



TMF Standard Model Navigator

User guide

How to explore the TMF Standard Model V1 draft and record your company's assessment of it.

Navigator version 2.0 · Guide issued 19 October 2026
For the CDISC TMF Standard Model V1 draft (19 October 2026)

DRAFT FOR COMMUNITY REVIEW

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NOTE

The screenshots in this guide show a sample assessment in progress by a fictitious user, “Alex Assessor”. Red numbered circles have been added to point out features; they do not appear in the navigator itself.

1 About the navigator

The TMF Standard Model Navigator is an interactive way to read and assess the **TMF Standard Model V1 draft**. It shows every record type in the draft spreadsheet, lets you search and filter them, and lets you record your company's assessment of each one.

What it contains

The full V1 draft dated 19 October 2026: **12 zones, 55 record groups** and **571 record types**, with each record type's purpose, record contexts, subsets, dating convention and ICH E6(R3) mapping. It also includes the Dating Convention, Metadata, Attributes and Acronym lists from the spreadsheet.

What you can do

Explore the model by zone, record group, record context and subset. Rate each record type's impact on your company (No impact, Minor change, Significant change or Not applicable), add notes, track your progress, and keep your assessment as a file or a spreadsheet.

One file, fully offline

The navigator is a single HTML file. It needs no installation and no internet connection, and it sends nothing anywhere. Your notes stay on your computer.

Faithful to the spreadsheet

The navigator shows the draft exactly as written. Where the spreadsheet disagrees with itself (for example a Zone # that does not match its Zone Name), the navigator shows it as it is and marks it in amber.

ABOUT THIS DRAFT

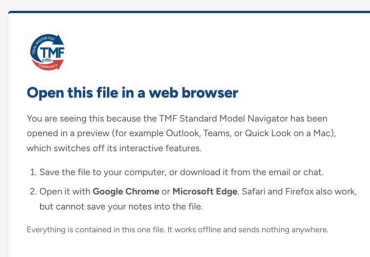
This is the draft of the TMF Standard Model V1 for community review, dated 19 October 2026.

2 Getting started

Open the file in a web browser

- 1 **Save the file to your computer.** If it arrived by email or chat, save or download the attachment first. Do not open it from the preview.
- 2 **Open it with Google Chrome or Microsoft Edge.** Double-click the file, or right-click it and choose **Open with**. Safari and Firefox also work, but cannot autosave your assessment into the file (see section 7).

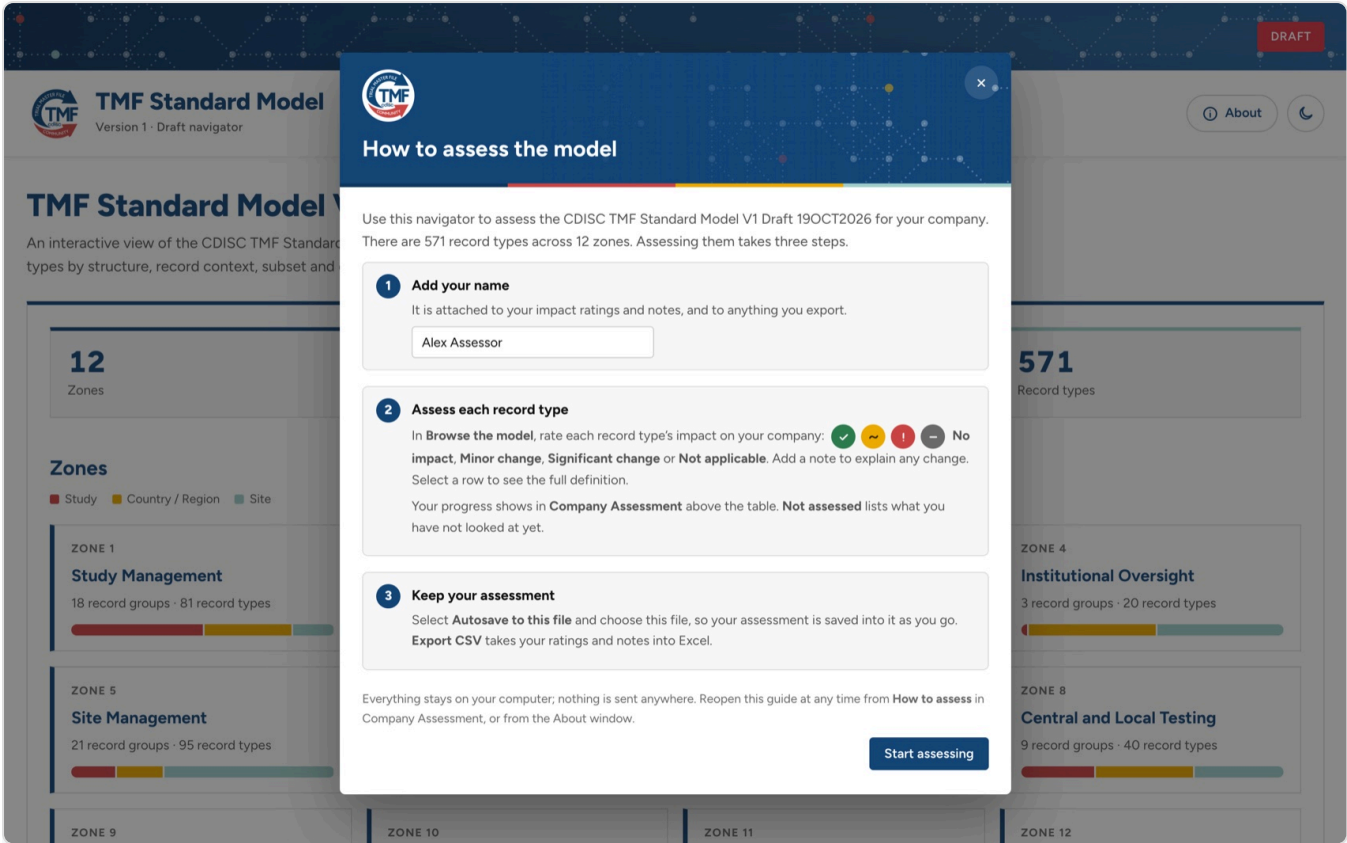
If you open the file in a preview (for example in Outlook, Teams, or Quick Look on a Mac), the interactive features are switched off and you will see this message instead. Save the file and open it in a browser.



What you see if the file is opened in a preview rather than a browser.

The assessment guide

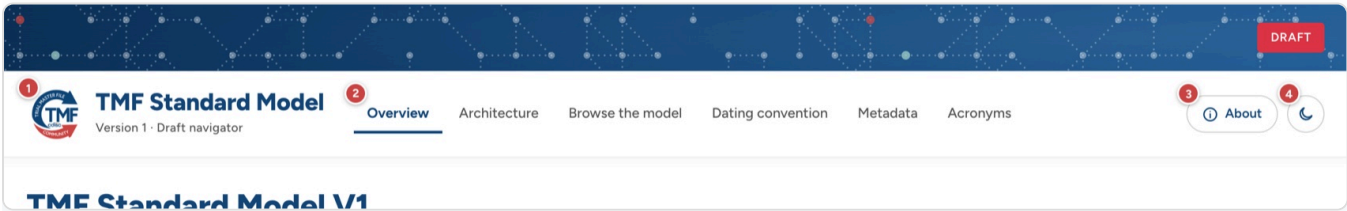
The first time you open the navigator, a short **How to assess the model** guide appears. You can type your name straight into it, then select **Start assessing**. You can reopen it at any time from **How to assess** above the table, or from the **About** window.



The assessment guide, shown the first time you open the navigator.

Finding your way around

The navigator always opens on the Overview, whichever page you were on when you last closed it.



The header stays at the top of the page as you scroll.

- 1 TMF Standard Model:** select it at any time to return to the Overview.

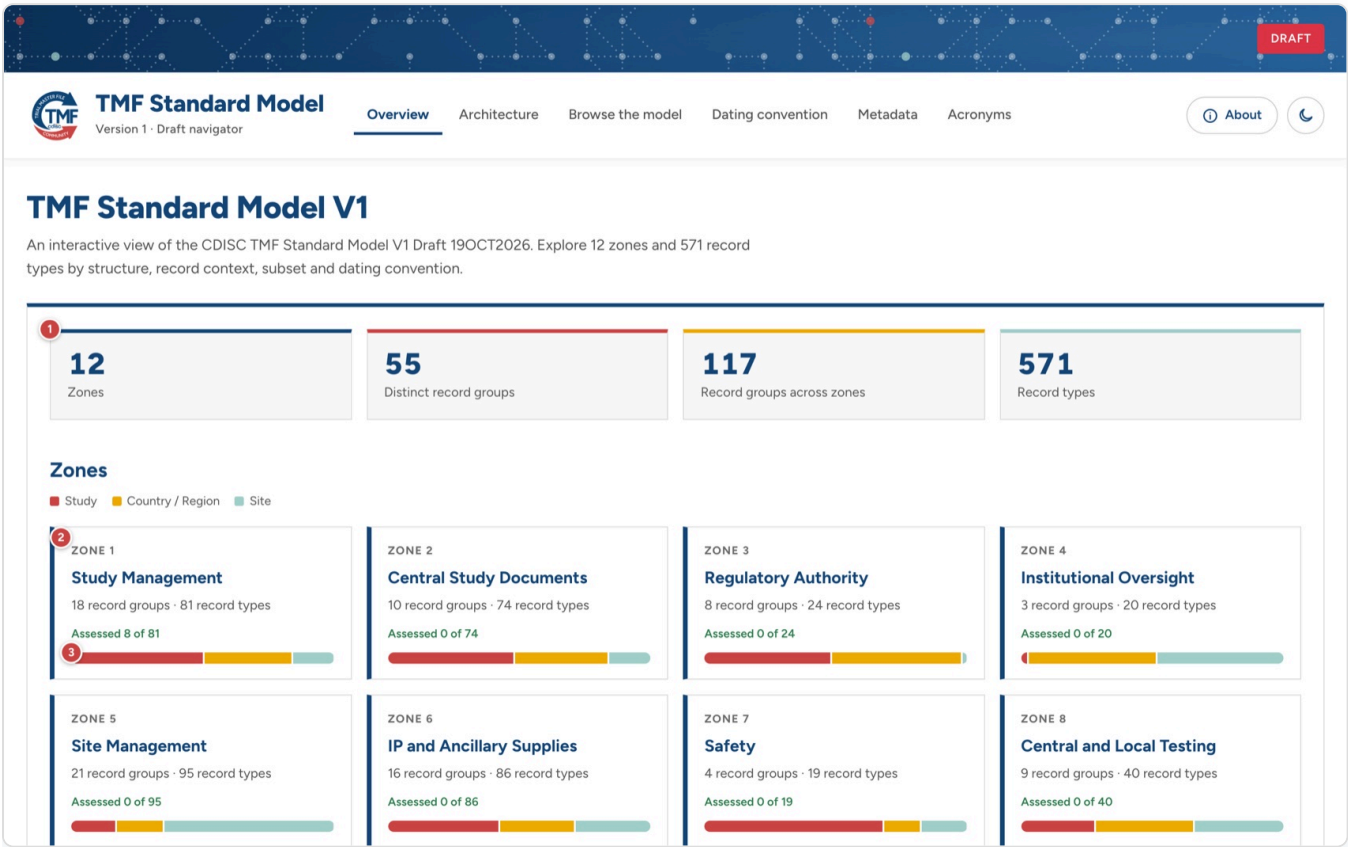
2 Tabs: Overview, Architecture, Browse the model, Dating convention, Metadata and Acronyms.
- 3 About:** the draft's version and date, what is in it, how to use the navigator and a link to the assessment guide.

4 Light / dark: switch between light and dark display. Your choice is remembered.

The red **DRAFT** label in the banner is the status marking from the spreadsheet.

3 Overview

The Overview shows the model at a glance, and every number on it is a shortcut into the detail.

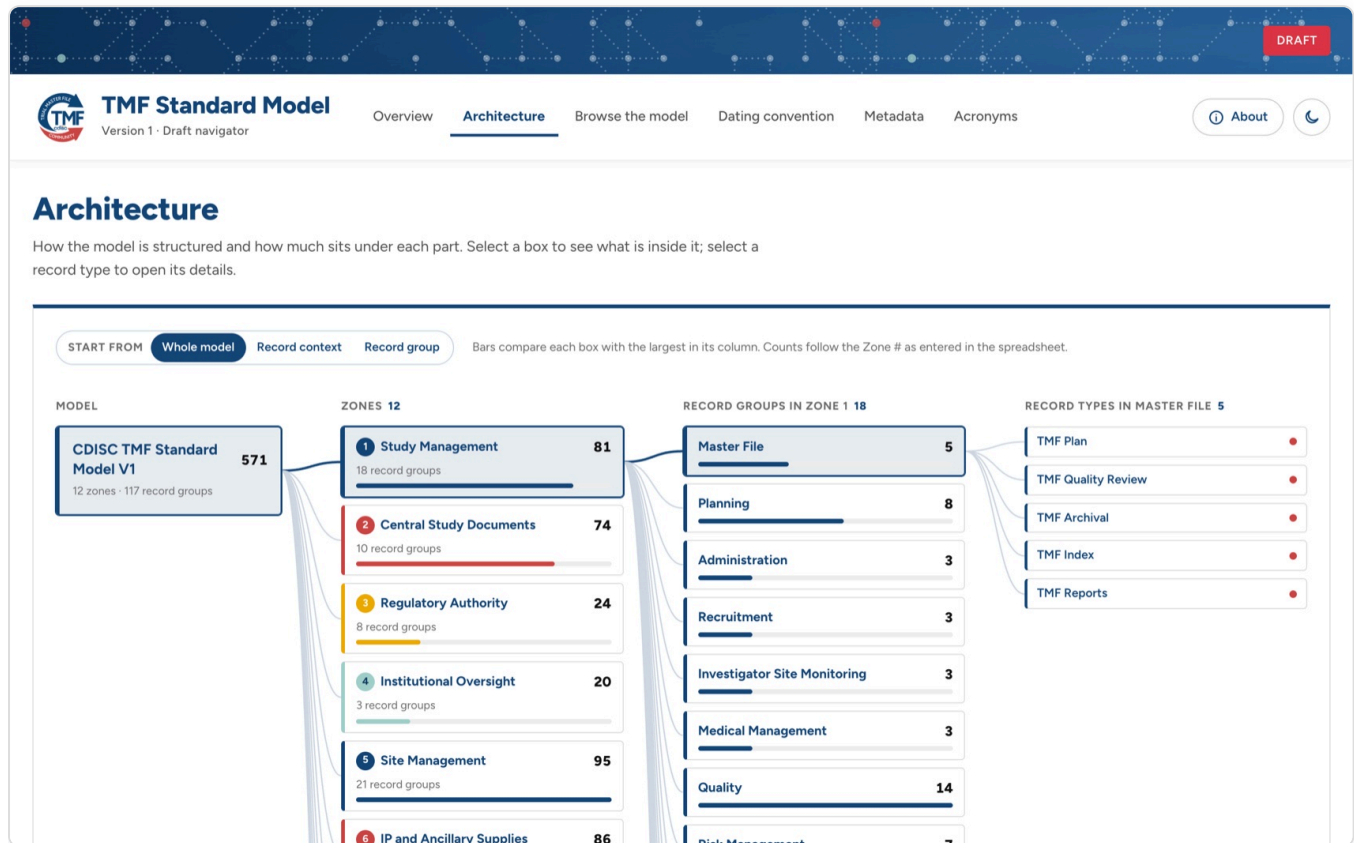


The Overview page.

- 1 Headline counts:** zones, distinct record groups, record groups across zones, and record types.
- 2 Zone cards:** select a card to browse that zone. Once you start assessing, each card also shows how many of its record types you have assessed.
- 3 Record context bar:** the red, amber and teal sections show how many record types sit in the Study, Country / Region and Site record contexts. Hover over a section for the numbers; select it to browse that zone in that record context.
- 4 Applicability by zone:** how many record types in each zone are marked for each record context and subset. Darker cells mean a larger share of the zone. Select a number to see those record types.

4 Architecture

The Architecture tab shows how the model is structured and how much sits under each part, reading left to right like a sideways organisation chart.



The Architecture tab, starting from the whole model.

- **Columns:** the whole model, then zones, then the record groups in the selected zone, then the record types in the selected group.
- **Boxes:** each shows its count and a bar comparing it with the largest box in the same column.
- **Moving through it:** select a zone to see its record groups, and a record group to see its record types. The connecting lines show the path you have selected. Select a record type to open its details.
- **Start from Record context:** puts Study, Country / Region and Site in the first column. Everything to the right then counts only record types in that record context. A record type can sit in more than one record context, so those counts add up to more than 571.
- **Start from Record group:** lists every record group by name, as Browse does with **By record group**. Select a group to see the zones it is used in, and a zone to see the group's record types there. The zone and record type columns move down to sit beside the box you selected.

5 Browse the model

Browse is where you read and assess the record types. It combines filters, your assessment tools and the table of record types.

Type part of a record type name to filter, or pick one from the suggestions. Narrow further by zone, record context, subset or dating convention. Select a column heading to sort and any row for the full definition.

RECORD TYPE: 1. Type a name, or paste a reference

RECORD CONTEXT: 2. Study 81, Country / Region 55, Site 26

SUBSET: Pharmacologic 81, Medical Device 81, IVDR 53, RWE 68, ISF 34

ZONE: 3. 1. Study Management (81)

DATING CONVENTION: 4. Any (81)

5. Show structure, 6. Export CSV

COMPANY ASSESSMENT: How to assess, Your name: Alex Assessor

8. SHOW, Not assessed 73, No impact 4, Minor change 2, Significant change 1, Not applicable 1, With notes 3

8 of 571 assessed, saved in this browser

9. Autosave to this file, Delete all assessments

Showing 81 of 571 record types

ORDER: As in spreadsheet, Grouped by record group, Clear all filters

Zone 1: Study Management

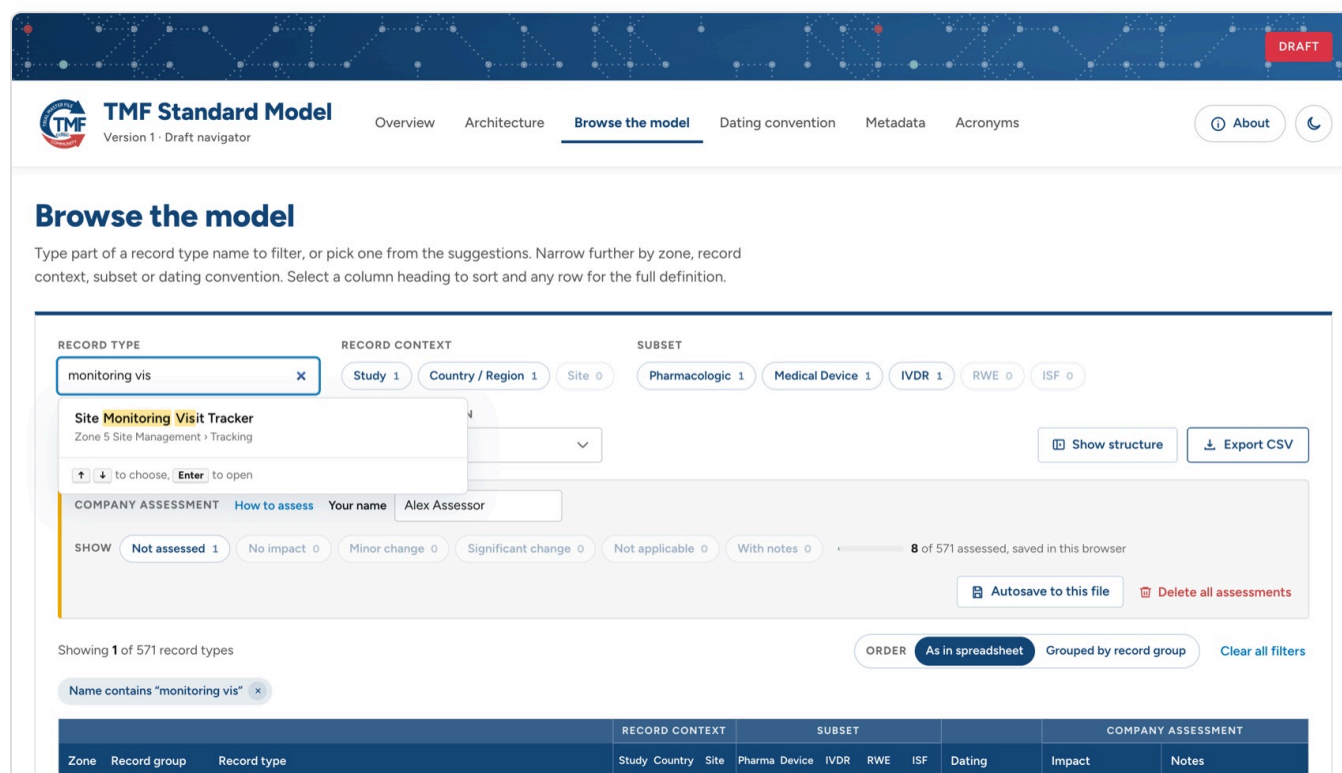
Zone	Record group	Record type	RECORD CONTEXT	SUBSET	Dating	COMPANY ASSESSMENT							
			Study	Country	Site	Pharma	Device	IVDR	RWE	ISF	Dating	Impact	Notes
1	Master File	TMF Plan To describe the strategy, responsibilities, processes, systems, and co...	●			●	●	●	●		Version Date	✓ ~ ! -	Add a note...
		TMF Quality Review To provide evidence that the TMF and its records were evaluated for ...	●			●	●	●	●		Completion Date	✓ ~ ! -	Should this also cover periodic sponsor QC of CRO-held TMF content?
		TMF Archival To provide evidence that the TMF and its records were migrated or tr...	●			●	●	●	●		Completion Date	✓ ~ ! -	Suggest adding "retrieval testing" to the purpose; archival evidence

The Browse page with an assessment in progress.

- 1 **Record type:** search by name. Suggestions appear as you type.
- 2 **Record context** and **Subset:** filter by Study, Country / Region or Site, and by Pharmacologic, Medical Device, IVDR, RWE or ISF. Each button shows how many record types it would give.
- 3 **Zone:** show one zone. Each zone shows how many record types it would give.
- 4 **Dating convention:** show only record types that use a particular date.
- 5 **Show / Hide structure:** open or close the tree of zones and record groups beside the table.
- 6 **Export CSV:** save the listed record types, with your impact ratings and notes, as a spreadsheet file.
- 7 **Your name:** entered once, then used with your ratings and notes.
- 8 **Show:** list only what you have not assessed yet, or only record types with a particular impact rating, or with notes.
- 9 **Autosave to this file:** save your assessment into the file itself (Chrome and Edge). See section 7.
- 10 **Order:** *As in spreadsheet* (the default) or *Grouped by record group*.
- 11 **Impact:** your rating of each record type's impact on your company. See section 6.
- 12 **Notes:** type your comments directly in the table.

Finding a record type

Type part of a name in **Record type**. The words can be partial and in any order: “monitoring vis” finds *Site Monitoring Visit Tracker*. Suggestions show the zone and record group underneath each name. Use   and **Enter**, or click, to open one. The table also filters as you type.



Browse the model

Type part of a record type name to filter, or pick one from the suggestions. Narrow further by zone, record context, subset or dating convention. Select a column heading to sort and any row for the full definition.

RECORD TYPE monitoring vis 

RECORD CONTEXT Study 1 Country / Region 1 Site 0

SUBSET Pharmacologic 1 Medical Device 1 IVDR 1 RWE 0 ISF 0

COMPANY ASSESSMENT How to assess Your name Alex Assessor

SHOW Not assessed 1 No impact 0 Minor change 0 Significant change 0 Not applicable 0 With notes 0 8 of 571 assessed, saved in this browser

Showing 1 of 571 record types

ORDER As in spreadsheet Grouped by record group Clear all filters

Name contains "monitoring vis" 

RECORD TYPE			RECORD CONTEXT			SUBSET				COMPANY ASSESSMENT		
Zone	Record group	Record type	Study	Country	Site	Pharma Device	IVDR	RWE	ISF	Dating	Impact	Notes

Suggestions appear as you type a record type name.

Reading the table

- **Dots:** navy dots ● show the record contexts a record type applies to; blue dots ● show its subsets. An empty cell means not marked.
- **Company Assessment:** the **Impact** and **Notes** columns at the right sit under this heading. They hold your company's assessment of each record type.
- **Descriptions** are shortened to one line. Select any row to read the full definition in the side panel.
- **Sorting:** select any column heading to sort by it. Select it again to reverse the order, and a third time, or **Reset sort**, to return to spreadsheet order.
- **Zone name mismatch:** an amber ring on the zone number and an amber “Zone Name: ...” label mean the row's Zone Name in the spreadsheet does not match its Zone #. The row is shown under its Zone #, as in the spreadsheet.
- **The tree:** select **Show structure** to browse by zone, then record group, then record type, or by record group across zones.
- **Narrow windows:** when the window is narrower than about 1,200 px (for example beside another application), the Record context and Subset columns are hidden so the record type names stay readable, and a line above the table says so. Widen the window to see them again, or select a row: the side panel always shows them.

The side panel

Select any row, tree item or record type on the Architecture tab to open the side panel with everything about that record type.

The screenshot displays the TMF Standard Model Navigator interface. The main panel shows 'Zone 1: Study Management' with filters for Record Type, Record Context, and Subset. The side panel is open for 'TMF Quality Review' (Spreadsheet row 5). It includes a 'PURPOSE / DESCRIPTION' section, a 'COMPANY ASSESSMENT' section with buttons for 'No impact', 'Minor change', 'Significant change', and 'Not applicable', and a 'Notes' section. The side panel also shows 'RECORD CONTEXT' and 'SUBSET' filters, a 'DATING CONVENTION' section, and a 'Completion Date' field. The bottom of the side panel shows 'Spreadsheet row 5 - 2 of 81' and navigation buttons for 'Previous', 'Next', and 'Copy reference'.

The side panel for a record type.

- 1 **Record type**, with links to its zone and record group above it.
- 2 **Spreadsheet row**: the row number in the draft spreadsheet, useful when discussing a record with colleagues.
- 3 **Company Assessment**: your impact rating, with larger labelled buttons.
- 4 **Notes box**: space for longer comments. It shows the same note as the table.
- 5 **Copy reference**: copies a reference you can paste into an email or chat (section 8).
- 6 **Previous / Next**: move through the record types in the current list without closing the panel.

Below these are the record type's record contexts and subsets, its dating convention with the definition, its ICH E6(R3) mapping, and the other record types in the same group. Acronyms with a dotted underline show their meaning when you hover over, click or tap them. Close the panel with **x** or **Esc**.

6 Assessing record types

For each record type, rate its impact on your company and, where helpful, add a note. Everything saves as you go.

- 1 **Add your name** in **Company Assessment** above the table, or in the assessment guide. It is attached to your ratings, notes and exports.
- 2 **Rate the impact** in the **Impact** column, or with the larger buttons in the side panel:
 **No impact**  **Minor change**  **Significant change**  **Not applicable**. Select the same rating again to clear it. *No impact* also means “looked at, nothing to change”.
- 3 **Add a note** to explain any change: click in the **Notes** cell and type, or use the notes box in the side panel. Cells with a note turn pale amber.
- 4 **Track your progress** in **Company Assessment**: the green bar and “N of 571 assessed” count every record type with a rating or a note. Use **Show: Not assessed** to see what is left.

Changing your mind

Select the trash icon in a note, or **Delete note** in the side panel, to remove a note. **Delete all assessments** removes all your ratings and notes. You are always asked to confirm, and **Cancel** is selected by default.

Zone 1: Study Management

Zone	Record group	Record type	RECORD CONTEXT			SUBSET					Dating	COMPANY ASSESSMENT	
			Study	Country	Site	Pharma	Device	IVDR	RWE	ISF		Impact	Notes
1	Master File	TMF Plan To describe the strategy, responsibilities, processes, systems, and co...	•			•	•	•	•		Version Date	   	Add a note...
		TMF Quality Review To provide evidence that the TMF and its records were evaluated for ...	•			•	•	•	•		Completion Date	   	Should this also cover periodic sponsor QC of CRO-held TMF content?
		TMF Archival To provide evidence that the TMF and its records were migrated or tr...	•			•	•	•	•		Completion Date	   	Suggest adding "retrieval testing"

Delete note, are you sure?

CancelDelete

Notes in the table, with the confirmation shown when deleting one.

7 Saving your assessment

Your assessment saves automatically in your browser as you work. To keep it safe, save it into a file.

In Chrome or Edge: autosave into the file (recommended)

- 1 Select **Autosave to this file** in **Company Assessment**.
- 2 In the window that opens, choose the navigator file you are using and select **Save**. Confirm if asked to replace it.
- 3 From then on, every rating and note is saved into that file. The button reads **Autosaving to file ✓** and the status shows the time of the last save.
- 4 That file now holds your assessment. Keep it somewhere safe, and share it within your company if colleagues need it.

TIP

After you close and reopen the file, the browser may ask for permission again. Select **Resume autosave to file** to carry on.

In Safari or Firefox: download a copy

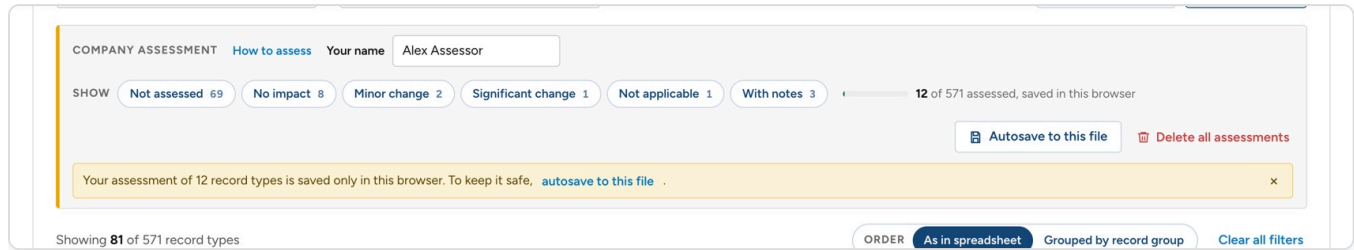
Select **Download copy with notes**. This saves a copy of the navigator with your assessment built in, named with your name and the date. Keep that file. Download a fresh copy whenever you have made more progress.

Export to a spreadsheet

Export CSV saves the listed record types as a spreadsheet file with your impact rating, notes, when each was last changed and your name. Rows are always in spreadsheet order. In a full export, every row number matches the draft spreadsheet: the headings are on row 3 and each record type sits on the same row as in the original.

Reminder

If you have assessed several record types but they are saved only in your browser, an amber reminder appears with a one-click fix.



The reminder shown when your assessment is saved only in the browser.

IMPORTANT

Your assessment is kept in the browser on this computer. Clearing browser data, or using another browser or computer, will not show it. Autosave or download a copy regularly.

8 Sharing a record with colleagues

Because everyone has their own copy of the file, web links do not work between people. Instead, use a **reference**.

- 1 Open the record type's side panel and select **Copy reference**.
- 2 Paste it into your email or chat. It looks like this:
TMF Quality Review
Zone 1 Study Management > Master File · CDISC TMF Standard Model V1 Draft
190CT2026, spreadsheet row 5
[TMF SM ref: 1 > Master File > TMF Quality Review]
To open it, paste this text into the Record type box on the Browse page of the TMF Standard Model Navigator.
- 3 Your colleague pastes the whole message into the **Record type** box on Browse in their copy, and that record type opens.

References use the record type's name, so they keep working in later drafts even when row numbers change. If the record type has been renamed or removed, the navigator says so and shows the closest match.

9 Other tabs and settings

Dating convention

Each date type with its definition and typical record types. Select a count to see the record types that use it. The dating convention is marked in the draft as still in development.

Metadata

The six standard metadata fields the draft defines for records (Record Type, Study, Country, Site, Filing Level and Record Date), with descriptions, examples, when each is required and its data type. Below them, the definition of each column in the model.

Acronyms

All 71 acronyms used in the model, with a filter box.

Standard metadata				
The 6 fields the draft defines for records in the TMF. In the model sheet every record type marks all 6 with an R (required); the Required column below says when each applies.				
Field	Description	Example	Required	Data type
Record Type Standard	The Record Type within the Record Group the record is associated with The Record Type is part of the structure to help organize records	Study Master File Plan	Required	Controlled from Standard Model but ability to add
Study Standard	The unique identification value given by the Sponsor. Usually the Protocol Number/Identifier. The Study value is required to help distinguish one TMF to another	STD_PIII_01	Required	Text
Country Standard	The country which the record belongs to, applicable for Country and Site level records only Studies may contain multiple countries and understanding which approval is related to which country is essential	GBR	Required for all country level records	Controlled Value: ISO 3166-1 alpha-3
Site	A unique identification value assigned to the site within a study which	UK001	Required for all site	Text

The Metadata tab.

Dark mode

The moon / sun button in the header switches between light and dark display. The layout and colours of meaning stay the same.

Browse in dark mode.

10 Troubleshooting and questions

The page is blank, or says “Open this file in a web browser”.

The file has been opened in a preview (Outlook, Teams, Quick Look). Save it to your computer and open it in Chrome or Edge.

My ratings and notes have disappeared.

Your assessment is kept in the browser you used. Check you are using the same browser on the same computer. If you used **Autosave to this file** or **Download copy with notes**, open that file: your assessment is inside it. When a file with an assessment is opened, its notes are combined with any in the browser, and the most recent version of each note is kept.

Autosave asks for permission again.

Browsers ask again after the file is closed and reopened. Select **Resume autosave to file**.

I chose the wrong file when turning on autosave.

The navigator asks before saving into any file other than the one you have open, and only accepts HTML files. To change file, select the autosave button again and choose the right one.

Can I use it on an iPad or phone?

You can read the model in Safari on an iPad, but it is designed for a computer. Previews in the Files app will not work, and autosave to file is not available. Use a computer for assessing.

A reference a colleague sent me does not open the right record.

Check you pasted the whole message, including the part in square brackets. If the record type has been renamed in your version of the draft, the navigator shows the closest match.

Why do some rows show an amber “Zone Name” label?

In the spreadsheet, that row's Zone Name does not match its Zone #. The navigator keeps it under its Zone #, exactly as the spreadsheet does, and flags it in amber.

Does the navigator send my data anywhere?

No. It works entirely offline. Your assessment only leaves your computer if you share the file or spreadsheet yourself.

Which browser should I use?

Google Chrome or Microsoft Edge. Safari and Firefox work, but cannot autosave into the file, and Safari may not keep your assessment after it is closed, so download a copy there.

11

Quick reference

To...	Do this
Find a record type	Browse › type part of its name in Record type , then pick a suggestion
See a record type's full definition	Select its row, tree item or Architecture box
Browse one zone	Browse › Zone , or Overview › select the zone card
See one zone in one record context	Overview › select that coloured section of the zone's bar
Filter by record context, subset or date	Browse › the Record context, Subset and Dating convention filters
Group rows by record group	Browse › Order › Grouped by record group
Sort the table	Select a column heading (again to reverse; Reset sort to undo)
Rate the impact	    in the Impact column or the side panel
Add a note	Type in the Notes cell, or in the side panel's notes box
See what is left to assess	Company Assessment › Show › Not assessed
Save your assessment into the file	Company Assessment › Autosave to this file (Chrome, Edge)
Save a copy (Safari, Firefox)	Company Assessment › Download copy with notes
Export to a spreadsheet	Browse › Export CSV
Point a colleague to a record	Side panel › Copy reference, then paste into email or chat
Open a reference you were sent	Paste it into the Record type box on Browse
Remove a note or all assessments	Trash icon or Delete note; Delete all assessments (you are asked to confirm)
Reopen the assessment guide	Company Assessment › How to assess, or About
Switch light / dark	The moon / sun button in the header

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