# Oracle Life Sciences Site Activate Release Notes





Oracle Life Sciences Site Activate Release Notes, Release 24.2

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# Revision history

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## **Preface**

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

## Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <a href="http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc">http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc</a>.

## **Diversity and Inclusion**

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

#### Related resources

Product documentation and other supporting materials are available on the <u>Oracle Help</u> <u>Center</u>.

## Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Oracle Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<a href="https://hsgbu.custhelp.com/">https://hsgbu.custhelp.com/</a>)
- Japanese interface Customer Support Portal (<a href="https://hsgbu-jp.custhelp.com/">https://hsgbu-jp.custhelp.com/</a>)

You can also call our 24x7 help desk. For information, visit <a href="https://www.oracle.com/life-sciences/support/">https://www.oracle.com/life-sciences/support/</a> or visit <a href="https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab">https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab</a> if you are hearing impaired.

# Release 24.2.2.1 (available for this release 26Aug2025)

Oracle Site Activate release 24.2.2.1 includes one infrastructure update.

<u>Stability improvement</u>
 This is the correction included in this hotfix.

# Stability improvement

This is the correction included in this hotfix.

• <u>Infrastructure</u>

#### Infrastructure

Description	Ticket	<u>Severity</u>
We made a required version update for an Oracle internal software component. This fix has no customer impact.	CHK-49588	3

### Release 24.2.2

Oracle Site Activate release 24.2.2 introduces Phlex eTMF integration enhancements.

What's new

#### What's new

Phlex integration

With release 24.2.2, Oracle Site Activate introduces enhancements in support of Phlex eTMF integration.

### Phlex integration

With release 24.2.2, Oracle Site Activate introduces enhancements in support of Phlex eTMF integration.

#### Site Personnel Surname and Expiry date

We added a new configuration option labeled "Requires Site Personnel Surname for Phlex integration" to Configuration Designer and the internal item configuration area in Oracle Site Activate. When checked, it flags the item for inclusion of Site Personnel Surname metadata in Phlex eTMF messages.

We also added a flag for items that should include the Document Expiry date in Phlex Integration eTMF message. The new check box settings that enable this functionality have been added to Configuration Designer and the internal item configuration area in Oracle Site Activate. If a user populates the Expiration Date field for an item in Oracle Site Activate, the eTMF message will include an "Expiry Date" attribute. If the Expiration Date field is available on the item but is not populated, the eTMF message includes the field with a null value.

#### Item Effective date

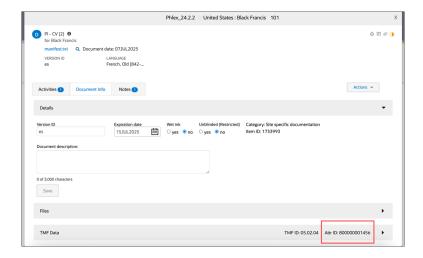
eTMF messages will now include Effective date when this option is enabled at the account level. If the field is not populated in the item in Oracle Site Activate, the eTMF message will send a null value with the Effective date attribute. Please contact your Oracle services representative to discuss enabling this option for your account.

#### **Attribute ID**

With this release, "Reference Code" is now updated to "Attribute ID" to reflect use of the Phlex Attribute ID in eTMF integrations. An Oracle representative, or a customer resource with permission to access Configuration Designer, will populate the customer-provided Attribute ID to the appropriate artifacts in Configuration Designer and publish the configuration to Oracle Site Activate.

In Oracle Site Activate, the Attribute ID appears in the internal artifact configuration area, the user interface, and the eTMF message when the Vendor type is "Phlex." In the Oracle Site Activate user interface, the Info tab in item modals will label the Attribute ID as "Attr ID" in the TMF Data section. eTMF messages will include the Attribute ID field as attribute id.





#### Supported file types

Development for this release included testing the Phlex eTMF integration to ensure it supports the following file

types: .pdf, .doc, .docx, .xls, .xlsx, .jpg, .jpeg, .tif, .tiff, .zip, .png, .gif, .odt, .rar, .tar, .bmp, .msg, .ppt, .pptx, .eml, and .xml.



Oracle Site Activate allows upload of the following additional file types; however, they are not supported in Phlex eTMF integration: xlsm, gzip, gz, 7z, 7zip, bz2, rtf, txt, csv, tab, pps, pot, pptm, potx, potm, xlw, xlt, psd, sxw, stw, sxc, stc, sxi, sti, key, pages, and numbers.

#### Default and supported languages

We enhanced Phlex eTMF integration to default to English when a document's language field does not have any value (null). When generating an eTMF message for Phlex, if a document in Oracle Site Activate doesn't specify a language, the "Language" attribute in the Transformed Message section will default to "English-American (Default)."

For reference, the Phlex eTMF integration supports the languages listed in the table below.

Language	Language code
Dutch	nl
English	en
French	fr
German	de
Hebrew	he
Hungarian	hu
Italian	it
Lithuanian	lt
Polish	pl
Slovak	sk
Spanish	es
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#### **API** enhancements

As part of our 24.2.2 release, we made the following updates to the eTMF messages to support our Oracle Site Activate-Phlex eTMF integration. They are visible when an endpoint has vendor = Phlex.

- reference\_code has been updated to attribute\_id
- pi\_last\_name has been updated to person\_full\_name, and the format is lastname, firstname
- phlex\_requires\_sps field is added when configured on an artifact in Oracle Site Activate, and indicates that artifact requires the site personnel surname
- phlex\_requires\_expirydate field is added when configured on an artifact in Oracle Site Activate, and indicates that artifact requires the document expiry date
- phlex\_requires\_iprelease is added when configured at the account level and is set to True for all artifacts

Additionally, for all eTMF messages:

- expiry date is added when configured on an artifact in Oracle Site Activate
- effective\_date is added when configured at the Account level

We've updated our API documentation to reflect these changes.

#### Oracle Site Activate-Phlex eTMF testing recommendations

Before testing, please contact your Oracle services representative to validate settings and configuration for your Phlex eTMF integration. When confirmed, use the steps below for end-to-end testing:

- 1. For a site known to both Oracle Site Activate and Phlex, build an IP package with at least the following artifacts. (Note: the configuration does not currently include study-level artifacts.)
  - a. country level
  - b. country level (Non-English language (See supported languages list above))
  - c. site level site specific
  - d. site level PI specific (Site Personnel Surname required)
  - e. site level staff specific (Site Personnel Surname required and name that exists in two sites)
  - f. one artifact that does not have an Attribute ID defined (Message will fail, and other messages will succeed)
  - one artifact with Attribute ID defined, but no file attached (Message will fail per standard eTMF messaging functionality)
- 2. For a country known to both Oracle Site Activate and Phlex, build an IP Release package with at least:
  - a. country level
  - b. country level (Non-English language (See supported languages list above))
  - c. site level optional
- Upload documents to artifacts in Oracle Site Activate, approve all artifacts, and complete the packages



- 4. Check Event Messages:
  - a. Oracle Site Activate should create one eTMF message for each artifact
  - b. Each message should be successful
  - c. If not successful, clear error messages should be returned to guide triage

# Release 24.2.1.11 (available for this release 20Jun2025)

We corrected several reported issues in this hotfix release.

<u>Stability improvements</u>
 These are the corrections included in this hotfix.

# Stability improvements

These are the corrections included in this hotfix.

- Audit trail
- <u>Document management</u>
- Exports
- User interface

#### Audit trail

Description	Ticket	<u>Severity</u>
We corrected an issue where audit logs for workflow-related changes (including artifacts, activities, workflow definitions, and dependencies) occasionally showed the wrong user. The logs now correctly show the system (nil) as the source of these changes.	CHK-48382	3

### Document management

Description	Ticket	<u>Severity</u>
Duplicate items could be created when a user created a site through the user interface or API and then shared an item from the Study library to that site.	CHK-48362	3
If a site was created via API for a country not already in the study and an item was auto-shared to that site from the Study library, the item could be duplicated at the country level.	CHK-48535	2



# **Exports**

Description	Ticket	Severity
An Export error occurred when a user attempted to export a package larger than 250MB.	CHK-48374	3

## User interface

Description	Ticket	<u>Severity</u>
Time zone differences between the user's computer and Oracle Site Activate could result in discrepancies when dates were saved. We updated date components in Oracle Site Activate to prevent this issue.	CHK-48363 CHK-48364 CHK-48412	2

# Release 24.2.1.10 (available for this release 28Apr2025)

We corrected API integration and Infrastructure issues in this release.

<u>Stability improvements</u>
 These are the corrections included in this hotfix.

# Stability improvements

These are the corrections included in this hotfix.

- API integration
- Infrastructure

## **API** integration

Description	Ticket	Severity
Multiple event messages were sent if users retried the request to complete IP package activities while the first request was still processing. We made performance improvements to reduce the time required to complete the IP package activities.	CHK-47652	2

### Infrastructure

Description	Ticket	<u>Severity</u>
We made infrastructure	CHK-47763	2
enhancements to ensure proper	CHK-47890	
access to the Data Export Utility, Study Planning, and	CHK-47892	
Configuration Designer in multi- tenant environments.	CHK-47893	

# Release 24.2.1.9 (available for this release 11Apr2025)

We corrected multiple reported issues in this release.

Stability improvements
 These are the corrections included in this hotfix.

# Stability improvements

These are the corrections included in this hotfix.

- Bulk work
- <u>eTMF</u>
- Infrastructure
- Reporting

#### **Bulk work**

Description	Ticket	Severity
Bulk work did not always return results as expected.	CHK-47627	2

#### eTMF

Description	Ticket	<u>Severity</u>
Deleted study, country, site, etc. items incorrectly continued to display in the Oracle TMF Viewer.	CHK-47625	2

#### Infrastructure

Description	Ticket	<u>Severity</u>
We made an infrastructure enhancement to ensure proper access to the Data Export Utility and Study Planning in multitenant environments.	CHK-47599	2
We improved internal logging to better capture error condition information when running an automatic, scheduled process.	CHK-47623	2



# Reporting

Description	Ticket	Severity
For a user with the Analyze role permission, an error could occur when creating the user's account in Oracle Analytics Cloud.	CHK-47622	3

# Release 24.2.1.8 (available for this release 07Feb2025)

We corrected multiple reported issues in this release.

<u>Stability improvements</u>
 These are the corrections included in this hotfix.

# Stability improvements

These are the corrections included in this hotfix.

- <u>Document management</u>
- <u>Electronic signature</u>
- Exports
- <u>Infrastructure</u>

#### Document management

Description	Ticket	Severity
When discontinuing or reinstating a document placeholder, users could click Done multiple times, which incorrectly generated multiple Event messages and audit records. In this release, we changed the Done button behavior so users can now click the button just once.	CHK-46841	3

## Electronic signature

Description	Ticket	Severity
Oracle Site Activate did not recognize mixed case email addresses from Adobe Sign.	CHK-46944	3

## **Exports**

Description	Ticket	Severity	
An export error occurred when users attempted to export a ZIP file from a package's Selected documents tab.	CHK-46943	2	



Description	Ticket	<u>Severity</u>
We made an infrastructure update to ensure CSV queries will retry if an interruption or error occurs.	CHK-47015	2

## Infrastructure

Description	Ticket	<u>Severity</u>
We made performance improvements to ensure timely record matching.	CHK-46986	3

# Release 24.2.1.7 (available for this release 24Dec2024)

We corrected an API issue in this hotfix.

<u>Stability improvement</u>
 This release includes a correction for one reported API issue.

# Stability improvement

This release includes a correction for one reported API issue.

• API integration

## **API** integration

Description	Ticket	<u>Severity</u>
In SharePoint migrated environments only, Artifact GET calls for staff level items were not successful for items with files attached.	CHK-46842	1

# Release 24.2.1.6 (available for this release 09Dec2024)

We corrected multiple issues in this release.

<u>Stability improvements</u>
 These are the corrections included in this hotfix.

# Stability improvements

These are the corrections included in this hotfix.

- Alerts
- <u>Document management</u>
- Notes
- Site management

#### **Alerts**

Description	Ticket	Severity
Oracle Site Activate email notification alerts were not sent as expected.	CHK-46743	2

### Document management

Description	Ticket	Severity	
We updated display logic to ensure that the document export link displays only when the package export file exists in the account's enabled document storage type (i.e., Box or SharePoint).	CHK-46755	3	

#### Notes

Description	Ticket	Severity
When the user's time zone was set to Bogota or Azores, the time stamps on notes they created did not reflect the correct year (2024).	CHK-46759	3



# Site management

Description	Ticket	Severity
When changing the site IRB type using the editable IRB drop-down list on the site page, the site's Network value was incorrectly removed when the page was refreshed.	CHK-46744	3

# Release 24.2.1.5 (available for this release 06Dec2024)

See the correction made in the 24.2.1.5 release.

- Stability improvements
  - This hotfix includes one correction for CSV extracts.
- New known issue

This section identifies an unresolved issue found during the development of this release.

# Stability improvements

This hotfix includes one correction for CSV extracts.

Extracts

#### **Extracts**

Description	Ticket	Severity
CSV extracts incorrectly reflected Boolean values as "1" or "0" instead of "true" or "false."	CHK-46722	2

## New known issue

This section identifies an unresolved issue found during the development of this release.

Exports

## **Exports**

Description	Ticket	<u>Severity</u>
In Site Analyze, some Booleans are not yet defined as a number (1,0) data type.	LSRPT-6564	1

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# Release 24.2.1.4 (available for this release 26Nov2024)

See the correction made in the 24.2.1.4 release.

<u>Stability improvements</u>
 This hotfix includes one correction for CSV extracts.

# Stability improvements

This hotfix includes one correction for CSV extracts.

• Extracts

#### **Extracts**

Description	Ticket	Severity
CSV extracts incorrectly included an extra new line separator. We corrected this issue, and CSV extracts now use only \n as the new line separator.	CHK-46694	2

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# Release 24.2.1.3 (available for this release 25Nov2024)

See the corrections made in the 24.2.1.3 release.

<u>Stability improvements</u>
 This hotfix includes one API correction.

# Stability improvements

This hotfix includes one API correction.

• API integration

## **API** integration

Description	Ticket	Severity
The Users GET API response did not include a user's study, country, or site assignments as expected.	CHK-46681	2

# Release 24.2.1.2 (available for this release 25Nov2024)

See the corrections made in the 24.2.1.2 release.

<u>Stability improvements</u>
 This hotfix includes multiple issue corrections.

# Stability improvements

This hotfix includes multiple issue corrections.

- API integration
- <u>Document management</u>
- Exports
- User experience

## **API** integration

Description	Ticket	Severity
Event messages did not trigger as expected for completed Study library items.	CHK-46632	2

### Document management

Description	Ticket	<u>Severity</u>
Files that included non-ASCII characters in the file name did not upload and migrate to SharePoint as expected.		2



# **Exports**

Description	Ticket	<u>Severity</u>
Extract columns in study_level_artifacts.csv and study_level_activities.csv were not in the expected order. We corrected this issue to move Display_revision and TMF_identifier to the end of the study_level_artifacts.csv and unblocked_at to the end of the study_level_activities.csv.	CHK-46672	3

# User experience

Description	Ticket	Severity	
An error occurred when the Home page Your tasks tab took longer than expected to load.	CHK-46657	4	

# Release 24.2.1.1 (available for this release 18Nov2024)

See the enhancements and corrections made in the 24.2.1.1 release.

What's new

This release includes one document management enhancement.

Stability improvements

This hotfix includes multiple issue corrections.

New known issue

We identified an unresolved issue during the development of this release.

#### What's new

This release includes one document management enhancement.

<u>Document management</u>
 File preview removed from the item modal Previous files section.

#### Document management

File preview removed from the item modal Previous files section.

#### File preview

SharePoint Embedded does not currently support previewing specific files and always previews the most recent version. To prevent confusion for users, we updated item modals to remove preview functionality for files in the modal's Previous files section. Previous files no longer have a magnifying glass  $(^{\mathbf{Q}})$  icon.

# Stability improvements

This hotfix includes multiple issue corrections.

- Alerts
- API integration
- Contracts
- Document management
- Reports
- Single Sign On (SSO)
- Site experience
- User roles and permissions



## **Alerts**

Description	Ticket	<u>Severity</u>
Users with over 1,000 alert notifications did not receive email alerts as expected.	CHK-46593	3

# API integration

Description	Ticket	Severity
In Milestone Publish messages, system dates (e.g., updated_at) were not in the expected YYYY-MM-DDTHH:MM:SS.MSS-UTCoffset datetime format. We corrected this issue and Milestone Publish messages now use ISO datetime format. Note that this correction also updated Activity Change messages to ISO datetime format.	CHK-46501	2
Intermittently, response time for Artifacts GET messages was longer than expected and could result in timeout errors.	CHK-46530	3
After creating a site via the Study sites POST API, the items created for the new site did not accept attachments as expected.	CHK-46574	1

### Contracts

Description	Ticket	Severity
Item modals for contract and sub- contract items did not open as expected from the Corrections tab.	CHK-46546	2
An error occurred when saving a contract item.	CHK-46600	3

# Document management

Description	Ticket	<u>Severity</u>
Item creation took longer than usual.	CHK-46506	2



## Reports

Description	Ticket	Severity
In CSV extracts, dates were incorrectly formatted to include timestamps (i.e., YYYY-MM-DD HH:MI:SS) instead of using the expected YYYY-MM-DD format.	CHK-46590	2
Some CSV extract zips were empty or included no readable items.	CHK-46618	2
CSV extracts did not reflect special characters as they appeared in the Oracle Site Activate user interface.	CHK-46622	3

# Single Sign On (SSO)

Description	Ticket	<u>Severity</u>
Oracle Site Activate SSO to Oracle Site Analyze did not route users to Site Analyze as expected.	CHK-46489	2

## Site experience

Description	Ticket	Severity
When a customer logo was uploaded to the account, the logo did not display as expected in site email notifications.	CHK-46602	2

# User roles and permissions

Description	Ticket	Severity
An error occurred when attempting to deactivate a user who had a business role with access to Oracle Site Analyze.	CHK-46544	2

## New known issue

We identified an unresolved issue during the development of this release.

Reports



# Reports

Description	Ticket	Severity
An error occurred when attempting to preview a report from 2023 in Data Export Utility.	CHK-46628	3

### Release 24.2.1

Review the enhancements and corrections made in the 24.2.1 minor release.

- What's new
   Learn about new and enhanced functionality included in the 24.2.1 minor release
- <u>Stability improvements</u>
   This minor release includes corrections for several reported issues.

#### What's new

Learn about new and enhanced functionality included in the 24.2.1 minor release

- <u>Document management</u>
   Microsoft SharePoint replaces Box for Oracle Site Activate document storage.
- <u>eTMF</u>
   With release 24.2.1, Oracle Site Activate introduces a new eTMF feature.
- Reporting
   Oracle Analytics Cloud replaces Tableau for reporting.
- <u>Service notice</u>
   Oracle Site Activate introduces support for a multi-tenant deployment model.

#### Document management

Microsoft SharePoint replaces Box for Oracle Site Activate document storage.

#### Microsoft SharePoint Embedded

With release 24.2.1, Oracle Site Activate introduces Microsoft SharePoint Embedded as its document storage solution. SharePoint Embedded replaces Box, which will be removed from Oracle Site Activate in January, 2025. Oracle representatives will work with your organization to ensure the successful migration of all documents you currently store in Box.

Oracle Site Activate document management functionality (i.e., upload, download, and preview of new and existing files) is unchanged with this migration and works as it did previously. However, migration to SharePoint does not include document editing or document annotation functionality. As no customers currently have document editing/annotation functionality enabled, this change will not impact your organization when upgrading to release 24.2.1.

API documentation now refers to "storage" where it previously referred to "Box." Please note that if your organization uses artifact file\_urls in Artifact or eTMF messages to download documents, we recommend adding the SharePoint URL (\*.sharepoint.com) to your organization's allowlist. If you have permission to access the Oracle Site Activate Event Messages page, you can access API documentation to review the API update summary.



#### (i) Note

Your Oracle services representative is actively working to finalize migration scheduling for your organization. For any questions, please contact your Oracle Site Activate lead or Oracle services representatives.

EPIC: CHK-46026 (release 24.2.1)

#### eTMF

With release 24.2.1, Oracle Site Activate introduces a new eTMF feature.

#### eTMF feature in Oracle Site Activate

The eTMF feature is a new repository used to collect essential documents related to proper study conduct and the quality of the study's data. When the feature is licensed and configured for your account, users in your organization can manually upload documents, or the documents can be transferred via integration from other systems (e.g., CTMS). The TMF feature uses document metadata attributes and permission controls to govern document access.

The feature's initial release supports the industry-standard CDISC TMF Reference Model, version 3.3.1. As CDISC releases updated specifications, the eTMF feature will maintain compliance with the standard through necessary product updates.

#### **Business role permissions**

The eTMF feature has four related business role permissions:

- Enable access to Oracle eTMF: You can see the navigation from Oracle Site Activate to TMF pages and access TMF viewer URLs for TMF functionality.
- Enable access to unblinded documents: You can access an unblinded (restricted) document (i.e., a document with the lock icon <sup>△</sup> in the user interface).
- 3. *Enable TMF status change*: You can see the TMF status as an editable drop-down, and you can change the status in the document modal and in the TMF viewer.
- **4. Enable eTMF Export**: You can see the Export button in the TMF viewer to generate a Study TMF export zip file.

#### **TMF Viewer**

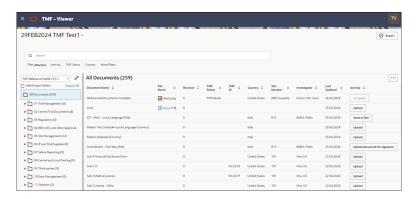
When you have *Enable access to Oracle eTMF* business role permission, you can access the new TMF Viewer page, which is the hub for TMF document management. The viewer has two sections:

- A folder tree to the left includes the TMF folder levels listed below. You can adjust the folder tree to your preferred view using Expand/Collapse, Hide empty folders, and Hide folder tree options.
  - a. TMF Zones: first-level folders
  - b. TMF Sections: second-level folders
  - c. TMF Artifacts: third-level folders that contain one or more documents. Each uploaded file will be associated with an artifact.
- 2. A document grid to the right lists the documents and contracts contained in the folders of the TMF Viewer folder tree. You can adjust displayed columns by clicking the column



selector button to show/hide available columns. The customized column selection will be saved per user. You can also sort columns by clicking the column header.

Between the two sections, you'll see a divider line. Adjust the width of the tree and grid sections by grabbing the line with your cursor and sliding the divider left or right.



#### Search component

The TMF Viewer features an enhanced searching component displayed above the document grid. Search by any of the following methods:

- Click the buttons below the text search field to use default filters. When you select a default filter, it gets pinned in the search bar. Click the filter again to display the available list of values. You ca also search for a specific value to select.
  - Files Attached or Not Attached (default is Attached)
  - Activity (select multiple with search bar)
  - TMF Status (select multiple with search bar)
  - Country (select multiple with search bar)
  - More Filters drop-down list with Site Number or Investigator (select multiple with search bar)
- Click the search bar to see a list of filterable columns:
  - Document Date
  - Revision
  - Document Status
  - Last Updated (user time zone)
  - File Upload date
- You can look for a free text string among all the searchable columns by entering it in the search field. Searchable columns are:
  - Document Name
  - Document ID
  - File Name
  - Version ID
  - Protocol
  - Person
  - Last Updated By



#### File Uploaded By



#### Open document modal from TMF Viewer

You can access the document modal from the grid to see document information or complete activities. At any row in the TMF viewer's document grid, click the document name or the action button in the Activity column (if available) to open the associated document modal.

You can upload a file, adjust metadata, specify dates, etc., within the modal. You'll also see the "TMF Status" field in the gray document activities panel or under the document Info. When you have *Enable TMF status change* business role permission, you can select one of the following values for the status field:

- Not Applicable
- Not Started
- · Received from Site
- Collected
- Ready for Review
- Approved
- Rejected
- TMF Ready
- Inspection Ready
- Obsoleted
- Superseded

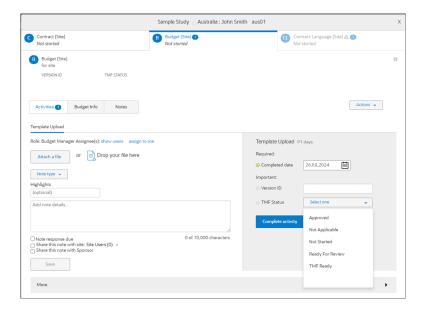
You can choose to turn on or off any of the statuses and you can also update the display name of any statuses with the help of your service lead.

By design, if you don't have *Enable access to unblinded documents* permission, you cannot open the document modal from the TMF Viewer, and the file link will not be clickable for any item marked as unblinded. If you don't have the permission, you can still view blinded (unrestricted) items.

#### Note

Study library documents in the document modal offer read-only review for completed and uncompleted documents. When you select a Study library document from the TMF viewer document grid, it opens in read-only mode, and you can't take any action on that document; however, the document's metadata will be displayed for your review.





#### Access TMF documents in other Oracle Site Activate areas

The TMF feature's permission controls are in place to allow feature access and prevent access to unblinded (restricted) TMF documents if appropriate. In Oracle Site Activate, you can identify restricted documents by the lock icon  $^{\triangle}$  which displays on all unblinded documents regardless of your access permission. To interact with unblinded documents, you must have the *Enable access to unblinded documents* business role permission.

When you have permission to access unblinded documents, you can click the documents to open or select them from any area where you see the document name in Oracle Site Activate (e.g., your Document activities list). When you do not have permission, you will have access to the document only if it has sub-items that are not unblinded. For instance, within a contract document modal, sub-item tabs that require unblinded documents permission are locked (grayed out), and you can't interact with them. In other Oracle Site Activate areas, such as the Study home page "Your Tasks" list, the Activity name will not be clickable, and you'll see the lock next to the name.

If a submission or IP package includes an unblinded document, you will not have the ability to preview or download the file unless you have the *Enable access to unblinded documents* business role permission. For example, you will need unblinded document access to preview or download files in all of the following workflows:

- You navigate to the submission widget and access the file via 'Document in package' in the 'More' area or via the 'Export to zip' option
- You are planning a submission or IP package
- You navigate to the IP package and access the file via review activities, 'selected documents' in the 'more' area, or the 'export to zip' option

By design, unblinded documents are completely excluded from the Country or Site Actions menu "Export completed documents" feature and package export, even when you have permission to access those documents. To clarify exclusion of those documents, Oracle Site Activate displays the message, "Export does not include unblinded (restricted) items."

Please get in touch with your organization's account administrator to request access to unblinded documents if appropriate to your role.

#### Unblinded document access audit



The eTMF feature audits all user access to unblinded document file attachments. When you preview or download the file attachment for an unblinded document, it records the following information:

- User email
- Timestamp
- Artifact ID
- File name
- Action (preview or download)

The creation of the access audit record applies only to unblinded documents. It is triggered when an authorized user accesses the file from any access point in Oracle Site Activate.



#### (i) Note

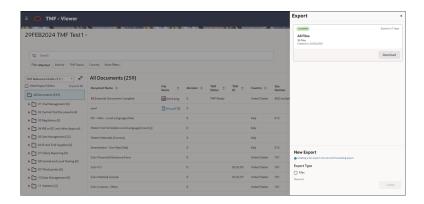
With release 24.2.1, the access audit is available to your organization upon request. Please get in touch with your Oracle services representative to request the audit report.

#### **TMF Export**

When you have the Enable TMF export business role permission, you can export documents for the entire study using the TMF viewer's Export button.

The export feature generates a comprehensive export of the study Trial Master File with all the study documents and metadata information in ZIP file format. Your permission to access unblinded documents further restricts export content. For example, if you have Enable TMF export permission and Enable access to unblinded documents permission, the export contains the files on all documents, including the unblinded documents. However, if you don't have access to unblinded documents, the export includes the files on all the documents EXCEPT the unblinded documents.

When you click Export, a drawer control opens from the TMF viewer's right side. In this drawer, you'll see your available exports (if any) and the export's upcoming expiration (seven days from the creation date). When an export is available for download (i.e., not currently processing), the drawer's Download button will be enabled for use. At the bottom of the drawer, you'll see the option to create a New Export, including a check box option to include Files. Click the Files check box to enable the Create button. Note that creating an export will overwrite an existing export.





By design, you can create only one export at a time. You'll know the export is in progress by the status shown inside the drawer and by the TMF Viewer's Export button icons, which update to show in progress or completed.

The exported ZIP file will include all current versions of the file on the documents for a study regardless of document status ("current" as of the datetime of the request). The generated file will be in the same structure as the TMF study folder structure but will not include folders without files.

#### Optional global navigation

When enabled for your organization's account, the Oracle Site Activate user interface will replace the previous horizontal global navigation with new vertical navigation accessed via menu icon

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. When you sign into Oracle Site Activate, the study home page displays by default, as it did previously. At the top left of the page, click menu to expand a list of navigational links to Oracle Site Activate and TMF functional areas.



Navigation options in the left menu reflect your Oracle Site Activate business role permissions. For example, the Study Library option in the new menu's Oracle Site Activate section will be active only if you have been granted one or more Study Library business role permissions. When expanded to include all available options, the menu includes:

#### Reports

- Audit Report
- Analyze Reports
- Data Export

#### **Team Members**

#### More

- Quarantined Files
- Expiring Items
- Configuration Designer
- Submission Details
- Event Messages
- Manage Submission Agencies
- Manage Publish Endpoints
- Study Planning



- Manage Site Matching
- View Tasks for All Studies

#### **Activate**

- Study Home
- Study Library
- **Bulk Work**

#### **TMF**

Viewer

When vertical navigation is enabled for your organization's account, you'll also have a new drop-down menu under your user badge at the upper right. Again, options available to you in this drop-down menu reflect your Oracle Site Activate business role permissions (i.e., you will see Admin and Settings options only if you have been granted permissioned access to these areas).



#### (i) Note

Please contact your Oracle services representative to discuss enabling the new eTMF feature and/or vertical navigation for your organization's account.



#### **API** integration

In preparation for release of the eTMF feature, we made related API enhancements in release 24.2. For details about these enhancements, please review the eTMF API integration section in the Oracle Site Activate 24.2 release notes in this book.

EPIC: CHK-45169 (release 24.2)

## Reporting

Oracle Analytics Cloud replaces Tableau for reporting.

#### **Oracle Site Activate - Oracle Analytics Cloud integration**

We updated Oracle Site Activate account settings to ensure users in enabled accounts can access Oracle Site Analyze reports that have been migrated from Tableau to Oracle Analytics Cloud.





Access to reports in Oracle Analytics Cloud requires user authentication via Oracle Identity Cloud Service (IDCS). Please contact your Oracle services representative to discuss requirements and scheduling for your organization's account.

Please note that export limitations exist in Oracle Analytics Cloud. When you create an Oracle Analytics Cloud instance for your production or non-production environment, you either specify the number of Oracle Compute Units (OCPUs) you want to deploy or the number of people you expect to use the service. The compute size determines the maximum number of rows you can export, and there are different limits for formatted (Microsoft Excel) and unformatted (CSV) data. Please reference the documented sizing options.

EPIC: CHK-45582 (release 24.2)

#### Service notice

Oracle Site Activate introduces support for a multi-tenant deployment model.

#### Multi-tenant model

With the Oracle Site Activate 24.2.1 minor release, we made the necessary infrastructure updates to support Oracle Site Activate in a multi-tenant model. This is an optional deployment model, and the updates in this release will not affect current installations for Oracle Site Activate customers.



#### Note

Please contact your Oracle services representative to discuss how the multi-tenant model would be used for your organization.

EPIC: CHK-46026 (release 24.2.1)

## Stability improvements

This minor release includes corrections for several reported issues.

- API integration
- **Notes**
- Site management

## **API** integration

Description	Ticket	<u>Severity</u>
Intermittently, when a user clicked "Send to eTMF" on a submission package, the generated eTMF message was missing the submission_package segment that identifies which package the message originated from.	CHK-46120	2



### Notes

Description	Ticket	Severity
The Add a note section in the notes modal was incorrectly enabled for a user with view only permission.	CHK-46136	3
A user with view only permission was incorrectly allowed to create an Reply note in an item with an existing note and in the Notes history table on the Notes tab.	CHK-46195	3

## Site management

Description	Ticket	Severity
When editing a PI record, the Replace PI button displayed when it should not have been available if the site was created via API and had no specified IRB/EC type.	CHK-46135	2

### Release 24.2

See descriptions of new features, enhancements, and stability improvements, as well as issue lists published in the 24.2 GA release notes.

#### What's new

Learn about new and enhanced functionality in the 24.2 release.

#### Impact analysis

See a quick summary of the business and functional impact of enhancements included in the 24.2 release.

#### Service notice

Upcoming removal of Standard and Operational reports.

#### Stability improvements

These are the issue corrections included in this release.

#### Previously reported known issues

See the unresolved issues reported prior to this current release.

### What's new

Learn about new and enhanced functionality in the 24.2 release.

#### Integration

The Event Messages page has significant user experience enhancements, we added an enhancement to eTMF Publish messages triggered by the "Send to eTMF" feature, and the User GET API has a new field and filter.

#### Milestone management

We made an infrastructure improvement to improve load time for Milestone and Submission timelines.

#### Reporting

We added internal monitoring and alerting for the CSV generation service.

#### User interface

We made user experience enhancements to improve the site status pie chart and standardize button display in the notes modal.

#### <u>User management</u>

The local time zone feature on the My profile page now shows an error if the system time zone doesn't have a match in Oracle Site Activate.



### Integration

The Event Messages page has significant user experience enhancements, we added an enhancement to eTMF Publish messages triggered by the "Send to eTMF" feature, and the User GET API has a new field and filter.

#### **Event messages**

In release 24.2, we redesigned the Event Messages page to improve your user experience. The page now uses Oracle standard design elements for fields, buttons, and user actions (e.g., search, infinite scroll, etc.). We've reformatted the page's Download CSV and API documentation links as buttons at the upper right; these options provide the same navigation functionality they did previously. Download CSV also contains three additional columns: Study Name, Country, and Site Number to match the grid in the user interface.

The enhanced page includes search (text string) and filter options. The default display when landing on the page is yesterday and today's messages. You can also filter messages shown in the grid by selecting an option from the Status, Type, and Endpoints drop-down lists.

At the top left of the message grid, you'll see a message count reflecting the total messages available for display, with any filters applied. Note that the message retention schedule is unchanged with this release. You can find successful messages in the message grid for one week, while failed messages are retained for two weeks.

The message grid, which now features infinite scroll functionality, includes the following columns:

Created At: Message date and timestamp

Study Name: Study display name

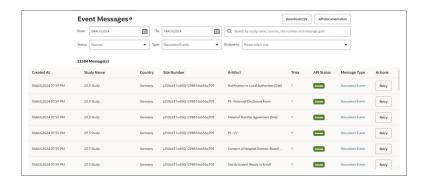
Country: Country name
 Site Number: Site number
 Artifact: Placeholder name

Tries: Number of times the message has been tried (0-5)

API Status: Success (green), Failed (red), Trying (blue), Processing (blue) status badge

Message Type: eTMF Message, Milestone Message, Document Event, etc.

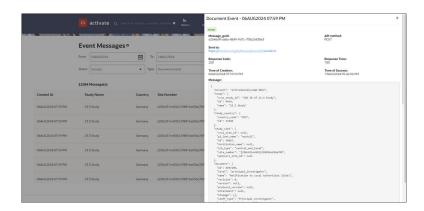
 Actions: Retry button. The Retry button is active for messages in Success and Failed status and inactive for messages in Trying and Processing status.



Click on a message's linked Message Type (e.g., Document Event, Activity Change Message, eTMF Message, etc.) to open a drawer component from the right side of your screen. The



message details (like the status badge, message GUID, endpoint address, etc.) show at the top of the drawer, followed by the message body (in formatted JSON), transformed message (if any), and response (if any). Scroll to the bottom of the drawer to access an active Retry button for messages in Success or Failed status.



#### eTMF API integration

#### **Artifacts GET**

The Artifacts GET response now includes an "unblinded" field in support of eTMF functionality targeted for a future release. As of the 24.2 release, artifacts where unblinded = true cannot be called via API. They can be accessed via the Oracle Site Activate user interface by users with appropriate permissions. An API user calling Artifacts GET for a specific artifact (ex: /api/v1/ artifacts?id=2144277) where unblinded = true, will receive a 403 Forbidden error message: "Unblinded documents cannot be returned via API call."

#### Artifacts POST and Artifacts Attachment POST and PUT

The Artifacts POST API provides a route that creates a document placeholder based on a study's configuration. An API user (e.g., CTMS or other partner) can use the Artifacts Attachment POST messages to add a file to a document placeholder. When successful, the file will be visible on the placeholder, the user name will be identified from the transmitter\_email in the call, and the file\_version will be set to 1.

Artifacts POST API accepts the inputs listed below and outputs an artifact ID and artifact URL. The API inputs are:

- artifact level (study, country, or site)
- study id (required)
- country code (required for country or site artifact level (2 or 3 characters))
- site id (required for site artifact level)
- artifact name (required, and will be held in a mapping table in CTMS and match the Oracle Site Activate configuration)
- unblinded status (Boolean (true/false), if not sent, default to false)
- tmf status (optional, part of future eTMF product functionality)

Use the Artifacts Attachment PUT API to replace a file on a document placeholder. When successful, the new file will be visible on the placeholder, and the replaced file moves to the placeholder's "previous files" section. Also, the user name will be identified from the transmitter\_email in the PUT call, and the file\_version value will be incremented.



#### eTMF Publish API

eTMF Publish messages triggered by the "Send to eTMF" feature on a submission package now include a new completed\_by field in the submission\_package segment. The completed\_by field populates with the email address of the user who clicked the Complete activity button on the submission package.

#### **User GET API**

We enhanced the User GET API to include a last\_edit\_date field and an updated\_after filter. These additions allow your organization to pull latest updates rather than all users to improve query performance.

### Milestone management

We made an infrastructure improvement to improve load time for Milestone and Submission timelines.

#### Milestone timelines

Milestone and Submission milestone timelines at the Study, Country, and Site levels now load faster due to a performance improvement we made in this release.

### Reporting

We added internal monitoring and alerting for the CSV generation service.

#### **CSV** service monitoring

In release 24.2, we made infrastructure improvements to CSV extract service monitoring.

### User interface

We made user experience enhancements to improve the site status pie chart and standardize button display in the notes modal.

#### Site status graph

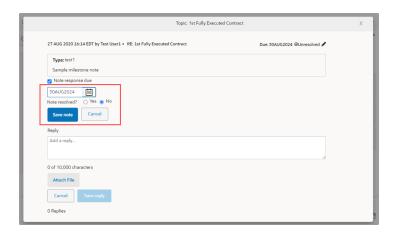
On the Study country Dashboard tab, the Site status tab's pie chart now shows you the site count within each of the chart's sections instead of separately in the chart's legend. You can also hover over each chart section to see a percent value for that section.





#### Study, Country, and Site Notes

We made a minor usability update to the Note reply modal. Now, when you change the Note response due date, the "Save note" and "Cancel" button options are active.



### User management

The local time zone feature on the My profile page now shows an error if the system time zone doesn't have a match in Oracle Site Activate.

#### My Profile

We enhanced the My profile page to improve error messaging. Previously, if your system time zone didn't have a match in the Oracle Site Activate application, and you clicked the "Set to my local time zone" button, no action was taken and no error was displayed. With the enhancement in release 24.2, if you don't select an available time zone from the Oracle Site Activate "My time zone" list, the message, "Please select a timezone from the drop-down on the left" will display.



## Impact analysis

See a quick summary of the business and functional impact of enhancements included in the 24.2 release.



Enhancement	Enablement setting	Impact
Integration Event messages	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Enhanced usability for Event Messages users
Integration  eTMF API integration	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Allows for restriction of unblinded items
Integration eTMF Publish API	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: Y (role permission 'Enable manual 'Send to eTMF' button on Submission packages' and feature flip 'Enable manual 'Send to eTMF' button on Submission packages' must be on.</li> </ul>	Adds visibility of 'completed by'
Integration User GET API	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	More filters allow for improved query performance
Milestone management Milestone timelines	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Performance improvement
Reporting CSV service monitoring	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Improved CSV extract monitoring
User interface Site status graph Study, Country, and Site Notes	<ul> <li>Feature flip: N</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Improved usability



Enhancement	Enablement setting	Impact
User management  My Profile	<ul><li>Feature flip: N</li><li>Config related: N</li></ul>	Timezone selection validation
	<ul> <li>All studies: Y</li> </ul>	
	<ul> <li>New role permission required: N</li> </ul>	
	<ul> <li>Dependent feature: N</li> </ul>	

### Service notice

Upcoming removal of Standard and Operational reports.

#### Upcoming report option removal

With the upcoming release 24.3, we will deprecate the Standard reports and Operational reports options from the Oracle Site Activate Reports menu. The reports are unused, and this upcoming change will not impact Oracle Site Activate customers. Please note that the Audit report, Analyze reports link, and Data export options will remain available in the Reports dropdown for users who have permission to access these features.

## Stability improvements

These are the issue corrections included in this release.

- API integration
- Bulk work
- Document management
- Milestones
- Reports
- Submissions
- Site experience
- <u>Site management</u>
- Workflow wizard

### **API** integration

Description	Ticket	Severity
For some but not all environments, our API proxy did not properly route requests to configured environment values.	CHK-45908	1



Description	Ticket	<u>Severity</u>	
Send to eTMF functionality on a Submission package was incorrectly tied to the Enable eTMF publishing setting's "New file uploaded to document or contract" option. Instead, this functionality should have been triggered by the top level Enable eTMF publishing endpoint setting. We corrected this issue so that all three sub-settings (IP package completed, Document or contract completed, or New file uploaded) can be disabled if preferred and the manual Send submission to eTMF will work as expected.	CHK-46021	2	

## Bulk work

Description	Ticket	Severity
In Bulk work or Planning, when entering a submission Planned Date, the date incorrectly saved as one day prior to the actual date selected.	CHK-45083	3
The Your alerts filter showed inconsistent alert counts for the number of items per individual role.	CHK-45973	2

## Document management

Description	Ticket	Severity
Study level ad hoc documents were not generated when they did not specify a protocol version to indicate uniqueness. We updated this behavior to prevent blocking the creation of these documents. Now study level ad hoc documents will be created as expected because the items will be unique when compared to items configured in the configuration and items generated within the same study.	CHK-45061	3
At the country level, an error occurred when users attempted to create a new non-protocol ad hoc document when a protocol-related ad hoc document with the same name already existed.	CHK-45289	3



## Milestones

Description	Ticket	Severity
When submission summary milestones were being calculated for a study, the "Summary milestones are being calculated" message displayed and prevented access for other studies that did not have a submission change.	CHK-45165	2
We modified this behavior so that now when there is an update to a submission on a study site, and submission summary milestones are being calculated for that study, the calculating summary milestone message displays for that study, and the summary milestone table is accessible to other studies that did not have a change to a submission.		
For suggested dates, Contract Executed did not always take precedence over Essential Documents Sent to Site as expected in the unusual circumstance that the user nulled the completed dates, created new artifact/activity versions, and then completed them later.	CHK-45275	3

## Reports

Description	Ticket	Severity
When creating an audit report, the Study field did not respond on the first click and instead required users to click twice to view the drop-down list.	CHK-45281	4

## **Submissions**

Description	Ticket	<u>Severity</u>
The initial submission Planned date was not updated to the Planned date of the active package after the latest package was discontinued.	CHK-45941	3



## Site experience

Description	Ticket	Severity
The activities list on the Site experience home page took longer than expected to load. We improved performance for this page.	CHK-44934	3
The Site experience home page Submissions tab took longer than expected to load all available submissions. We improved performance for this page.	CHK-45282	3

## Site management

Description	Ticket	Severity
When creating a site via the site creation API, Oracle Site Activate could incorrectly generate a "create" audit item for study sites that failed to be created due to an error (for example during PI email validation, under an unusual network error, etc.).	CHK-45915	3

### Workflow wizard

Description	Ticket	Severity
Workflow wizard did not load items as designed when workflows had a very high number of associated lifecycles.	CHK-45636 CHK-45712	2
Workflow wizard did not provide the option to select contract Type when creating site contract items in the study country creation workflow, so the page's Done button remained unavailable and users could not add contract activities as designed.	CHK-45687	2
Intermittently, after clicking the Expand all checkbox, some items were not selected even when the collection had been checked.	CHK-45797	3

## Previously reported known issues

See the unresolved issues reported prior to this current release.

API integration



- Bulk work
- Contracts
- CRO and sponsor collaboration
- Document management
- Electronic signature
- Global search
- IP release
- <u>Milestones</u>
- Site experience
- Site library
- Staff documents
- Study library
- Submissions
- <u>Team member assignments</u>
- User interface

## **API** integration

Description	Ticket	Severity
When identifying a site, principal_investigator PUT calls should validate the uniqueness of cros_pi_id and sponsors_pi_id fields, and does not return an error if the call specifies a preexisting value for either field.	CHK-20128	3
The Study Site API (POST or PUT) allows the creation or update of a site with a duplicate cros_site_id or sponsors_site_id value.	CHK-27914	3
When a user updates a submission activity date, the published Activity Change Message includes a null value for "updated_by."	CHK-38494	3

### **Bulk work**

Description	Ticket	<u>Severity</u>	
Columns and icons are misaligned in the bulk area for items that require an expiration date.	CHK-42289	4	



### Contracts

Description	Ticket	Severity
If contract activities are blocked by budget and contract language activities, and the activities are completed, the "view blocking items" link displays until the page is refreshed.	CHK-18192	3
When editing a completed budget to replace the currency value, the new value does not display after clicking Done in the edit modal.	CHK-20273	4
Workaround: Refresh the page.		
Creating a new budget version on a contract item successfully adds a new version, but the new version does not include a revision number as expected.	CHK-20631	3
The database value for the Account Overview Studies tab "Items completed" calculation does not properly exclude subcontract items in discontinued, on hold, and terminated status, so the values in reports and data extracts are incorrect.	CHK-43740	3

## CRO and sponsor collaboration

Description	Ticket	<u>Severity</u>
The business partner or site assignments icon has inconsistent display logic for submission packages.	CHK-20086	3
The hover-over tooltip showing an activity is assigned to an external user displays only one name when the role "Country Lead" is assigned to two external users from different accounts.	CHK-23407	3
On country level submissions, the icon that indicates an activity assigned to an external user does not display.	CHK-35736	3



## Document management

Description	Ticket	Severity
No alert message is generated when a duplicate Country ad hoc protocol-related document is created.	CHK-8844	3
For an item configured with an Activity due date, the calculated Due date displayed to users may be off by up to one day.	CHK-37764	3

## Electronic signature

Description	Ticket	Severity
An error message pop-in related to the electronic signature configuration is partially obscured.	CHK-20216	3
When a tagger sends a document to multiple signers, and the tagger uploads a new document before the signers have provided the electronic signature, Adobe Sign does not send an email notification to the recipients that the first document has been cancelled.	CHK-20291	3
After a document has been signed via electronic signature, an Oracle Site Activate user can see the file within the widget under File History, but the file does not display under File History for a site experience user.	CHK-20627	3

### Global search

Description	Ticket	Severity
Global search does not return results when a search keyword has a dash (e.g., "Study-1068").	CHK-10472	3
When performing a search with results for a PI or Sub-I who is inactive or replaced, the search does not indicate that they are replaced.	CHK-10502	3



## IP release

Description	Ticket	<u>Severity</u>	
After rejecting a review package and completing the activities, if the user double clicks the Done button, two identical notes are created.	CHK-21747	3	
It is possible for a user to modify the expiration date on a completed item when it should not be possible. An Artifact API POST message is triggered by the date change, but the change does not trigger an eTMF API publish message.	CHK-22848	3	
In the Review Package modal, the Due date field incorrectly displays in the completion panel's list of Required items; however, users can complete the item if the Due date field is blank.		3	

### Milestones

Description	Ticket	Severity	
On the home page Planning tab, when viewing Milestones a duplicate tooltip displays instead of a single instance.	CHK-24393	4	
When multiple versions of a milestone are created (via smart milestones or by adding a PV) then we incorrectly display the old version(s) on the milestone timeline in addition to the latest version.	CHK-34222	3	
When site level submissions are enabled for summary milestones, users experience delayed response when filtering by Protocol version, Type, or Category from the summary milestone tabular view or bar chart view.	CHK-36460	3	



## Site experience

Description	Ticket	Severity
When a site user discontinues a submission, the submission erroneously disappears from Site experience.		3

## Site library

Description	Ticket	<u>Severity</u>
After replacing the PI in matching sites and completing a document enabled for Site Library in one site, Site Library is not immediately available for the sites.	CHK-39683	3
Workaround: Site Library is enabled for the sites after an hour elapses. Wait one hour and attempt to access Site Library again		

### Staff documents

Description	Ticket	Severity
If a staff document is assigned a display order number, and then that staff member is deactivated, the document will continue to display in the original order, instead of at the end of the list.	CHK-10104	4

## Study library

Description	Ticket	Severity
In a newly created study site or study country, multiple lineage documents are created from the new version of an already shared study document.	CHK-8606	3
While in the Study Library area, if a user chooses a favorite study from the study drop-down menu, the screen refreshes as expected but the favorite icon in the persistent header is not active.	CHK-31464	4



Description	Ticket	Severity
Results are not returned as expected when a user enters a combined alphabetic and numeric search term (e.g., Form FDA 1572).	CHK-44357	4

### **Submissions**

Description	Ticket	Severity
On the submissions planning page, the standard date format is DDMMMYYYY, but when dates are set or updated, they display in non-standard, hyphenated format: DD-MMM-YYYY.	CHK-22928	4
Users are able to share item level notes with site experience users, which is not by design.	CHK-24766	3
An assigned define package activity does not display on the assigned user's Your activities list after the activity is completed and later uncompleted.	CHK-37815	3
Additional submission packages created on EU Submissions incorrectly show an open activity even after the item is completed. Additionally, in the modal's item completion panel, there is no Actual date present in the date field even though the date field indicator displays a green check mark (complete).	CHK-37837	3
Configured TMF Agency (Agency field) values do not display as a drop-down list in the submission modal's Submission Info tab as designed.	CHK-44226	3

## Team member assignments

Description	Ticket	Severity	
After assigning a site role to multiple users, no "role successfully applied" confirmation message displays.	CHK-22611	4	



## User interface

Description	Ticket	<u>Severity</u>
The site status pie chart does not accurately reflect site status if the country status has been changed to "on hold."		4

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# 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.

## 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 Site Activate	24.2	Google Chrome and Microsoft Edge (Chromium)	None
Site Experience and Oracle Site Activate LITE	24.2	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

# Post-upgrade refresh

You may need to complete a hard refresh after upgrading if search results don't work as expected.

If your organization recently completed an upgrade, and the Oracle Site Activate global search is returning no results, you can do a hard refresh, and it should fix the problem. The hard refresh will clear your browser cache for that specific page. The following table specifies refresh keyboard shortcuts for Mac and Windows computers:

Product	Google Chrome	Microsoft Edge	Firefox	Safari
Windows	Ctrl + press F5	Ctrl + press F5	Ctrl + press F5	None
Mac	Command + Shift + R	Command + Shift + R	Command + Shift + R	Option + Command + E



#### (i) Note

Please note that Safari is not an Oracle tested browser.

# **Revision history**

This book's revision date history and part number list will develop over time as we make major, minor, or hotfix releases available for 24.2.

Date	Part number	Description	
26Aug2025	G11503-18 Added 24.2.2.1 hotfix (av for this release 26Aug20		
19Aug2025	G11503-17	Added 24.2.2 Minor release	
18Jul2025	G11503-16	Corrected Release Notes book metadata. No customer impact.	
18Jul2025	G11503-15	Added <u>audit trail fix</u> description to the Stability improvements included in 24.2.1.11 hotfix	
20Jun2025	G11503-14	Added 24.2.1.11 hotfix (available for this release 20Jun2025)	
28Apr2025	G11503-13	Added 24.2.1.10 hotfix (available for this release 28Apr2025)	
11Apr2025	G11503-12	Added 24.2.1.9 hotfix (available for this release 11Apr2025)	
07Feb2025	G11503-11	Added 24.2.1.8 hotfix (available for this release 07Feb2025)	
24Dec2024	G11503-10	Added 24.2.1.7 hotfix (available for this release 24Dec2024)	
09Dec2024	G11503-09	Added 24.2.1.6 hotfix (available for this release 09Dec2024)	
06Dec2024	G11503-08	Added 24.2.1.5 hotfix (available for this release 06Dec2024)	
26Nov2024	G11503-07	Added 24.2.1.4 hotfix (available for this release 26Nov2024)	
25Nov2024	G11503-06	Added 24.2.1.3 hotfix (available for this release 25Nov2024)	
25Nov2024	G11503-05	Added 24.2.1.2 hotfix (available for this release 25Nov2024)	
18Nov2024	G11503-04	Added 24.2.1.1 hotfix (available for this release 18Nov2024)	
14Oct2024	G11503-03	Added 24.2.1 Minor release	
30Aug2024	G11503-02	General Availability Release Notes	
16Aug2024 G11503-01		Pre-General Availability Release Notes	