column.
- To reset all pinning, select Reset Columns.

5.4 Autosizing columns

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

- Select the menu button in the column header to open the column menu.
 - TMF level
- 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**.



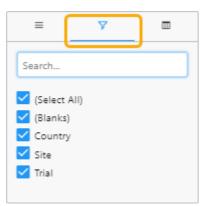
5 Filtering out data

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.

TMF	level		≡	
			_	

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).



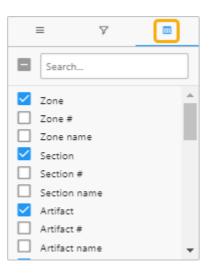
To select which columns to display on the Details page:

1

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.

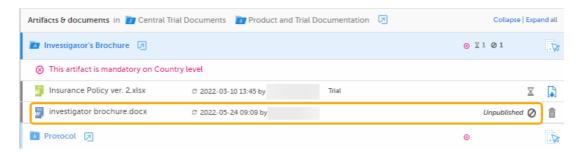
Column	Description
Country codes	The country codes of the countries that the document is linked to.
Sites	The names of the sites that the document is linked to.
Site codes	The site codes of the sites that the document is linked to.
Document version	The document version number as set by the user in the 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 <u>Introduction to Viedoc eTMF</u>.

To download a document:

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



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

1

investigator brochure.docx Uploaded as Unpublished 2022-05-24 09:09 by Maria Estuand (838) CCLSSFERIOR 22 Central Trial Documents 102 Central Trial Documents 104 Invation* 20.01 Product and Trial Documentation 105 Investigation* 105 Inves	🗐 Doc	Uploaded as Unpublished 2022-05-24 09:09 by Maria Extund (838)					
	doc W	Uploaded as Unpublished 2022-0			• î)		
TME location* 02.01 Product and Trial Documentation +			02 Central Trial Documents	•			
		TMF location*	02.01 Product and Trial Documentation	•			

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

Artifacts & documents in 🗾 Central	Trial Documents 📑 Product and Trial Documentation 🕻	Z Collapse Expand all
🔽 Investigator's Brochure 🛛		© I1 Ø1
⊗ This artifact is mandatory on Cou	untry level	
Insurance Policy ver. 2.xlsx	C 2022-03-10 13:45 by Trial	X 🚺
investigator brochure.docx	© 2022-05-24 09:09 by	Unpublished ⊘ 💼

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

Document proper	rties			Edit	lose				¢
AU- 20		13 Quality Report		•					ē
X Await	ting review		Approve						
CLASSIFICAT				/					
ΑT	MF location	📷 Trial Management	1	/					
		2 Quality Plan	- 1						
	TMF level	Country						₩1 I4 ¥2 Ø17	
Docu	ument type	Sub-artifact: Quality Report						2	
	eTMF URL		1				Trial	÷	
DOCUMENT	INFO		1						
Docur	ment name	Quality Report	1				Australia	Ξ	
	Version		1		- 1				
Ve	ersion Date	2021-09-13	1				Internation		
	Country	Australia	1			C 2021-08-18 09-10-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-	1000		
	Site		/						
	Id	43	(C 2021-12-02 13:37 by		Unpublished Q	
D	isplay label	AU- 20210913 Quality Report						Unpublished @	
Dow	nload label	Unicorns - AU Artifact 01.01.03 - Quality Report						Unpublished Q	
Ar	rchive label	Quality Report							

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 <u>Introduction to Viedoc eTMF</u>.

Note! it is not possible to edit a finalized document. To make changes, a new document version must be created. For more information, see <u>Creating a new version of a document</u>.

To edit the document properties:

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

Z	s	A	Ð.	product marketing.snag	2022-03-16 13:55	Unpublished	Ø
	5	A	dir. W	investigator brochure.docx	2022-05-24 09:09	Unpublished	0
z	s	A	ai.	Meeting Material	2022-05-24 09:48 Trial		X

2

1

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

Artifacts & documents in 👔 Central Trial Documents 🛐 Product and Trial Documentation 🗵 C						
🗾 Investigator's Brochure 🛛	⊚ ⊻1	Ø 1	-53			
S This artifact is mandatory on Country level						
Insurance Policy ver. 2.xlsx Ø 2022-03-10 13:45 by Trial		X	,			
investigator brochure.docx 🖉 2022-05-24 09:09 by	Ur	npublished 🖉	盲			
Protocol 🔊	0		-53			

Notel The upload button on artifact level indicates that you have write permission for the artifact.

The **Document properties** dialog is displayed:

Document properties		Cance
🗊 DV: 1 - DN: h.xls:	k FV: 1 VL:	👁 💼 😱
Previewed h.xlsx 03 Feb 2023 06 uploaded on 08 Dec 2022 09:11	14 by that wa	¹⁵ 123
4 Ø Unpublished		5
Added 05 Oct 2023 13:40 by	6	Resolve
	02 Central Trial Documents	•
TMF location*	02.01 Product and Trial Documentation	*
	02.01.01 Investigator's Brochure	*
Document type*	Select document type	v
TMF level*	Site	*
	Uppsala x Stockholm x Skåne x	
8 DOCUMENT INFO Document name*	Use artifact name	Custom name
Version label		
Version Date*	•	
Id	312	
Display label	DV: 1 - DN: h.xlsx FV: 1 VL:	
Download label	1-h.xlsx	
Archive label	1-h.xlsx	
9 FILE INFO		
Original file name	h.xlsx	- J
File size	8.36 KB	
File date	08 Dec 2022 09:11	
Devidenced building OT Fach 2027 Of 14 ho		

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.

Notel 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 <u>Editing document</u> <u>properties</u>.
- 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.

Select action	
Create new version 🔹	
Convitile from current version (2)	
Copy file from current version (2)	
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.

Doci	ment properties - Version	3 ~		Edit	Close		
	eTMF_factshe		2 DV 3 - FV 1		۹ 🕽		
	X Awaiting review			Approve			
	CLASSIFICATION	Flocation	7 Trial Management				

10 Adding notes to a document version

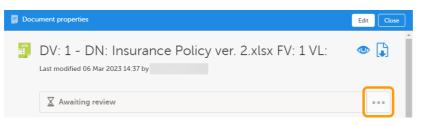
Document notes are a way to communicate with other users about documents without affecting the document status. The notes actions are not recorded in the document history.

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 <u>Editing document</u> <u>properties</u>.
- 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.

Select action	
Add note 👻	,
Add note text*	
This is a note.	

The note is then displayed like this:

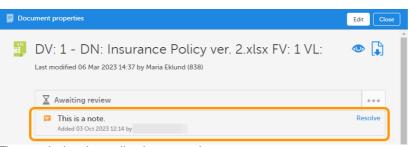


The note is associated with the selected document version.

11 Resolving notes

To resolve a note in a document:

- 1 Open the **Document properties** dialog according to the instructions in the section <u>Editing document</u> <u>properties</u>.
- 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 <u>Introduction to Viedoc eTMF</u>.

To publish a document:

- 1 Open the **Document properties** dialog according to the instructions in the section <u>Editing document</u> <u>properties</u>.
- 2 Make sure all mandatory fields (marked with red) are filled in.

5

Select Publish at the top of the dialog:

Document properties		Publish	Save as unpublished	Cancel
_			•	
	20220201 Insurance Policy.xlsx Saved as Unpublished 2022-03-03 11:00 by CLASSIFICATION 02 Central Trial Documents		•	
TMF location*	02.01 Product and Trial Documentation 02.01.06 Insurance	1	*	
Document type*	Main artifact		•	
TMF level*	Country		•	
	Australia 🗙			

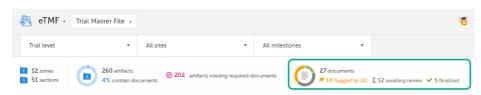
When the document is published, it is available for all eTMF users with at least read permissions for 4 that artifact and with access to the TMF level that the document is linked to.

📑 Doc	ument properties	Edit	Close
els I	AU 20220201 Insurance Policy.xlsx Awaiting review 2022-03-03 11:07 by	٢	
🔋 AU 20220201 Insurance Policy.xlsx 🛛 👁 🕽			
	TMF location 🛛 📷 Central Trial Documents		
	Product and Trial Documentation		
	insurance		

The document status is now Awaiting review:

13 Resolving issues for documents that are flagged by QC

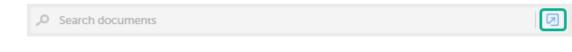
In the metrics area at the top of the page, the orange flags indicate if there are any documents that are flagged by QC.



Locating the documents that are flagged by QC 13.1

To locate the documents that are flagged by QC:

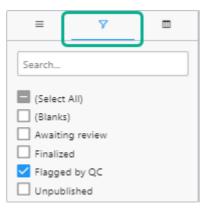
1 In the search field, select the Details page button.



2 On the Details page, locate the column Document status, and select to open the column menu.



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.

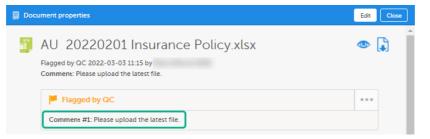
13.2 Resolving issues

3

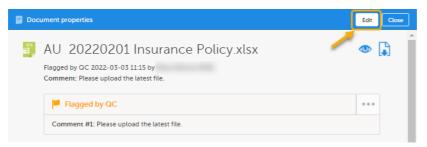
To resolve issues for documents that are flagged by QC, you need to edit the document metadata.

To edit the document metadata:

- 1 Open the **Document properties** dialog according to the instructions in the section <u>Editing document</u> <u>properties</u>.
- 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.



In the **Document properties** dialog, edit the applicable document metadata.

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

📑 Doci	ument properties					Cancel
xis	AU 20220201 In Flagged by OC 2022-03-03 11:15 Comment: Please upload the late				٢	Î.
	Flagged by QC				•••	
	Comment #1: Please upload th	ne latest file.				
	CLASSIFICATION	02 Central Trial Documents	•			
	TMF location*	02.01 Product and Trial Documentation 02.01.06 Insurance	•			- 1
	Document type*	Main artifact	•			
	TMF level*	Country	•			- 1
		Australia 🗙				- 1
	DOCUMENT INFO	Use artifact name		Custom na	ame	
		Insurance Policy.xlsx				
	Version					- 1
	Effective Date*	▼ 01 Feb 2022 🛗				- 1
	Id	69				- 1
	Display label	AU 20220201 Insurance Policy.xlsx				
	Download label	Unicorns - AU Artifact 02.01.06 - Insurance Policy	xls)			
	Archive label	Insurance Policy.xlsx				
	FILE INFO		_		_	
	Original file name	Insurance Policy.xlsx	_	+) _lm		
	File size	27.15 KB		Uplo	ad	
	File date	2022-03-02 12:50				

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 <u>Introduction to Viedoc eTMF</u>.

To delete an unpublished document:

4

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

Artifacts & documents in 👔 Central Trial Documents 👔 Product and Trial Documentation 🏼 🦻	Col	llapse Expa	nd all
📷 Investigator's Brochure 🕞	0 11 0	1	5
⊗ This artifact is mandatory on Country level			
Insurance Policy ver. 2.xlsx 🕫 2022-03-10 13:45 by Lina Gaggi Trial		X	Ţ,
investigator brochure.docx 🕫 2022-05-24 09:09 by Maria Eklu	Unpu	blished 🖉	Î
Protocol 🕅	0		-

2 Select Yes.

1

Confirm d	elete	Close
â	Are you sure you want to delete the investigator brochure.docx document?	

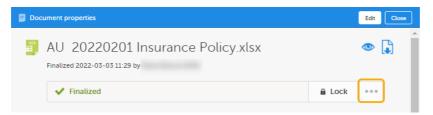
14.2 Deleting a published document

Deleting a document in Viedoc TMF requires write permission for the respective trial, country, or site. For more information about permissions, see <u>Introduction to Viedoc eTMF</u>.

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.

Document action	
Select action Delete document	
Reason* incorrect	li di seconda di second
Delete document	Cancel

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



Reviewing documents

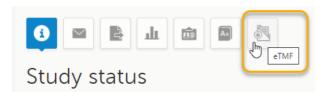
Reviewing documents

Published by Viedoc System 2023-10-09

1. Launching Viedoc eTMF 2. Searching for documents 3. Reviewing a document 4. Approving a document 5. Locking a document 6. Unlocking a document

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 <u>Introduction to Viedoc eTMF</u>.

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.

🧞 eTMF ⊦	Trial Master File 🔹						6
Trial level	•	All sites	•	All milestones	•		
z 12 zones 5 51 sections	260 artifacts 4% contain do	© 202 art	tifacts missing required d	ocuments	27 documents	🛙 11 awaiting review 🖌	7 finalized
🔎 insurance							\otimes

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

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

.○ insurance						0	ľ
ound 7 documents					View: Cust	omized	d+ ≡
= = = Name	■ Last modified datetime ■ Last modified by	■ TMF level ↑	■ Countries ♥ ■ Sites	Document status	Actions		
😰 📴 🔄 Insurance edited	2022-08-25 08:53	Country	Sweden	Unpublished 🖉	Ø		f
😰 🛅 🗾 Insurance edited	2022-11-18 15:06	Country	Sweden	₽ ✓	۲	٦	
😰 🛅 🗾 🥦 Insurance Certificate	2022-08-25 08:53	Country	Sweden	Unpublished 🖉	۲	٦	É
😰 🛅 🗾 👭 Insurance edited	2022-08-25 08:53	Country	Sweden	P	٢		
😰 🛅 🗾 📅 Insurance edited	2022-08-25 08:53	Country	Sweden, United	P	٢		
😰 📷 🗾 🥦 Insurance Certificate	2022-08-25 08:53	Country	Sweden, Iraq	P	٩		
😰 📷 📷 🚆 Insurance Certificate	2022-08-25 08:53	Country	Sweden	Unpublished Ø	0		í

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

3 Reviewing a document

3

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.

O insurance								8	(
ound 16 documents							Vi	w: Def	fault
= = = Name	Last modified datetime	■ Last modified by	TMF level	Countries	Sites	Document status	Actions		
😰 📷 🔝 舅 🛛 Insurance edited	2022-10-19 11:23		Trial			0 🖬 🗸	•		
😰 📷 🗾 👔 Insurance Policy ver. 2.xlsx	2023-03-06 14:37		Country	Sweden		X			
😰 📷 📷 👘 Insurance edited	2022-08-25 08:53		Country	Sweden		Unpublished Ø	Ø		Ê
🖅 📷 🎵 Insurance edited	2022-08-25 08:53		Country	Iraq		P	•		

2 Make sure that all document metadata is correct.

📑 Doo	ument properties				Edit	Close	
xis	Insurance Policy ve Previewed Insurance Policy ver. 2.xlsx on 2022-03-07 10:22		that wa	s uploaded	٢		*
	X Awaiting review			Approve		•••	
	CLASSIFICATION	77 Central Trial Documents					
	TMF location						
		Product and Trial Documentation					
		Investigator's Brochure					
	TMF level	Trial					
	Document type	Main artifact: Investigator's Brochure					
	DOCUMENT INFO						
	Document name	Insurance Policy ver. 2.xlsx					
	Version						
	Version Date						
	Country						
	Site						
	Id	67					
		Insurance Policy ver. 2.xlsx					
		Unicorns - Artifact 02.01.01 - Insurance	Policy v	er. 2.xlsx			
	Archive tabel	Insurance Policy ver. 2.xlsx					
	FILE INFO						
	Original file name	Insurance Policy ver. 2.xlsx					
	File size	27.15 KB					
	File date	2022-03-07 10:22					
	HISTORY						-

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 <u>Previewing a document</u>.

📑 Doc	ument properties	E	dit Close	
xis	Insurance Policy ver. 2.xlsx Previewed Insurance Policy ver. 2.xlsx 2022-03-25 10:15 by that we on 2022-03-07 10:22	as uploaded		
	X Awaiting review	Approve	•••	
	CLASSIFICATION			
	TMF location 🛛 🔽 Central Trial Documents			
	Product and Trial Documentation			
Altern	atively, click the download button to download the fi	le.		

Document properties
Edit Close
Edit Close
Insurance Policy ver. 2.xlsx
Previewed Insurance Policy ver. 2.xlsx 2022-03-25 10:15 by that was uploaded on 2022-03-07 10:22
Awaiting review
Approve ••••
CLASSIFICATION
TMF location
TMF location
TMF location
Product and Trial Documentation

4 Review the file contents.

3

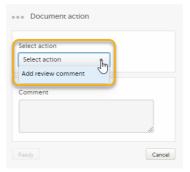
5 To navigate between versions of the document, use the version dropdown menu at the top of the **Document properties** dialog.

📑 Doc	ument properties - Version	3 ~		Edit	Close
₽d1	eTMF_factshe Awaiting review 05 Oct 20	2	DV 3 - FV 1	۲	Image: A start and a start and a start a st
	Awaiting review			Approve	
		MF location	🔁 Trial Management		

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.

Notel 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 <u>approved</u>.

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.

					0
Found 16 documents					View: Default
= = = Name	Last modified datetime	= TMF level	■ Countries ■ Sites	Document status	Actions
😰 📷 🔝 👮 🛛 Insurance edited	2022-10-19 11:23	Trial		0 🖬 🗸	•
😰 🛅 🔟 🧊 Insurance Policy ver. 2.xlsx	2023-03-06 14:37	Country	Sweden	X	•
😰 🛅 📷 📄 Insurance edited	2022-08-25 08:53	Country	Sweden	Unpublished Ø	🧇 🕻 🕯
📴 📷 🎵 Insurance edited	2022-08-25 08:53	Country	Iraq	P	•

2 In the **Document properties** window, click **Approve**.

📑 Doc	ument properties	E	lit	Close)
xis	Insurance Policy ver. 2.xlsx	•	▶ [3	
	Previewed Insurance Policy ver. 2.xlsx 2022-03-25 10:15 by that w on 2022-03-07 10:22	as uploaded			
	X Awaiting review	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.

,○ insurance						8
Found 16 documents					Viet	w: Default i
= = = = Name		fied by = TMF level	≡ Countries ≡ Sites	Document status	Actions	
📷 📷 🎽 🛛 Insurance edited	2022-10-19 11:23	Trial		a 🗸	٩	
😰 🛅 📓 Insurance Policy ver. 2.xlsx	2023-03-06 14:37	Trial	Sweden	~	•	
🔯 📷 📷 📳 Insurance edited	2022-08-25 08:53	Country	Sweden	Unpublished 🖉	ø	1
📷 📷 🎽 Insurance edited	2022-08-25 08:53	Country	Iraq	P	•	•

2 In the Document properties window, select Lock.

Document properties	Edit Close
Insurance Policy ver. 2.xlsx	۵ ال
✓ Finalized	🔒 Lock

3 The Lock button is now changed into an Unlock button.

Notel 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.

,O insurance									0	
Found 16 documents								Vi	ew: Def	fault ≡
≡ ≡ ≡ Name	■ Last modified datetime	■ Last modified by	■ TMF level	■ Countries	≡ Sites	■ Document state	15	■ Actions		
📴 🛅 📷 👮 Insurance edited	2022-10-19 11:23		Trial				×	۲		
📷 📷 📓 Insurance Policy ver. 2.xlsx	2023-03-06 14:37		Trial	Sweden		8	¥ .			
😰 🔯 📄 Insurance edited	2022-08-25 08:53		Country	Sweden		Unpublished	0	$\langle \!$		ô
😰 📴 📜 🦻 Insurance edited	2022-08-25 08:53		Country	Iraq			P	0		

2

lr	n the Docume	nt properties	window, c	lick Unlock .

📑 Doc	ument properties	Close
xis	Insurance Policy ver. 2.xlsx B Document locked 2022-05-30 12:46 by	•
	✓ Finalized	🔒 Unlock
	CLASSIFICATION	

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:

Document properties	Close
Document locked 2021-11-15 11:06 by	•
✓ Finalized	•••
Select Unlock:	
Document action	
Select action Select action Unlock Comment	
Ready Cancel	
••• Document action	Add your reason in the Reason field:
Select action Unlock •	
Reason* The document needs to be updated]	
Unlock document Cancel	
••• Document action	Click Unlock document to unlock the document:
Select action Unlock •	
Reason* The document needs to be updated.	
Unlock document Cancel	

4 The document is now unlocked.

3



Viedoc Share

Viedoc Share

Published by Viedoc System 2025-01-14

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 2. Definitions

 3. Prerequisites

 4. Workflow

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 6. Adding document fields

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 11. The Sharing section in the Document properties window

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 <i>unpublished</i> 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:

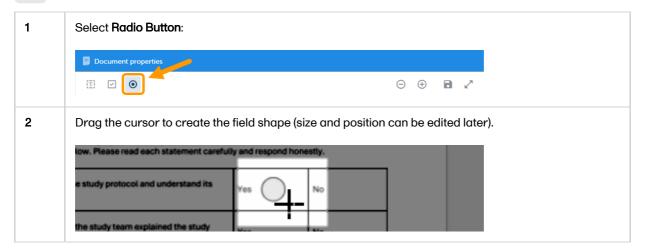
1 In the Trial Master File view, navigate to the <i>unpublished</i> document in the TM	IF structure.
---	---------------

2		Select the document to open the Document properties window. Select the eye icon to open a preview of the document.						
	📕 Document p	roperties					Publis	h Cancel
	🎢 Pro	tocol Acknow	ledge	ement	.pdf			
	0	Unpublished						•••
3			nent, t	the opt	ions	for add	ling/editing fields	are displayed:
	Document properties				Θ	⊕ ⊮*	Protocol Acknow	ledgement.pdf 💿 💼 〕
		Participant Protocol Ack	nowledgement	t			Previewed Protocol Acknowledger was uploaded on 08 Nov 2024 14: Unpublished	nent.pdf 08 Jan 2025 14:05 by Super Investigator (14869) that i0
		Sample Demo Study 2024 This document ensures that you, as a participant in this understand the study's protocol and procedures. Peas	e mark "Yes" or "N	io" to each of the			CLASSIFICATION	02 Central Trial Documents
		statements below. Please read each statement careful I have read the study protocol and understand its contents.	ly and respond hon Yes	No			TMF location*	02.02 Subject Documentation *
		A member of the study team explained the study protocol and procedures to me in detail.	Yes	No			Document type*	02.02.03 Informed Consent Form Main artifact
		I have had the opportunity to ask questions and received satisfactory answers.	Yes	No			TMF level*	Triat
		By completing and signing this form, you confirm that y Study's protocol, procedures and expectations and has you have any further questions, please feel free to reac Thank you for your cooperation and participation.	ou understand the ve had all your ques h out to the study to	Sample Demo stions answered. If earn at any time.			DOCUMENT INFO	Use artifact name 💿 Use original file name 🔿 Custom name
		Participant Name: Today's L	Date (MM/DD/YYY):				Version label	Protocol Acknowledgement.pdf
		Participant Signature (electronic)					Version Date*	▼ 01 Nov 2024 21
							Display label	21 Protocol Acknowledgement.pdf
							Download label	Protocol Acknowledgement.pdf
							Archive label TMF side	Protocol Acknowledgement.pdf Image: Construction of the second
							FILE INFO	

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:



3	Once the shape is c	reated, an edit window is displayed:
		understand the study's protocol and procedures. Please mark "Yes" or "No" to each of the
	Answer this	statements below. Please read each statement carefully and respond honestly. I have read the study protocol and understand its
	please	Contents. Ver No
		A member of the study if protocol and procedure Field Name*: Question 1
		There had the opport received satisfactory and Radio buttons with the same Field Name will belong in
		the same grouping. By completing and signing
		study's protocol, procedu you have any further cugat Thank you for your ed. 2 Read Only
		3 Required
		Participant Name: 4 Size: 32 Width 32 Height
		Participant Signature (star
		5 Document Field Indicators
		Answer this please
		Cancel OK
	1. To name th	ne radio button, click inside the text box to the right of Field Name and type the
	name (for ex name.	ample "Question 1". Then select the option that appears below to create the field
	nume.	
	Field Name*:	Question 1 🗸
	Radio buttons with the same grouping.	Create Orientian 1
		Create Question 1
	Field Flags	13
	the same fiel question mu	dio buttons to function properly, options belonging to the same question must have Id name. For example, both "yes" and "no" radio buttons belonging to the first st 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	e field as Read Only will not allow the recipient to select or deselect the button
	3. Setting the	e field as Required will prevent the recipient from signing the document until all
		ds have been completed.
	4. Setting the	e 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
		pient will see. Note! This may not be visible if the recipient is viewing the document
4	Once all of the desir	ed fields and settings have been completed, select save .
-		ea nelae ana collingo navo been completed, select eare .
	Document properties	
	(ī) 🗸 💿	

6.2 To create a checkbox:

1	Select Checkbox:		
	Document properties	⊖ ⊕ ⊮×≭	

2	Drag the cursor to create the field shape (size and position can be edited later).
	Please select each statement that is TRUE:
3	Once the shape is created, an edit window is displayed:
	Check this Document Field Indicators Ver, Isg Ver, Field Name Check this box please
	 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 .
	Document properties

6.3 To create a **Text Field**:

1	Select Text Field:
	Document progerties
0	Durge the surgest to success the field observe (size and position errors to adjuted later)
2	Drag the cursor to create the field shape (size and position can be edited later).
	Participant Name: Todar's Date (MM/DD/YYY): Participant Signature (electronic)
3	Once the shape is created, an edit window is displayed:
	 If the text field click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click inside the text field names do not affect the functionality as the click button names do. Intering a Default Value will autofill the text field with any text you enter here. Setting the field as Read Only will not allow the recipient to type any text in the text field. Setting the field as Required will prevent the recipient from signing the document until all cquired fields have been completed. 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 .
	Document properties

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.

	Close
:: 01 Oct 2024 File integrity: Cbj62ZpknlbzyQAfkQ+CKw== File version: 1	
	Step 1/2
Viedoc Clinic users Viedoc Me users Select recipient	
 Create a separate binder for each recipient 	
No Yes, request signature	
No Yes, add co-signatories 1	
	Select recipient

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.

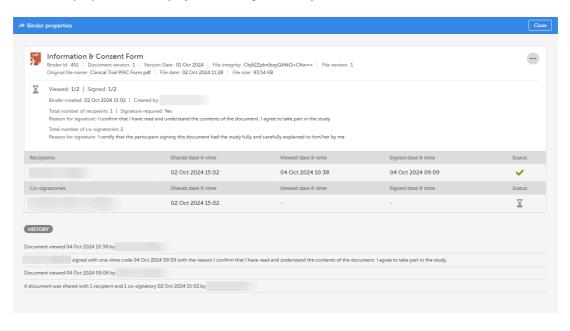
14 After confirming, a binder summary is displayed and an email is sent to each of the recipients with a link to Viedoc Share where the document can be viewed and/or signed.

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.

Ar Sharing								Cla
Information & Consent Form File integrity: Cbg622pknlbzyOAfkO+CKw== File version: 1 Original file name: Clinical Trial PIAC Form pdf File size: 02.0ct 2024 11.28 File size: 93.54 KB								
5 Binders								Ð
Binder Id	Recipients	Co-signatories	Document version	Created	Viewed	Signed	Status	
451	SE-001-30 - Uppsala		1	02 Oct 2024 15:02	1/2	1/2	X	⇒
450	SE-001-29 - Uppsala		1	02 Oct 2024 15:01	1/2	1/2 🥑	X	\rightarrow
449	SE-001-23 - Uppsala		1	02 Oct 2024 14:52	0/1	-	Ø	>
448	SE-001-17 - Uppsala		1	02 Oct 2024 14:51	1/1	1/1	×	\rightarrow

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.

A Sharing								
Information & Consent Form Enderstand File integrity: Cbj62ZpknlbzyOAfkO+CKw== File version: 1 Document version: 1 Version Date: 01 Oct 2024 File integrity: Cbj62ZpknlbzyOAfkO+CKw== File version: 1 Original file name: Clinical Trial PIAC Form pdf File date: 02 Oct 2024 11:28 File size: 9354 KB								
5 Binders								Ð
Binder Id	Recipients	Co-signatories	Document version	Created	Viewed	Signed	Status	
451	SE-001-30 - Uppsala		1	02 Oct 2024 15:02	1/2	1/2	X	\rightarrow
450	SE-001-29 - Uppsala		1	02 Oct 2024 15:01	1/2	1/2 🥑	X	\rightarrow
449	SE-001-23 - Uppsala		1	02 Oct 2024 14:52	0/1	-	0	>
449 448	SE-001-23 - Uppsala SE-001-17 - Uppsala		1	02 Oct 2024 14:52 02 Oct 2024 14:51	0/1 1/1	- 1/1	0 ~	\rightarrow

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

Dinde	r properties				
Pdf X	Original file name: Clinical Trial PIAC For Viewed: 1/2 Signed: 1/2 Binder created: 02 Oct 2024 15:02 C Total number of recipients: 1 Signatu Reason for signature: I confirm that I ha Total number of co-signatories: 1	Version Date: 01 Oct 2024 File integrity: C m pdf File date: 02 Oct 2024 11.28 File siz reated by: re required: Yes we read and understand the contents of the docu	e: 9354 KB ment. I agree to take part in the study.	Download	l original file I with sharing details I with signatures aring
tecip	Reason for signature: I certify that the p	articipant signing this document had the study fu Shared date θ time 02 Oct 2024 15:02	ly and carefully explained to him/her by me. Viewed date & time 04 Oct 2024 10:38	Signed date & time 04 Oct 2024 09:09	Status
Co-si	gnatories	Shared date & time	Viewed date & time	Signed date & time	Status
Co-si	gnatories				Status
HISTO		Shared date & time			
HISTO	RY nt viewed 04 Oct 2024 10 38 by	Shared date & time 02 Oct 2024 15:02		Signed date & time	
HISTO	RY nt viewed 04 Oct 2024 10 38 by	Shared date & time 02 Oct 2024 15:02	Viewed date 6 time	Signed date & time	

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:

viedoc		
Document is digitally cer 2024-10-02 11:58:24 UTC	tified by Viedoc	
Document name : Clinica Document version : 1 File integrity : Cbj62Zpkr		
÷		1
	Signed by Reason: I confirm that I have read and understand the contents of the document. I agree to take part in the study. Date: 2024-10-02 18:44:02 UTC	
	Signed by Reason: I certify that the participant signing this document had the study fully and carefully explained to him/her by me. Date: 2024-10-03 00:15:37 UTC	

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.

5

Select the arrow icon to open the Binder properties window.

Sharing								C	
Information & Consent Form Document version: 1 Version Date: 01 Oct 2024 File integrity: Cbj622pknlbzyQAfkQ=CKw== File version: 1 Original file name: Clinical Trial PIAC Form.pdf File date: 02 Oct 2024 1128 File is: 93.54 KB									
5 Binders								Ŧ	
Binder Id	Recipients	Co-signatories	Document version	Created	Viewed	Signed	Status		
451	SE-001-30 - Uppsala		1	02 Oct 2024 15:02	1/2	1/2	X	\rightarrow	
450	SE-001-29 - Uppsala		1	02 Oct 2024 15:01	1/2	1/2	X	\rightarrow	
449	SE-001-23 - Uppsala		1	02 Oct 2024 14:52	0/1	-	X	\rightarrow	
448	SE-001-17 - Uppsala		1	02 Oct 2024 14:51	1/1	1/1	4	Þ	
440									

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

Binder properties				Close
Information & Consent Form Binder Id: 449 Document version: 1 Version Date: 01 Oct 2024 File integrity: Cbj62ZpknlbzyOAfkO+CKw== File version: 1 Original file name: Clinical That PIAC Form.pdf File date: 02 Oct 2024 1128 File size: 95.54 KB				ad original file
Viewed: 0/1 Signed: N/A				ad with sharing details
Binder created: 02 Oct 2024 14:52 Created by:				ad with signatures
Total number of recipients: 1 S	ignature required: No			sharing
Recipients	Shared date & time	Viewed date & time	Signed date & time	Status Revoke sharin
SE-001-23 - Uppsala	02 Oct 2024 14:52			X
HISTORY				
locument was shared with 1 recipient 02 0	Oct 2024 14:52 by			

6 Select Revoke sharing.

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

pdf	Information & Consent Form Binder Id: 449 Document version: 1 Version D Original file name: Clinical Trial PIAC Form.pdf Fil				
	Viewed: 0/1 Signed: N/A Binder created: 02 Oct 2024 14:52 Created by: Total number of recipients: 1 Signature required:	No			
0	Revoked Binder revoked: 11 Oct 2024 08:29 Revoked by:				
Recip	pients	Shared date & time	Viewed date & time	Signed date & time	Status
SE-0	01-23 - Uppsala	02 Oct 2024 14:52	-		0

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.

📑 Doc	ument properties			Close
Pdt	Information & Cons Document (Binder Id: 448) viewed 04	Q	> 😱	
	✓ Finalized		🖬 Lock	•••
	Sharing	* 5	∑ 3 ✓ 2	
	CLASSIFICATION	1	23	4
	TMF location	📷 Central Trial Documents		
		Subject Documentation		
		informed Consent Form		
	TMF level	Trial		
	Document type	Sub-artifact: Consent Form Signature Sheet		

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 1.2 Generating and downloading the report 1.3 Included sheets 1.3.1 Report Info 1.3.2 Trial Master File 1.3.3 Sharing 1.3.4 Templates Management 1.3.5 Structure Management 1.3.6 Archive Management 1.3.7 Settings Management 1.3.8 Status management 2. eTMF-EMS repository 2.4 Introduction 2.5 Generating and downloading the EMS repository 2.6 The zipped folder structure and content

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.



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).

	vnload until a new file is generated. Mak	e sure to download the existing file if you need it. Generating a new	v file wi
replace the existing one.			
	A CONTRACT OF A	t-Unicorns-20210831082441.xlsx	
C	49.12 KB, Generated 2021-08 Audit trail report	-31 10:24 by Lina Gaggi (31)	
-	Trial level, All countries, All sit	es, All milestones	
	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		
	b		

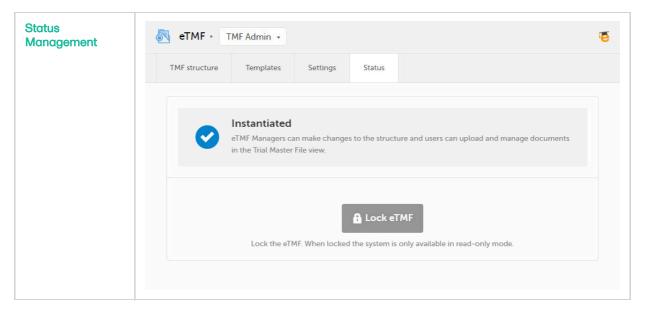
1.3 Included sheets

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:

rial Master File	eTMF → Trial Master File →				e
	Trial level 🔹	All sites 🔹	All milestones		
	12 zones 260 artifact 51 sections 4% contain	X 202 artifacts missing required d	ocuments 27 documents	awaiting review 🗸 7 finalized	
	Search documents				Ø
	Drop Zone #	Artifacts & documents in 📴 Trial Manage	ement 📑 Trial Oversight 🗵	Collapse Expar	nd all
	Shared 2	🚺 Quality Plan 🕞		⊨1 ⊻4 √2	- V
	2 Private	📷 List of SOPs Current During Trial 🗦		⊨1 √1	
	Zone & sections 🔰 🛛 🗸 Ø	🖞 CompleteAuditTrailReport 🛛 🖉	022-04-19 19:20 by Iraq, Australia	₽ ✓	
	🗾 Trial Management 💿 8 6 4 1	List of SOPs Current During Ø 2	021-12-22 11:27 by Trial		
	🚺 Trial Oversight 💿 6 6 4 1	Operational Procedure		X 1	-52
	S Trial Team				
	Trial Committee 💿 0 0 0 0	Recruitment Plan 🗔		⊻ 1	- [3
	S Meetings ⊗ 0 0 0 0	Communication Plan			- [3

Templates Management	eTMF · TMF Admin ·	۲
	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
Structure Management	© Viedoc Technologies AB 2021 Terms of Use - Privacy Policy Viedoc™ version 4.672108.150 [2021-08-06T11:39 UTC]	e
-	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	
	Trial Management Central Trial Documents	
	Regulatory	
	IRB or IEC and other Approvals	
	Site Management	
	IP and Trial Supplies	
	2 Safety Reporting	
	Central and Local Testing	
	Third parties Data Management	
	Statistics	
	Export structure	

• eTMF • TMF Archive •	10
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.	2
Generate a new file	
© Viedoc Technologies AB 2021 Terms of Use - Privacy Policy Viedoc™ version 4.67.2108.150 [2021-08-06T11:34 UTC]	
TMF Admin 🗸	ē
I MF structure lemplates 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:	
Download (StudyName) - {CountryCode}{SiteCc template: (DocumentName)	
	The first available role download until a new file is generated. Make sure to download the existing file if you need it. Concenting a new file



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	true forge (FG	
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	A	В	С	D	E	F	G	н	1	1	K	L	M	N	0	P
1							User Action	s on Documents								
2	Action	Document Version	File Version	Date/Time	Old Value	New Value	Reason	Done By	Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact Name	Document Name	Document Id
	Approve document	2		2023-09-07 11:40:23			Document		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
3							approved								20230901074918.xlsx	
	Publish document	2		2023-09-07 11:37:59	File = device_template5.xlsx	File = CompleteAuditTrailReport-	Document		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
					File date = 2023-09-07 11:35:52	4.65 ni-20230901074918.xlsx	published								20230901074918.xlsx	
4						File date = 2023-09-07 11:37:59										
	Upload file to structure	2	2	2023-09-07 11:37:59		Original file name -	File uploaded		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
						CompleteAuditTrailReport-4.65 ni-									20230901074918.xlsx	
5						20230901074918.xlsx										
	Create new version	2	2	2023-09-07 11:37:24			New document		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
6							version created								20230901074918.xlsx	
	Approve document	1		2023-09-07 11:36:25			Document		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
7							approved								20230901074918.xisx	
	Publish document	1		2023-09-07 11:36:17		Document type - Main artifact	Document		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
					Tmf level =		published								20230901074918.xisx	
				1	Version Date -	Tmf level - Trial					1					
8						Version Date = 2023-09-07										
	Upload file to structure	1	1	2023-09-07 11:35:52		Original file name =	File uploaded		01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	CompleteAuditTrailReport-4.65 ni-	1
9				1		device_template5.xlsx			1		1		1	1	20230901074918.xlsx	

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.

Action	Binder Id	Document Version	File Version	File Integrity	File Size	File Date	Original File Name	Recipients	
Document viewed	448	1	1	Cbi62ZpknlbzvQAfkQ+CKw==	93,54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-17	
Document signed	454	1	1	ksc/+Lkxvca+lkJSLksnAw==	104.48 KB	2024-10-04 09:09:43	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Document signed	454	1	1	ksc/+Lkxvcq+lkJSLksnAw==	104.48 KB	2024-10-04 09:09:43	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
		-	-						
Document viewed	454	1	1	ksc/+Lkxvcq+lkJSLksnAw==	104.48 KB	2024-10-04 09:09:43	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Certified copy created	454	1	1	ksc/+Lkxvcq+lkJSLksnAw==	104.48 KB	2024-10-04 09:09:43	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Binder created	454	1	1	ksc/+Lkxvcq+lkJSLksnAw==	104.48 KB	2024-10-04 09:09:43	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Document viewed	451	1	1	Cbi62ZpknIbzvQAfkQ+CKw==	93,54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-30	
Document signed	451	1	1	Cbi62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-30	
Document signed	451	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-30	
Document signing failed	451	1	1	Cbj62ZpknIbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-30	
Document viewed	451	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-30	
Document signed	448	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-17	
Document signed	448	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-17	
		-		and and a second second					
Document viewed	448	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-17	
Document downloaded	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93,54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document downloaded		^	*	cojozzprinozyconikarcku-	55.54 Kb	2024-10-02 05.20.50	cimear mar Fixer of the put	36-001-14	
Document viewed	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93,54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document downloaded	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93,54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
bocument downloaded	447	1	1	cojozzpkilozydalkdrekw	33.34 KD	2024-10-02 05.28.38	clinical mar Pixe Pornipul	35-001-14	
Document signed	447	1	1	Cbi62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document signed	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document signed	***/	1	1	CDJ022pkiliD2yQAlkQ+CKW	55.34 ND	2024-10-02 05:28:38	clinical mar PIAC Form.put	32-001-14	
Document viewed	447	1	1	Cbi62ZpknlbzvQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document viewed	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14 SE-001-14	
	447	1	1		93.54 KB				
Document viewed	452	4	1	EqvktcMeEdm00YMLiJXsBw==	76.7 KB 76.7 KB	2024-10-02 09:58:13	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Document viewed		1	1	EqvktcMeFdm00YMLiJXsBw==		2024-10-02 09:58:13	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Document viewed	453	1	1	EqvktcMeFdm00YMLiJXsBw==	76.7 KB	2024-10-02 09:58:13	Clinical Trial Protocol Form.pdf	Super Investigator (14869)	
Document downloaded	447	1	1	Cbj62ZpknIbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document downloaded	447	1	1	Cbj62ZpknIbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document signed	447	1	1	Cbj62ZpknlbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
Document signed	447	1	1	Cbj62ZpknIbzyQAfkQ+CKw==	93.54 KB	2024-10-02 09:28:58	Clinical Trial PIAC Form.pdf	SE-001-14	
	447			chicate below of the rest.	03 54 80	2024 10 02 00:20-50	clinited that place to see a de	CE 003.14	

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.

			D	E							Q
			tions on Templates								
Action	Date/Time	Action Details	Done By	Template Name	Template Type						
Import	2021-08-05 12:19:47	Imported template NoneDevice.xls	and the second second	NoneDevice	Organization						
Import	2021-08-05 12:19:15	Imported template NoneDevice.xls	and the second second	NoneDevice	Study						
Import	2021-08-04 13:04:34	Imported template Human body.xls		Human body	Organization						
Select	2021-08-04 12:34:49	Selected template RestuarantChain.xls	and the second se	RestuarantChain	Study						
Import	2021-08-04 12:34:30	Imported template RestuarantChain.xls	and the second se	RestuarantChain	Study						
User action	ns on templates in TMF Ad	min.									
_									_	_	_
	Report Info Trial Ma	aster File Templates Management Structure M	anagement Archive Management	t Settings Management 📔 🕀							

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.

User Action Detry/line Identifier Identifier Identifier Identifier Of Value Detry Value <th colspan="4" detry="" th="" value<<=""><th></th><th></th><th></th><th></th><th></th><th>F</th><th></th></th>	<th></th> <th></th> <th></th> <th></th> <th></th> <th>F</th> <th></th>									F	
Delete artifact 2 021084/2112150 010.102 Trial Management Plan Add zone 1 0210.08.17 112150 None Device None Device (customized) Add zone 1 0201.08.16 1129:23 01 Zone name = Trial Management Add section 1 2021.08.16 1129:23 01.01.01 Zone name = Trial Management Add artifact 1 2021.08.16 1129:23 01.01.01 Zone name = Trial Management Add artifact 1 2021.08.16 1129:23 01.01.01 Zone name = Trial Management Add artifact 1 2021.08.16 11:29:23 01.01.01 Zone name = Trial Management Add artifact 1 2021.08.16 11:29:23 01.01.01 Zone name = Trial Management Image: Comparison of the trial will be managed and stored during and artific he vir scored for the trial will be managed and stored during and artific he vir scored for the trial will be managed and stored during and artific he vir scoreds. Artifact and hain of customeriation for archiving and descurets. Norther Heaper, TMF Transmittal form, TMF Setup Request Spoord document = NO Virtue of United Stored Stor											
Delete artifact 2 2021-08-17 121:50 0.01.02 Trial Management Plan None Device [cutomized] Image: Cutomized [cutomized] Add zone 1 2021-08-16 11:29:23 01 Zone name = Trial Management Image: Cutomized [cutomized] Image: Cutomized [cutomized] Add section 1 2021-08-16 11:29:23 01.01 Zone name = Trial Management Section name = Trial Management Add artifact 1 2021-08-16 11:29:23 01.01.01 Zone name = Trial Management Section name = Trial Management Add artifact 1 2021-08-16 11:29:23 01.01.01 Zone name = Trial Management Section name = Trial Management Image: Cutomized Cu	Action	Structure Version	Date/time	Identifier		New Value	Done By				
Apply changes 2 2021-08-16 11:29:23 01 Zone name = Trial Management Add score 1 2021-08-16 11:29:23 01.01 Zone name = Trial Management Add section 1 2021-08-16 11:29:23 01.01 Zone name = Trial Management Add artifact 1 2021-08-16 11:29:23 01.01 Zone name = Trial Management Add artifact 1 2021-08-16 11:29:23 01.01.01 Zone name = Trial Management Add artifact 1 2021-08-16 11:29:23 01.01.01 Zone name = Trial Management Image: Comparison of the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial, will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and after the trial, including study-specifie how records for the trial will be managed and stored during and the tre		2	2021-08-17 11:21:50				the local diffe				
Add zone 1 2021-08-16 11:29:23 0.1 Zone name = Trial Management: Add section 1 2021-08-16 11:29:23 0.1.01 Zone name = Trial Management: Add artifact 1 2021-08-16 11:29:23 0.1.01 Zone name = Trial Management: Add artifact 1 2021-08-16 11:29:23 0.1.01.01 Zone name = Trial Management: Section name = Trial Master File Management: Section name = Trial Master File Management: Section name = Trial Master File Management: Image: Section name = Trial Master File Management: Section name = Trial Master File Management: Section name = Trial Master File Management: Image: Section name = Trial Master File Management: Section name = Trial Ownsight: Artifact name = Trial Master File Management: Image: Section name = Trial Master File Management: Section name = Trial Master File Management: Section name = Trial Ownsight: Image: Section name = Trial Master File Management: Section name = Trial Master File Management: Section name = Trial Ownsight: Image: Section name = Trial Master File Management: Section name = Trial Ownsight: Section name = Trial Ownsight: Image: Section name = Trial Master File Management: Section name = Trial Ownsight: Section name = Trial Ownsight: Image: Section nam		2		01.01.02			and the second second				
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Section name = Trial Oversight Artifact name = Trial Master File Plan Definition = To describe how records for the trial will be managed and storated the trial, including study - specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF filing structure to be used. May include TMF filing structure and chain of costody records, Artifact can include any vidence of plan searchicin including, but not limited to plan, reports, checklists, etc. Sub at not limited to plan second the start Hespert, TMF Transmittal Form, TMF Setup Request Sponsor document = XO Trial livel document = NO	Add section	1	2021-08-16 11:29:23	01.01							
	Add artifact	1	2021-08-16 11:29:23	01.01.01		Section name = Trial Oversight Artifact name = Trial Master file Plan Definition = To describe how records for the trial will be amanged and stored during and ther the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filling structure to be used. May include TMF content list, filling structures and chain of custody records. Artifact can include any widence of jain accession including, but not limited to plan, reports, checilists, etc. Sob artificits = Concounnet List, UNF Report, TMF Transmittal Form, TMF Setup Request Sponsor document = X Investigator document = NO Trail level document = NO Stel level document = NO					

1.3.6 Archive Management

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

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1			User A						
2 Action	Date/time	Included Documents	Filtered By	TMF Side	Done By	User Roles	User Permissions		_
Create audit trail report	2021-08-06 09:20:54		All milestones		and the second second	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		and a second second second	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		the logic state	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		100 May 100	Sponsor study, Sponsor country, Sponsor site, eTMF Manager	Download audit trail		
Download audit trail report 7	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		
9									
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User log on TMF Archive.									
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33									
34			L						
 → Report Info 	Trial Master File Templates Man	agement Structure Management	Archive Management	Settings Ma	nagement 🛛 🕀	E 161			

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.

A	В	С	D	E	F
		User Actions on Settings			
Action	Date/time	Old Value	New Value	Done By	
Edit Settings	2021-08-05 09:44:06	Enable Milestones filter = true	Enable Milestones filter = false	and the second second	
Edit Settings	2021-08-05 09:43:50	Enable Milestones filter = false	Enable Milestones filter = true	and the second se	
User changelog of eTMF setting	gs.				
1					
			3		
✓ ► Report Info Tr	rial Master File 🕴 Templates Mana	igement 🕴 Structure Manaj 🕂 🗄			

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.

			D	E				L
			ser Actions on eTMF Status					
2 Action	Date/time	Old Value	New Value	Reason	Done By			
	2022-02-01 12:17:59	Locked	Instantiated	Unlocking the eTMF to finalize a document	Contraction of the local division of the loc			
	2022-02-01 10:49:35	Instantiated	Locked	Locking the eTMF for archiving	and the second second			
	2021-08-16 11:29:23			Initiate structure	Concerning and the second			
Edit status	2021-08-16 11:26:36		Enabled	Enable eTMF	And the second se			
в								
User changelog of eTMF status.								
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 ↔ Report Info Trial N 	Master File Templates Managem	ent Structure Management A	rchive Management 📔 Settings Mar	agement Status Management 🕀				

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 <u>here</u>.

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).

replace the existing one.	oad until a new file is generated. Make :	ure to download the existing file if you need it. Generatin	g a new file will
	Unicorns_eTMFArchive_2	0211118121612.zip	
	Unicorns_eTMFArchive_2 4.23 MB, Generated 2021-11-		
	eTMF - EMS repository		
	Sponsor, Investigator, Trial lev	el, All countries, All sites, All milestones	
	Generate a new file		
	Generate a new file		
	eTMF - EMS repository		
	Include		
	TMF side:	Sponsor X Investigator X	
	Trial level documents:	Trial level ×	
	Country level documents:	All countries ×	
	Site level documents:	All sites ×	
	2 Filter by		

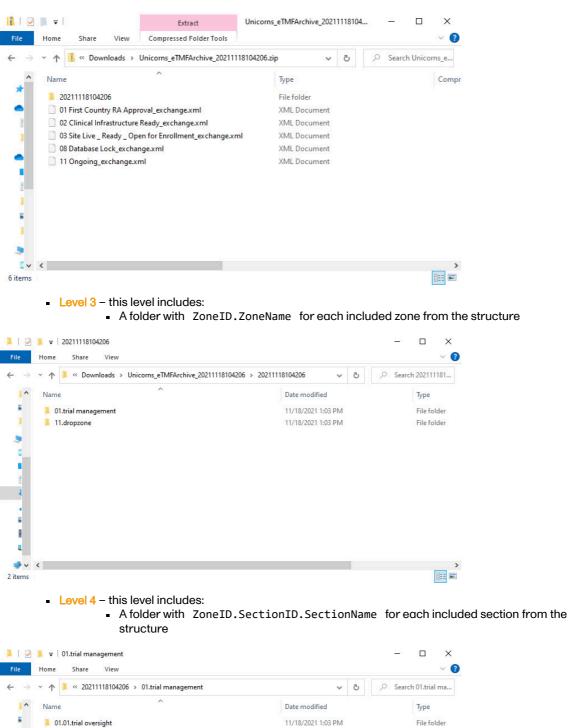
2.3 The zipped folder structure and content

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

Unicorns_eTMFArchive_20211118104206.zip

- Level 2 this level includes:
 - A subfolder that has the name TransferID (datetime stamp of generating the eTMF-EMS repository) in the format YYYYmmDDHHMMss
 - An exchange.xml file for each chosen milestone. You can read about the content of the xml files and find an example <u>here</u>



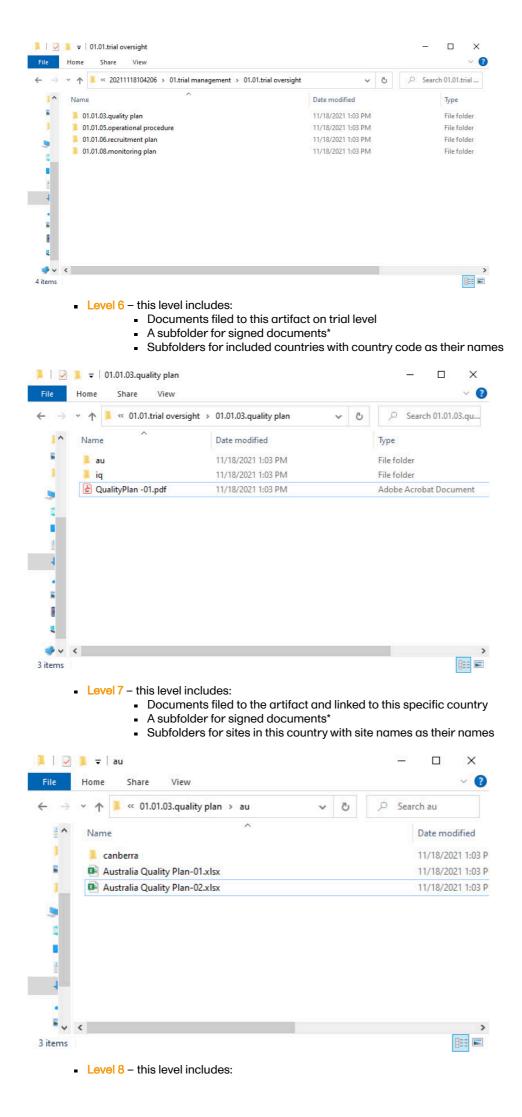
01.01.trial oversight 11/18/2021 1:03 PM File folder 01.02.trial team 🤹 v < ::: **.**

Level 5 – this level includes:

F

2 items

 A folder with ZoneID.SectionID.ArtifactID.ArtifactName for each included artifact from the structure



- A subfolder for signed documents*
- Documents filed to the artifact and linked to this specific site

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-	Name	^				Date modified
1	ABSc-01.xlsx					11/18/2021 1:03 F
	B ABSc-02.xlsx					11/18/2021 1:03 P
1	Dr. X CV-01.xlsx					11/18/2021 1:03 P
- 100						
•	<					>
3 items						

*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

eTMF access use cases

Published by Viedoc System 2023-03-07

1. Study roles, eTMF roles, and permissions

2. Scenarios

- 3. Frequently asked questions
 - 3.1 Why can't the end user see the artifact?
 - 3.2 Why can the end user see the artifact but not upload or edit?
 - 3.3 Why can the end user see the artifact but not review or approve?
 - 3.4 Why can the end user only see their own documents in the drop zone?
 - <u>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?</u>

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.

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	

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
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*		 Download audit trail Archive sponsor TMF 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 Regulatory inspector	Read-only access to all documents* and settings Access to audit trail	No role, permissions only	All production sites**		 Read-only Trial Master File* Read-only TMF Admin 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.

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.
elSF: 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).

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