

Oracle Life Sciences eTMF

Release Notes



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G45297-02
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Oracle Life Sciences eTMF Release Notes, Release 25.1

G45297-02

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What's new

Learn about new and enhanced functionality in this release.

TMF Viewer

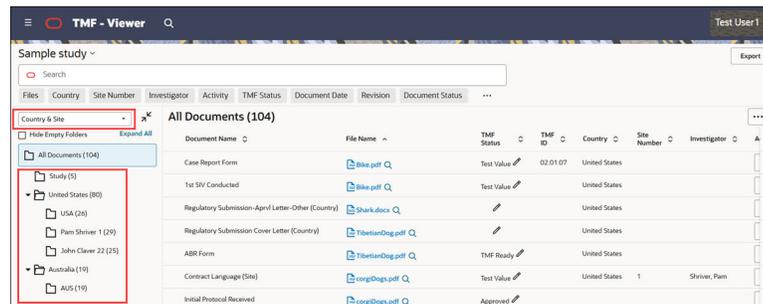
This release includes multiple usability enhancements that make it easier to interact with the TMF Viewer and new features that improve document management activities.

Country site view

The TMF Viewer now lets you switch between the standard TMF Reference Model v3.3.1 view and a new Country & Site view using a drop-down control above the folder structure. When you change to Country & Site view, the folder structure under "All Documents" updates to display study, country, and site-level folders.

When you change the view, you'll always land on the "All Documents" folder regardless of your previous location. The folder naming conventions include study documents; country and site documents with the full country name; country-level only documents listed by country code; and site-level folders identified by the PI's name and site number.

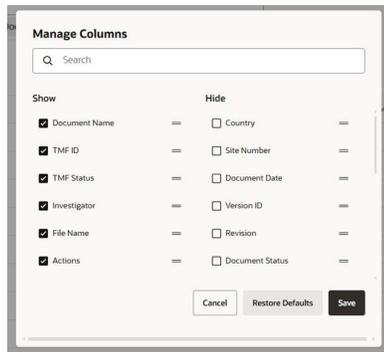
Any smart search filters you've applied will remain active after switching views, and all filter and column options (including default and your selected columns) are available in both views. You can change the Country & Site view back to TMF Reference Model v3.3.1 view at any time.



Column enhancements

In this release, you'll see enhancements that make document actions and activities in the TMF Viewer more accessible and intuitive. You'll also see changes to the TMF Viewer default columns and column ordering.

A new Actions column now appears in the TMF Viewer, showing an Actions button for each document. When you click this button, you'll see options specific to that document like Activity name, Activity name – Blocked, View Document – Completed, or View Document – Read only. Each option opens the item drawer, giving you direct access to view or manage the document. After clicking the Actions button, you may also see actions like Discontinue/Reinstate this version, Add a new version, or Add an associated version after clicking the Actions button. The



Finally, we added three new columns in this release that you can select in the Manage Columns modal:

1. TMF Zone (e.g., 01 Trial Management)
2. TMF Section (e.g., 02 Trial Team)
3. TMF Artifact (e.g., 01.02.01 Trial Team Details)

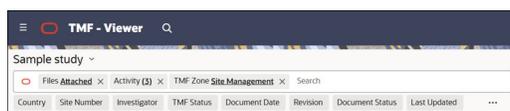
The new columns/fields are also available as options under the more filters menu ******* in smart search, allowing you to search and filter by trial management details, trial teams, and specific artifact information.

Smart search

For the TMF Viewer's smart search field, we enhanced the following multi-select filters so that if you select only one value, the selected value will display in the smart search bar, and if you select multiple values, you'll see a count of the total values you selected:

- Activity
- TMF Status
- Country
- Site Number
- Investigator
- TMF Zone
- TMF Section
- TMF Artifact
- Document Status
- Revision

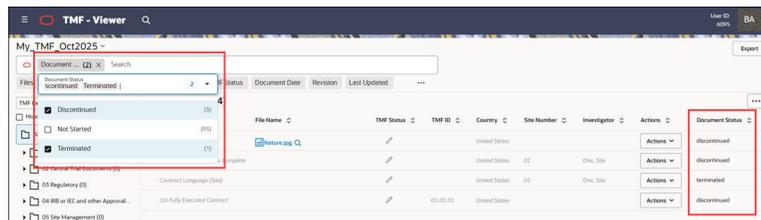
You can still use free text search to narrow down the available options, and when you search, only one input field will be used to display both the selected values and your search text. We removed the redundant input field in this release.



Discontinued document filter

Discontinued documents are now clearly distinguished in the TMF Viewer to help you avoid confusion with active items. Discontinued, Terminated, and On hold documents appear in gray, italicized text. You can still preview or download these files directly from the table and open the item drawer as usual.

Document status search filters let you include or exclude Discontinued, Terminated, and On hold items. By default, these statuses are excluded from the results. The Document Status column reflects all applicable statuses if you add it to the table. If there are no documents with a specific status, that status will not be shown in the filter options. Additionally, for discontinued items, the Actions option in the TMF Viewer is now labeled Reinstate.



Live refresh

To make sure you see the most up-to-date information in the TMF Viewer document grid, the page now automatically refreshes when you open or close the item drawer, update document or item metadata (such as TMF status), change folder locations, or adjust filters. You no longer need to manually refresh the page, as these actions will automatically update the displayed values.

Document (Record) management

Now you can generate placeholders in the TMF Viewer, drag and drop files, rename files, capture the reason for document rejection, and more.

Add new documents

eTMF users can now generate placeholders while navigating the TMF Viewer, making it easier to manage documents directly from the folder structure. From within a defined folder (for example, 01.01.01), you can click the new plus (+) icon at the far right to add a placeholder. When you select this option, a modal appears with the following fields:

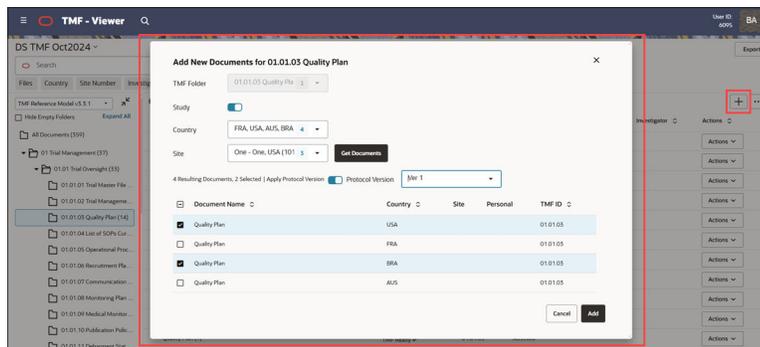
- TMF Folder – Read-only field displaying the TMF Artifact and ID
- Study toggle – Enable to include study-level items in the document list
- Country – Multi-select field showing current countries in the study
- Site – Multi-select field showing current sites within the selected country or countries

After selecting the country and site, click the 'Get Documents' button to create a list of available placeholders based on artifacts mapped to the TMF ID of the selected folder and your chosen country or site. Select one or more available artifacts, and you'll see both the number of items found and the number you've selected above the table. Above the table, you'll also see an Apply Protocol Version toggle. Apply the protocol to your selected documents by enabling the toggle and choosing a protocol from the drop-down. Below the table, click the "Add" button; the placeholders will be generated and added to the TMF folder, following existing artifact

versioning rules. If no placeholders are available based on your selections, you will see the message “No placeholders available based on your selection.”

When you add new documents, you’ll see one of the following feedback messages depending on the outcome:

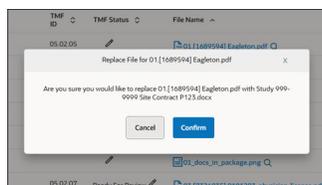
- **Documents added:** *New activities for the workflow you ran are being generated. Please refresh the page to check status.*
 - This message shows for as long as the jobs are in progress. It displays even after a page refresh, if jobs are still in progress.
- **Document added, with some failures:** *New activities for the workflow you ran are being generated. Please refresh the page to check status. Documents for <x> and <y> are not added. Activities are already being generated. Please wait a few minutes and try again.*
 - This message indicates both success and failure and remains displayed, including after page refresh, as long as the jobs are in progress.
- **Documents are NOT added:** *Activities are already being generated. Please wait a few minutes and try again.*
 - The failure message displays once and can be closed manually. It will not display after page refresh since no jobs are triggered.



Drag and drop files

With this release, you can now drag and drop files directly from your desktop into a document in the TMF Viewer, provided the open activity allows file uploads and you have permission to work on the item. This functionality also allows you to replace files for documents that already have an attachment. If you attempt to replace a file, you’ll be prompted to confirm the change before the file is replaced. Please note that this new drag and drop upload functionality applies only to the TMF Viewer’s Document Name, File Name, and Activity columns.

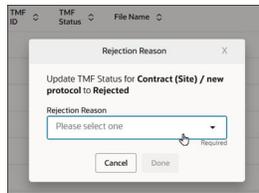
You can continue uploading additional files even while one or more files are processing, but if you attempt to drag and drop multiple files into a single document, no action will occur. Once uploaded, the file is saved automatically to the item, so you won’t need to take further steps. If you drop a file in an unsupported format or one that exceeds size limits, an error message displays, and you’ll need to modify the file type or file size in order to proceed.



Document rejection reason

With release 25.1, you can now capture the reason for rejection when a document's eTMF status is set to "Rejected." You'll be required to specify a rejection reason if the "Collect reason when marking a document with eTMF status Rejected" feature is enabled for your organization's account.

You'll select a reason from the list configured for your account before you can save the status as Rejected. The reason you select from the list will be captured and stored, and the rejection reason will also be included in the audit trail when the eTMF status is changed.



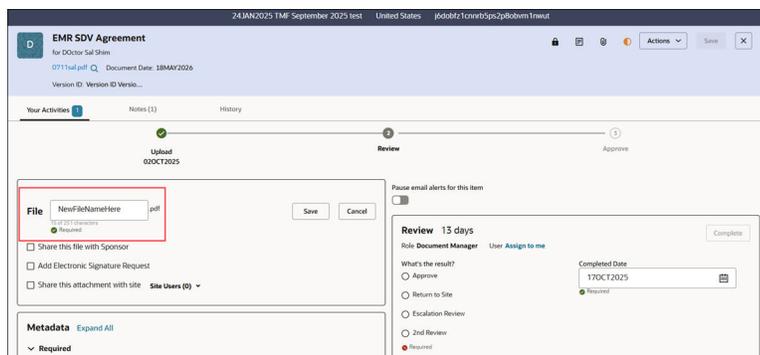
Note

Please contact your Oracle project manager to discuss requirements for enabling rejection reason functionality for your organization's account.

Rename files

You can now rename files on open activities to help ensure file names accurately reflect their contents and comply with study naming conventions. When you upload a file and save the item, an edit  icon appears next to the file name if the activity is still open and you have the necessary permissions to edit. You cannot rename files if the activity is closed or completed, and only users who can act on the activity are allowed to edit the file name.

When you select the edit option, a text field lets you enter a new file name, excluding the extension, with the total file name and extension limited to 254 characters. A character counter shows how many characters you have left after accounting for the extension. Click Save to update the file name in real-time. When you rename and save an existing file, a new file version is created, showing who renamed it and when. The previous version appears in the file history. An audit record is also created for each rename action to ensure a clear version history.



Unblinded value carryover

Currently, when you create a new version or an associated version of an item with Unblinded (Restricted)=False, this status is carried over to the new item. With release 25.1, we've extended the same behavior to items marked as Unblinded (Restricted)=True, so that when you upversion or associate a restricted item, the new version will also retain its restricted status.

For restricted items, unauthorized users will not be able to open the new version, and all users will see a lock icon next to it in the document list. This ensures that both restricted and non-restricted statuses are consistently preserved across new and associated versions.

TMF ID

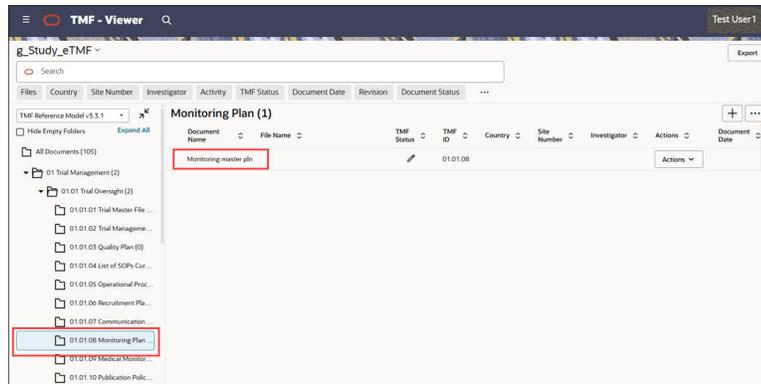
You can now optionally include a TMF ID in ad-hoc document metadata. When this feature is enabled for your organization's account, a new 'TMF Reference ID' field will be available when you add an ad-hoc document at the Study, Country, or Site level. The field has a searchable drop-down list that includes values from the TMF reference model version tied to the study's configuration. Once you select a TMF Reference ID, it will display on the confirmation screen and remain associated with the document when reusing it. Additionally, eTMF event messages will include the TMF Reference ID (e.g., 01.02.05) under the TMF Artifact section.

The screenshot shows a web form titled "g_Study_eTMF" with two numbered steps: "1 View or add a document" and "2 Confirm". The current step is "1 View or add a document". Under the heading "Or add a new ad-hoc document for this study", there are several input fields:

- Enter a document name:** A text box containing "Monitoring master pln" with a character count of "21 of 50 characters" and a "Required" indicator. This field is highlighted with a red box.
- TMF Identifier:** A text box containing "12345".
- What type of document is it?:** A dropdown menu with "Core" selected and a "Required" indicator.
- TMF Sub Type:** An empty text box.
- If protocol is related, which protocol version?:** A dropdown menu with "uuy67" selected.
- TMF Sub Sub Type:** An empty text box.
- Choose a workflow to process this document:** A dropdown menu with "etest B4-RO" selected and a "Required" indicator.
- Attribute ID:** A text box containing "123 456" with a character count of "Enter 1 to 32 characters." and a "Required" indicator.
- TMF Reference ID:** A dropdown menu with "1.1.8 - Monitoring Plan" selected. This field is highlighted with a red box.

At the bottom of the form, there are "Next" and "Cancel" buttons.

When you create an ad-hoc document with a TMF Reference ID value, it will be displayed in the appropriate section of the TMF Viewer. If no TMF ID is set, the document will instead be placed in the TMF Viewer's generic ("All documents") folder.



Note

If no TMF version is configured for the study, the TMF Reference ID field will not be available when adding an ad-hoc document. Please contact your Oracle project manager to discuss requirements for enabling this functionality for your organization's account.

User interface

Now you can minimize the global navigation menu if preferred.

Global navigation

At the bottom of the vertical menu, you can optionally click minimize  to pin the menu to the left and view icons only. Your minimize/maximize selection (i.e., icon pinned view vs. full hidden view) will be saved and the next time you sign in, the menu will load as you left it.

User management

We updated permissions required to access contract documents.

Business role permission

We updated user permissions in this release to ensure proper access to contract documents. With release 25.1, you must have a contract business role permission to view contract and subcontract documents in the TMF Viewer. This enhancement is intended to limit visibility of sensitive information to authorized personnel only.

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Stability improvements

These are the issues we fixed in release 25.1.

TMF Viewer

Description	Ticket	Severity
If you updated the search to remove the "Files attached" filter, sub-folders in the document tree could display an incorrect count of applicable documents.	CHK-47624	2
When a study was created via the POST Studies API method, the "Enable Oracle eTMF Functionality" setting was not turned on as expected in an account licensed with Oracle eTMF.	CHK-50681	2
The TMF Viewer did not display documents as expected after the "Enable Oracle eTMF Functionality" setting was turned on for an existing study in an account licensed with Oracle eTMF.	CHK-50700	2
When a file was uploaded and then replaced within a short time frame, the TMF Viewer could display the original file instead of the new one.	CHK-50733	2

3

New known issues

These are the unresolved issues found during release 25.1 development.

TMF Viewer

Description	Ticket	Severity
When you upload files larger than 126 MB, you may experience slow upload speeds and occasional errors.	CHK-47225	2
When you continue or discontinue an item and choose Other as the reason, there is no text box available to enter the reason for your action.	CHK-47841	3
When you turn off the 'Enable Oracle eTMF functionality' setting for a TMF viewer study, the study still appears in the TMF Viewer study drop-down.	CHK-50790	4
If a network error occurs during the upload of a large file, no error message is displayed to suggest that you try uploading again.	CHK-50866	2
When you turn off a study's "Enable Oracle eTMF functionality" setting, documents from that study still appear in the TMF Viewer. Turning this setting off should remove all documents from the TMF Viewer for the entire study, but currently, they remain visible.	CHK-51059	3
When you filter by Document date, Last updated, or file upload date, the filter you're using incorrectly disappears from the search area after you select the End date. Workaround: Quickly select both start and end dates (for example, from the current month) and filter data, then go back and enter your desired dates; the date filter should remain active.	CHK-51182	3

4

Severity definitions

Learn more about how we describe the four issue severity levels.

Severity	Description
1	Your production use of the supported programs is stopped or so severely impacted that you cannot reasonably continue work. You experience a complete loss of service. The operation is mission critical to the business and the situation is an emergency.
2	You experience a severe loss of service. Important features are unavailable with no acceptable workaround; however, operations can continue in a restricted fashion.
3	You experience a minor loss of service. The impact is an inconvenience, which may require a workaround to restore functionality.
4	You request information, an enhancement, or documentation clarification regarding your software but there is no impact on the operation of the software. You experience no loss of service. The result does not impede the operation of a system.

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Browser support

Use a supported or certified web browser to ensure expected functionality and technical support.

Our goal is to provide customers with the best experience and advanced capabilities while maintaining maximum security. As products are enhanced, older browsers may no longer provide the capabilities required to support these key objectives. We test the current release as follows to certify and/or support browsers:

- **Certified browsers** undergo full testing for new features and regressions. Browser-related issues found after release are prioritized for fixes in future patches or releases.
- **Supported browsers** undergo focused testing on commonly-used pages. We also address all browser-related critical and blocker issues that originate in our applications.

The following table specifies the certified and supported browsers for desktop and laptop computers:

Product	Release	Certified (Latest versions as of GA)	Supported (Latest version as of GA)
Oracle eTMF	25.1	Google Chrome and Microsoft Edge (Chromium)	None

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Revision history

This book's revision date history and part number list will develop over time as we make minor or hotfix releases available for release 25.1.

Date	Part number	Description
10Feb2026	G45297-01	25.1 General Availability Release Notes