

Oracle Life Sciences eTMF

Release Notes



Release 26.1
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Contents

1	Release 26.1	
	What's new	1
	TMF Viewer	1
	Document management	5
	User account management	11
	Impact analysis	12
	Stability improvements	14
	TMF Viewer	14
	New known issues	15
	TMF Viewer	16
	Previously reported known issues	16
	TMF Viewer	16
2	Severity definitions	
3	Browser support	
4	Revision history	

1

Release 26.1

What's new

Learn about new and enhanced functionality in this release.

TMF Viewer

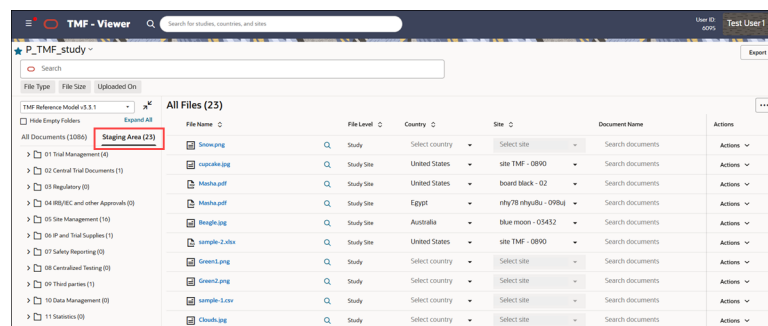
This release enhances TMF Viewer with a new Staging Area for managing files before document assignment, streamlined navigation between documents in the artifact drawer, a default sortable Type column in All Documents, and consistent study favorites behavior between TMF Viewer and Oracle Site Activate.

Staging Area in TMF Viewer

Release 26.1 introduces a new Staging Area in the TMF Viewer, giving you a dedicated place to upload, review, organize, and manage files before they're attached to documents. This provides a single workspace for files that have been added to a study but aren't yet associated with a document, so you can prepare them for assignment without uploading them again later.

The new Staging Area tab appears next to All Documents in the TMF Viewer. Switch between the TMF Reference Model v3.3.1 folder structure and the Country & Site folder structure to work with unassigned files in the context that best fits your workflow. Only files that aren't attached to documents appear in the Staging Area.

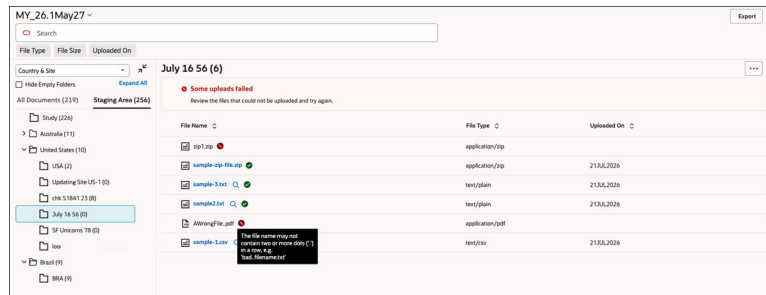
By default, the table includes File Name, TMF ID, File Level, Country, Site, Document Name, Uploaded On, and Uploaded By columns. Use the Manage Columns control to show, hide, or reorder available columns. Your Staging Area column preferences are saved separately from your All Documents preferences. Most columns also support sorting, and Smart search lets you search by file name or uploader and filter by file type, file size, or upload date.



To add files, drag and drop multiple files into supported TMF, study, country, or site folders. During an upload session, status icons indicate whether each file is Queued, In Progress, Failed, or Completed. Hover over a failed upload to see additional information, or cancel an individual upload while it's still queued.

While uploads are in progress, a warning reminds you to keep the page open because leaving or refreshing will cancel incomplete uploads. When the session finishes, the message changes

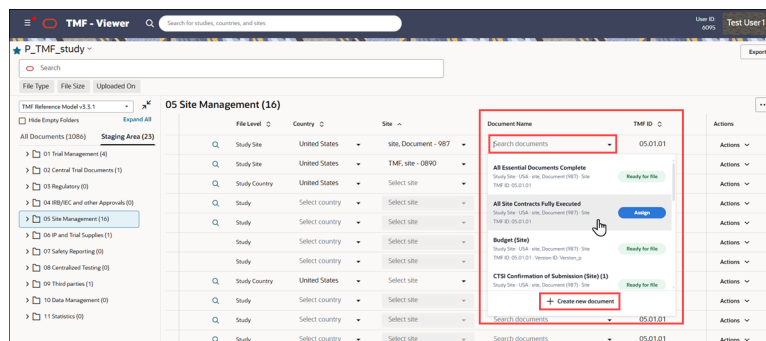
to indicate whether all uploads completed successfully or whether some files failed. If you leave or refresh during an active upload session, incomplete uploads are canceled, while successfully uploaded files remain available in the Staging Area.



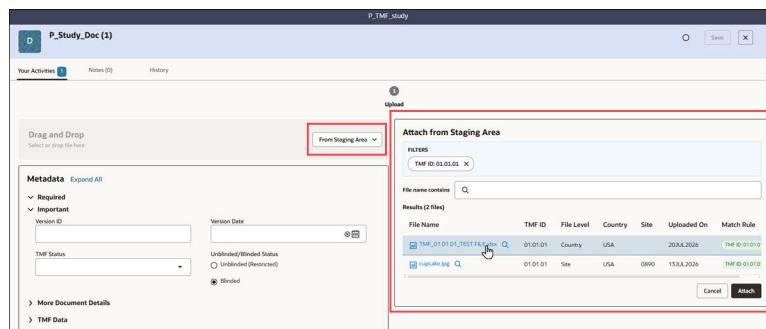
Before assigning a file to a document, use the Staging Area to organize its filing information. Files added through the TMF folder structure initially use the Study file level. For unassigned files, selecting a country or site updates the file level and places the file in the corresponding folder. The TMF ID is also editable through a searchable list of available TMF IDs. Updating it moves the file to the applicable TMF folder and affects the documents available for assignment or creation.

When a suitable document placeholder already exists, the Document Name column provides a searchable list of eligible documents that don't have a file attached. Results are narrowed using applicable information such as TMF ID, file level, country, and site, and additional metadata helps you identify the correct document. After you select and confirm the assignment, the file is removed from the Staging Area and appears with the selected document in All Documents.

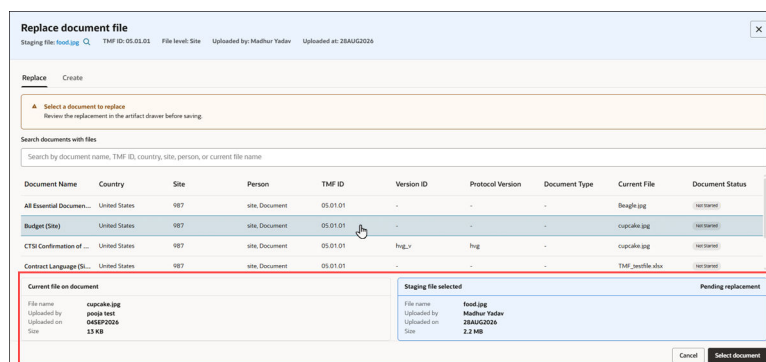
If a document doesn't already exist, select + Create new document at the bottom of the Document Name control or use the corresponding option from the Actions menu. This option is available when the staging file has a TMF ID. The create flow uses information from the file to identify applicable document options. After the document is created, it appears as the selected document so you can review the association before completing the assignment.



The artifact drawer also supports attaching a Staging Area file to a document that doesn't yet have a file. The Attach control lets you choose from From your computer and From Staging Area. Selecting From Staging Area opens a file picker where you can search and filter available files, review why each file matched the current document, and select one file to attach. The attachment remains an unsaved change until you select Save. After a successful save, the file is assigned to the document and no longer appears as unassigned in the Staging Area.



For documents that already have a file, you can use the Replace document file option in the Staging Area Actions menu if you need to correct or update a document file without creating a duplicate document. Search for an eligible document, review its current file and document information, and select the document you want to update. The artifact drawer then opens with the staging file loaded as a pending replacement. Nothing is replaced until you select Save in the artifact drawer. After a successful save, the previous file continues to follow existing file history and audit behavior, and the staging file is removed from the Staging Area. If you cancel or discard the change, or if the save fails, the existing document file remains unchanged, and the staging file stays available.



Staging files are also available for preview before assignment, provided they are of a previewable file type. Click preview  to view the file in a new tab, or click the file name to download it.

If you have the *Allow removing files from TMF staging area* permission, the Actions menu also includes Remove for files that were uploaded accidentally or are no longer needed. Removing a file requires confirmation and a reason, and the file is permanently deleted after you confirm the action. Without this permission, the Remove option isn't available.

Staging Area activity is recorded for traceability. Upload sessions and individual file status changes are tracked, and assignments, replacements, and removals are recorded in audit history with the applicable file, document, person, date and time, and action details.

Epic: CHK-50117

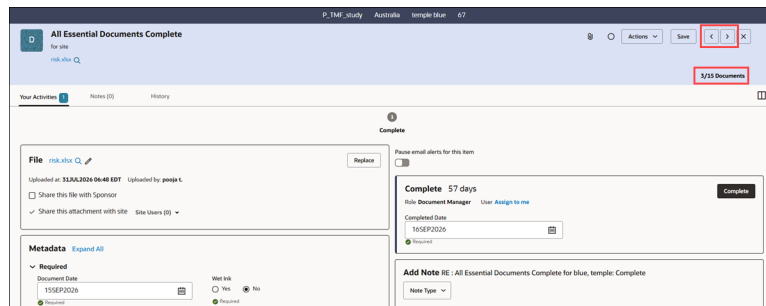
Document forward and back navigation

You can now move between documents directly from the artifact drawer in the TMF Viewer while keeping track of your position in the current document list. This navigation is available in both filtered and unfiltered views.

Use the new previous  and next  buttons to move through documents. A document counter, such as "1/20 Documents" or "3/15 Documents", shows which document you're currently

viewing out of the total number included in the list. The previous button is disabled for the first document, and the next button is disabled for the last document.

If you have unsaved changes and click previous or next, you're prompted to save or discard your changes before moving to another document.



This release also updates the document grid in the TMF Viewer to load a maximum of 1,200 rows. You can continue moving through documents in the artifact drawer even if a folder contains more documents than the TMF Viewer grid can display. This update ensures you can access documents using the previous and next buttons even when they're not displayed in the TMF Viewer.

If a folder contains more than 1,200 documents and you try to load additional rows in the grid, you'll see the message, "No more than 1200 results may be shown, please change search criteria to filter the list further." You can refine your search criteria to reduce the displayed results, or keep using the previous and next buttons in the artifact drawer to move from the first document to the last, including documents beyond the 1,200-row grid limit.

Epic: CHK-50117

Type column displays Document and Contract Type

The All Documents view in TMF Viewer now includes a default, sortable Type column that displays the document type or contract type associated with each item. If both types are available, the column displays the document type first, followed by the contract type, separated by a semicolon.

The new Type column displays to the right of the Document Name column. You can show or hide the Type column as preferred and it is included if you make changes to the displayed columns in the All Documents view and then restore the defaults.

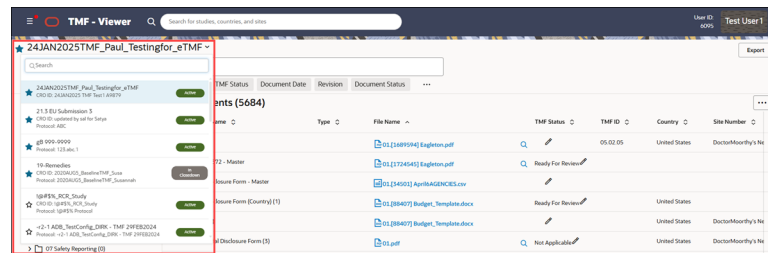
Document Name	Type	File Name	TMF Status	TMF ID	Country	Site Number
Budget Amendment (Sdg)	P1				United States	B40001
Contract (Sdg)	P1				United States	B40001
Budget Amendment (Sdg)	P1				United States	B40001
Contract (Sdg)	01_P_type				United States	all
Budget Entry Amendment	01_P_type				United States	all
Budget Entry Amendment	P_type				United States	all
Amendment (Sdg) (1)	P_type				United States	all
Budget (Sdg)	P_type				United States	all
Budget Amendment (Sdg)	P_type				United States	all

Epic: CHK-50117

Study selector uses shared favorites

The TMF Viewer study selector now uses the same favorite behavior as the Oracle Site Activate study selector. Favorite studies display a blue star and sort to the top of the list, while non-favorite studies display a hollow star.

You can favorite or unfavorite a study from either selector, and your saved favorite selections are shared between Oracle Site Activate and TMF Viewer. Existing search, study status, study selection, access, and permission behavior remain unchanged.



Epic: CHK-50117

Document management

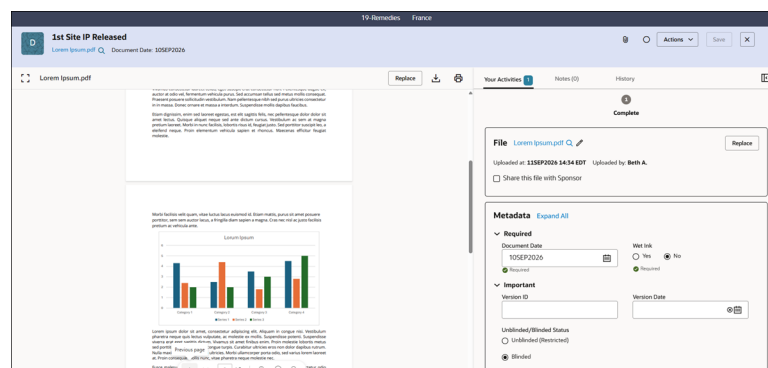
In this release, you'll see significant user experience enhancements to file management and the artifact drawer that improve navigation and simplify your work.

Artifact drawer split view

A new split view option in the document artifact drawer lets you view an attached file alongside artifact details and activity information. Click the new split view icon  at the drawer's upper right to split the drawer's lower section and display the file on the left and other activity panels on the right. If an attached file can't be previewed (e.g., a ZIP format file), or if no file is attached, the drawer will not include a split view icon.

In split view, you can replace, download, and print the attached file using the action options displayed above the file. Below the file, you'll see navigation options for pagination, search, zoom, etc.

Above the file, at the far left, click maximize  to open full file preview mode, then click minimize  to return to split view. Click the Full details icon  at the drawer's upper right to close split view and return to the full tab view.

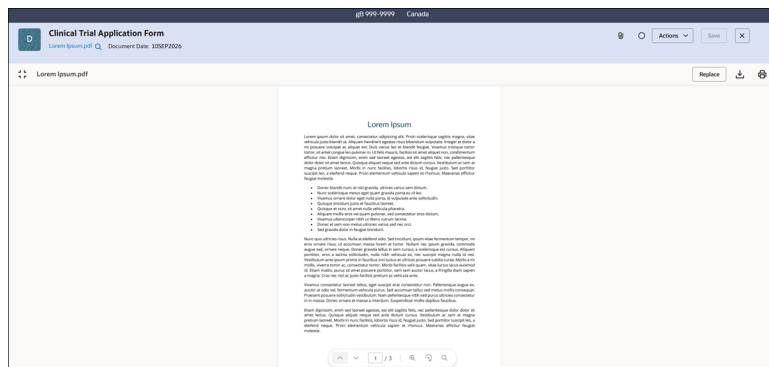


Epic: CHK-51233

Full window width file preview

Release 26.1 replaces the existing artifact file preview page with a new full file view. When you click  to preview files from Study, Country, and Site artifact lists or the eTMF Viewer, the full file view opens in the same window with the artifact context. From the Corrections tab and Submission or IP package workflows, preview opens in a new window or tab.

Study Library files and non-artifact files attached to notes for milestones, studies, countries, or sites still use the legacy preview page style.



Epic: CHK-51233

File renaming from naming convention template

Release 26.1 introduces the ability to automate file naming based on an account-level template applied at the study level. This helps you apply configured naming conventions more consistently and reduces the need to rename files manually.

An account's naming conventions can be configured to use up to 12 of the supported metadata tokens listed below. The tokens will be separated by dash, underscore, space, or other allowed single-character separator (e.g., Study ID_Site Number_Artifact ID):

- Study Name
- Study ID
- Protocol Number
- Country
- Country Code
- Institution Name
- Site Number
- PI First Name
- PI Last Name
- Artifact Name
- Artifact ID
- Version ID
- Document Type

- Contract Type
- TMF ID
- Protocol Version
- Document Date (Formatted as YYYY-MM-DD)
- Upload Date (Formatted as YYYY-MM-DD)
- Language

When the “Enable automatic file rename” setting is enabled and one or more conventions are configured for your account, an optional File naming convention setting is available on the study create and edit pages. If your account has a default naming convention configured, it’s populated automatically. Otherwise, you can select any one of the account’s configured conventions or leave the field blank. When the File naming convention drop-down has a selected value, you’ll see a Preview below the field that shows the configured metadata tokens and separators for that selection.

When a study has a file naming convention set, you can click Generate file name when editing a file name. The generated name follows the same validation, versioning, history, and audit behavior as manual renaming. If the generated name contains invalid characters, an error banner appears, and you must update the name before you can save it.

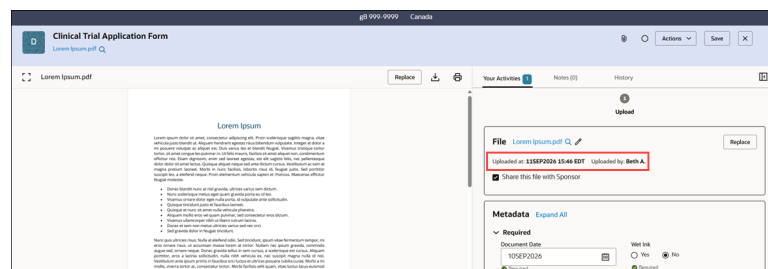
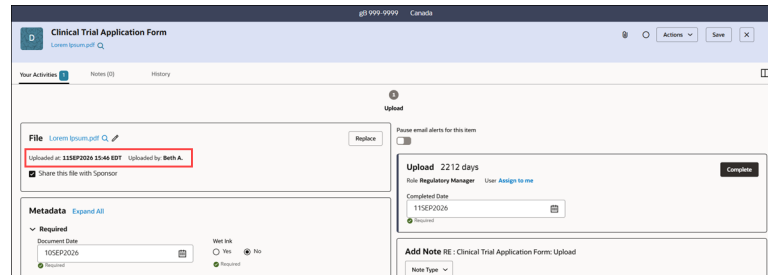
Note

Please contact your Oracle services representative to discuss requirements for enabling the new automatic file rename setting for your organization's account.

Epic: CHK-50117

File upload details

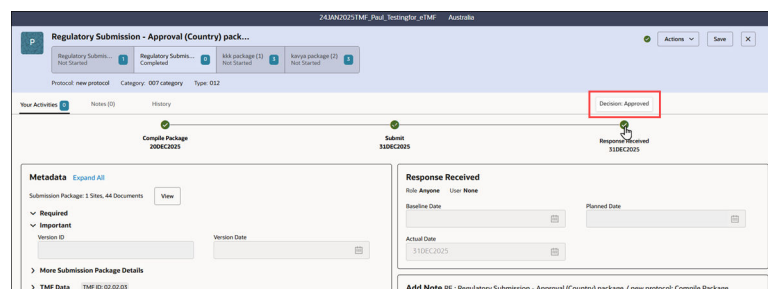
The File panel in the artifact drawer now includes Uploaded by and Uploaded at information, giving you the file details previously available in the legacy file preview's details tab. You can view the file upload information in both the regular artifact drawer view and split view.



Epic: CHK-51233

Completed activity decisions

The artifact drawer now makes completed activity decisions easier to find. When a completed activity includes a recorded decision, you can hover over or focus on the activity step in the train to view “Decision: <selected decision>” text as a tooltip. No decision tooltip appears when the activity did not record a decision.



We also made minor interface updates. To make it easier to identify the primary work area for items that are not yet complete, the activity panel for the current step now has a bold left border. Additionally, an enabled Complete button in the activity panel now uses the standard primary dark button style, while the Save button in the drawer's header uses the standard secondary button style. Disabled buttons retain the standard disabled appearance. These visual updates apply wherever the standard artifact drawer appears. The updates also do not change existing workflow behavior or the rules that control when the Complete and Save buttons are enabled.

Epic: CHK-51233

Version Date field

Using a new field added in this release, you can enter the Version Date for an artifact when “Enable Version Date Field” has been enabled for your organization’s account. The field appears wherever the existing Version ID field is available (i.e., Artifact Drawer, Corrections > Items > Edit, Bulk work, and the Overview page). If preferred, your organization can assign a custom field name of up to 25 characters. If no custom name is assigned, the field displays with the label "Version Date." When populated, the date value appears in the artifact list on the Study, Country, and Site work tabs.

The Version Date field follows the same required or optional rules as Version ID:

- If Version ID is required, Version Date is also required.
- If Version ID is optional, Version Date is optional.

You can save a Version Date only when Version ID is populated. If you enter a Version Date, Version ID becomes required regardless of the account or artifact settings.

In Corrections > Items > Edit, Version ID remains optional unless you enter a Version Date. In that case, the Save button remains disabled until you enter a Version ID.

Note

Please contact your Oracle services representative to discuss enabling the Version Date field for your account.

Epic: CHK-51233

File name character limit validation

As in prior releases, file names have a maximum allowed length of 254 characters or bytes. In this release, real-time file name validation now includes the period before the file extension and the file extension itself when calculating the character limit.

We also clarified the error message you see when a file name exceeds the limit. The error message now states the required maximum: “Please shorten the file name (including the file extension) to 254 characters or less and try again.”

Epic: CHK-51233

Document sub-status for Oracle Site Activate and Oracle eTMF items

If you use both Site Activate and Oracle eTMF, you can now more easily distinguish progress on study start-up work from filing and review work for the same item. A new combined sub-status uses existing lifecycle activity data to add context while preserving the existing overall artifact status.

For items that use both Site Activate and Oracle eTMF, new in-progress status icons show where the item is in the combined workflow. The unique icons identify the item's progress and display a sub-status label on hover:

-  Activate In Progress, TMF Not Started
-  Activate Complete, TMF Pending
-  Activate Complete, TMF In Progress

If start-up work is reopened after filing or review has begun, the combined sub-status returns to show that start-up work is in progress again.

You can see the new icons and hover text in supported Site Activate lists (e.g., study, country, site task lists), artifact drawer headers, tables, rows, cards, package planning, and IP package review views where status is shown. The existing overall artifact status remains the primary status you see. If you work with Site Activate-only or TMF-only items, their existing status behavior remains unchanged. Existing status filters, sorting, exports, and TMF Status also remain unchanged.

Your tasksPlanningCorrections

ActivitiesMilestonesItems

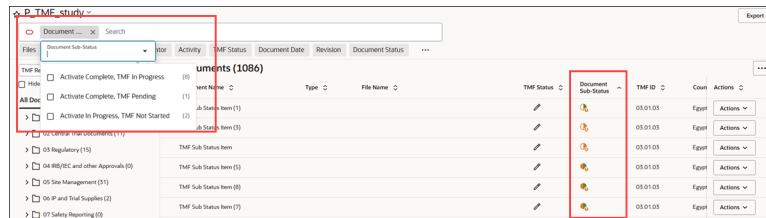
Show:AllItem:Documents

Filter by artifact ID, investigator name, site number, country, type, item name and version ID

Displaying 150 of 1079 rows

Investigator	Site	Country	Item	Version ID	Status	Actions	View
black, david	02	USA	TMF Sub Status Item (4) for black, david			 	Site
black, david	02	USA	TMF Sub Status Item (5) for black, david			 	Site
black, david	02	USA	P_substatus_RFF/UFR (4) for black, david			 	Site
black, david	02	USA	P_substatus_SIP (4) for black, david			 	Site

If your account is configured for both Site Activate and Oracle eTMF, you can also add the optional Document Sub-Status column to the eTMF Viewer's All Documents view. The column isn't displayed by default, but when you add it, you can see the new document sub-status values. You can also search by document sub-status using Smart Search or use the new Document Sub-Status filter to narrow the documents you see.



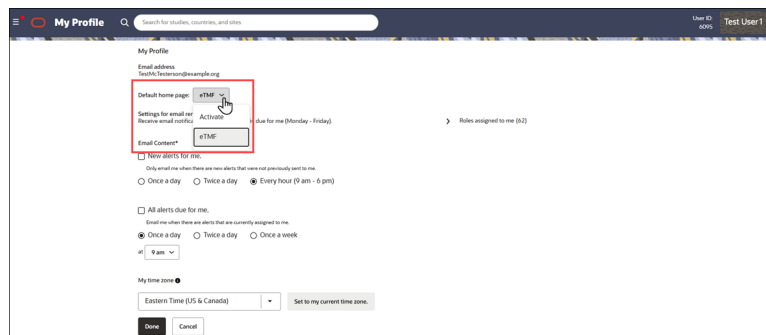
Epic: CHK-50117

User account management

Use a new setting on your My Profile page to choose your preferred default home page.

Preferred default home page

For accounts enabled for Oracle Site Activate + Oracle eTMF, you can now choose whether the study home page in Site Activate or the TMF Viewer opens by default when you log in. On your My Profile page, use the Default home page setting to select Activate or eTMF. Activate remains the default for new and existing users until you choose another option. Note that the new Default home page setting isn't available for Site Activate-only or Oracle eTMF-only accounts.



The Default home page drop-down provides context specific feedback when you make a selection that isn't compatible with your access permissions. You can select eTMF only when you have the required TMF Viewer access. Note that existing higher-priority login redirects, including supported deep links and relay states, continue to take precedence over your default home page selection.

If you select eTMF: and you don't have permission to access the TMF Viewer, you'll see a warning icon ⚠ to the right of the drop-down. Hover over the icon to view the following helper text: "eTMF is unavailable because you don't have access to the TMF Viewer. This selection will not be active until you gain the required permissions." If eTMF is selected and you later lose access, the selection remains visible in the drop-down but disabled, and you're directed to Activate at login until access is restored.

If you select Activate: and you don't have permission to access the TMF Viewer, you'll see an info icon ⓘ to the right of the drop-down. Hover over the icon to view the following helper text: "eTMF is unavailable because you don't have access to the TMF Viewer."

Epic: CHK-50117

Impact analysis

Review a quick summary of the business and functional impact of enhancements included in the 26.1 release.

Enhancement	Enablement setting	Impact
TMF Viewer - Staging area in TMF Viewer	- Feature flip: N - Config related: N - All studies: Y - New role permission required: Y (<i>Allow removing files from TMF staging area</i>) - Dependent feature: N	The new TMF Viewer Staging Area lets you upload, preview, search, and organize files before attaching them to documents. You can assign a staged file to an existing or new document, use it to replace a document file, or remove it with permission, with activity recorded in audit history.
TMF Viewer - Document forward and back navigation	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	The TMF Viewer artifact drawer now lets you move through all documents in the current list with previous and next buttons and a position counter, including documents beyond the grid's new 1,200-row display limit.
TMF Viewer - Type column displays Document and Contract type	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	The TMF Viewer's All Documents view now includes a sortable, optional Type column showing each item's document type, contract type, or both.
TMF Viewer - Study selector uses shared favorites	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	The TMF Viewer and Site Activate study selectors now share favorite selections, showing blue stars for favorite studies and sorting them to the top.
Document management - Artifact drawer split view	- Feature flip: N - Config related: N - All studies: Y	A split view in the document artifact drawer so you can preview an attached file alongside its details and activity, with controls for file actions, navigation, and full preview.

Enhancement	Enablement setting	Impact
	- New role permission required: N - Dependent feature: N	
Document management - Full window width file preview	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	26.1 introduces a full file view for artifact previews from Study, Country, and Site lists and the eTMF Viewer, while Corrections and package workflows open previews in a new window or tab and Study Library and note attachments retain the legacy preview.
Document management - File renaming from naming convention template	- Feature flip: Y (Enable automatic file rename) - Config related: N - All studies: Y - New role permission required: N - Dependent feature: Y (create file name in <i>File Name Configuration</i>)	Lets studies use an account-configured file naming convention to automatically name files from selected metadata, reducing manual renaming.
Document management - File upload details	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	The artifact drawer's File panel shows who uploaded a file and when, in both regular and split view.
Document management - Completed activity decisions	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	Decision tooltips to completed activity steps and updates the artifact drawer's current-step border and button styles without changing workflow behavior.
Document management - Version Date field	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N	Optional, customizable Version Date field wherever Version ID is available, displays saved dates in artifact lists, and requires a Version ID whenever a Version Date is entered.

Enhancement	Enablement setting	Impact
	Dependent feature: N	
Document management - File name character limit validation	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	Counts the period and extension in real-time file name validation and shows clearer errors when a name exceeds 254 characters or 255 bytes.
Document management - Document sub-status for Activate and eTMF items	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: Y (Site Activate and Oracle eTMF enabled)	If using both Site Activate and Oracle eTMF, new sub-status icons distinguish start-up progress from filing and review progress, while the eTMF Viewer offers an optional column, search, and filter for those sub-statuses.
User account management - Preferred default home page	- Feature flip: N - Config related: N - All studies: Y - New role permission required: N - Dependent feature: N	Users with access to both Activate and Oracle eTMF can choose which opens by default at login, with Activate remaining the default until they change the setting in My Profile.

Stability improvements

These are the issues we fixed in release 26.1.

TMF Viewer

Description	Ticket	Severity
Previously, when you filtered by Document date, Last updated, or file upload date, the filter you were using incorrectly disappeared from the search area after you selected the End date. This issue has been resolved and now the date filters now remain active.	CHK-51182	3

Description	Ticket	Severity
When you opened the global navigation menu from TMF Viewer, the Quarantine option could fail to display the red alert icon when new files were available for review. The alert icon now appears as expected when new files are in Quarantine.	CHK-51929	4
In TMF Viewer, long file names could take up too much table space and make other columns harder to review. The File Name column now opens at a default width of 400 pixels and can be resized as needed. Long file names are truncated with an ellipsis, and you can hover over the name to view the full value. As you resize the column, adjacent columns reflow with the table layout. Existing file name links, icons, sorting, and other table behavior remain unchanged. Resized widths do not persist after you refresh the page or leave and return to TMF Viewer.	CHK-52632	4
For customers using Oracle eTMF in eTMF-only mode, the Edit country page could fail to load and appear blank. The page now loads correctly as expected for Oracle eTMF only and Site Activate + Oracle eTMF environments.	CHK-52803	2
In TMF Viewer, some free-text searches using partial document-name substrings could fail to return matching documents. These searches now consistently return documents whose names contain the entered text.	CHK-52815	2

New known issues

This section identifies unresolved issues found in the development of this release.

TMF Viewer

Description	Ticket	Severity
Discontinued items are included in the drop-down record count for TMF Viewer but the table listing does not show discontinued items resulting in record count mismatch.	CHK-52852	3
In the TMF Viewer All Documents tab, selecting the Actions or TMF Artifact Name column header causes all records to disappear from the list. The records reappear when you select another column that contains data.	CHK-52941	4

Previously reported known issues

See the unresolved issues reported prior to this current release.

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 reinstate 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

2

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.

3

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	26.1	Google Chrome and Microsoft Edge (Chromium)	None

4

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 26.1.

Date	Part number	Description
09Oct2026	G58995-02	General Availability Release Notes
30Sep2026	G58995-01	Pre-General Availability Release Notes