

# Oracle Life Sciences Site Activate

## Release Notes



Release 24.1

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ORACLE®

Oracle Life Sciences Site Activate Release Notes, Release 24.1

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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 <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

## 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 [Oracle Help Center](#).

## 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 (<https://hsghbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsghbu-jp.custhelp.com/>)

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

# 1

## Release 24.1.1

Review the enhancements and corrections made in the 24.1.1 minor release.

- [What's new](#)  
Learn about Integration and Milestone enhancements in this minor release
- [Stability improvements](#)  
This minor release includes corrections for several reported issues.

### What's new

Learn about Integration and Milestone enhancements in this minor release

- [Integration](#)  
eTMF Publish messages triggered by the “Send to eTMF” feature on a submission package include a new field.
- [Milestones](#)  
Milestone timelines now load faster.

### Integration

eTMF Publish messages triggered by the “Send to eTMF” feature on a submission package include a new field.

#### **eTMF messages**

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.

### Milestones

Milestone timelines now load faster.

#### **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.

### Stability improvements

This minor release includes corrections for several reported issues.

- [API integration](#)
- [Milestones](#)
- [Site experience](#)

- [User interface](#)
- [Workflow wizard](#)

## API integration

Description	Ticket	Severity
Intermittently, when making a site status change via API, the change record was not created as expected.	CHK-45658	2

## 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.  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.	CHK-45653	2

## 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-45650	3
The Site experience home page Submissions tab took longer than expected to load all available submissions. We improved performance for this page.	CHK-45652	3



## User interface

Description	Ticket	Severity
Duplicate records could be created when adding staff members. To prevent duplicates, we updated the behavior so that the Save button is disabled while Oracle Site Activate creates the staff record. When the record has been created successfully, the Save button is available again.	CHK-45651	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-45515 CHK-45711	2

# 2

## Release 24.1

See descriptions of new features, enhancements, and stability improvements, as well as issue lists published in the 24.1 GA release notes.

- [What's new](#)  
Learn about new and enhanced functionality in this release.
- [Impact analysis](#)  
See a quick summary of the business and functional impact of enhancements included in the 24.1 release.
- [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.
- [Deprecated known issues](#)  
Issues listed here are no longer applicable (e.g., does not occur, will not be prioritized for a fix, working as designed, or does not affect current functionality). We removed these items from the known issues list.

## What's new

Learn about new and enhanced functionality in this release.

- [Document management](#)  
Now you can now create associated document versions, and you can add a Document description in the document modal's Info tab.
- [Integration](#)  
You can publish submission package files to eTMF from within the package if you have a new business role permission, we added a new field in support of Phlex eTMF integration, eTMF publish messages have new fields, and more.
- [Milestones](#)  
Milestone replanning functionality now includes an account level setting that requires you to select just one reason for replanning.
- [Site experience](#)  
We extended the Communication banner feature to Site Experience.
- [Smart site library](#)  
A new option allows Smart Site Library to automatically apply Document and Expiration dates.
- [Study management](#)  
The Account Overview Studies drawer component now includes Study Progress information, and we made enhancements to updates and display of IRB/EC type values.
- [Submissions](#)  
Now you can search for submission Category and Type in Submission modals.

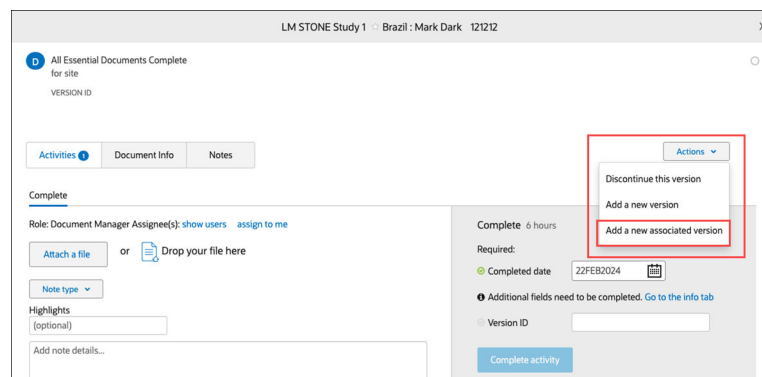
- [Workflow wizard](#)  
Your organization can now require you to specify submission Type or submission Category values, and submission Type and submission Category drop-downs now sort alphabetically.

## Document management

Now you can now create associated document versions, and you can add a Document description in the document modal's Info tab.

### Associated document versions

In release 24.1, Oracle Site Activate introduces a new feature that allows permissioned users to create associated document versions at study, country, and site levels. You must have the new business role permission *Enable adding associated document versions* to see the new associated versioning option in the Document modal's Actions menu.



This enhancement adds a new versioning method that distinguishes the associated document from the original. The new method uses decimals, which increment for each associated version. For example:

- The item you version is version 0, so the new associated version will be 0.1
- The item you version is version 1, so the new associated version will be 1.1
- The item you version is version 1.1, so the new associated version will be 1.2

When you upversion an associated version, the new associated version goes to the next associated version number in the group. So, when versions 1, 1.1, 1.2, and 1.3 exist, and you use version 1.2 to generate a new associated version, the new version will be 1.4. For lineage items, an associated version will have the same lineage information as the version it is being created from. The same versioning described above will apply.

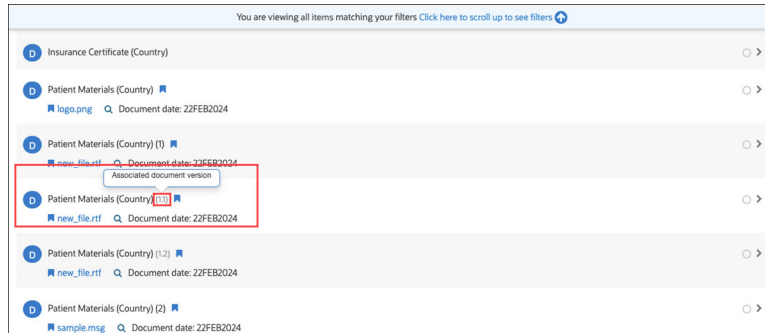
If you create and share a new master version from the Study library, it will be its own grouping and will not impact the unversioned items. The version numbering will be consistent with what was shared from the library, and all expected items will be generated.

Associated document versions display a tooltip, "Associated document version," in the following areas where document version displays:

- Document list under All items on Study/Country/Site details pages
- Activities list under Your activities on Study/Country/Site details pages
- Document artifact modal header
- Your tasks tab on the Home page

- Corrections > Activities and Items tabs
- Bulk work > Activities and Items tabs
- Submission and IP Release planning modals

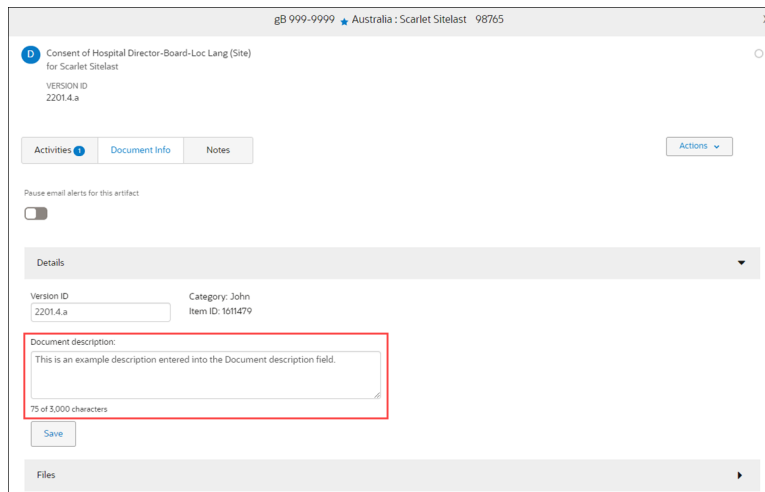
In the areas above, associated versions will be grouped together with their main version in order of revision number.



Epic: CHK-43974

## Document description field

Document modals now provide an optional Document description field where you can add a free-text description to differentiate the document from others. You'll find the new field in the Document Info tab's Details section. The Document description field accepts up to 3,000 text characters.



Epic: CHK-43974

## Integration

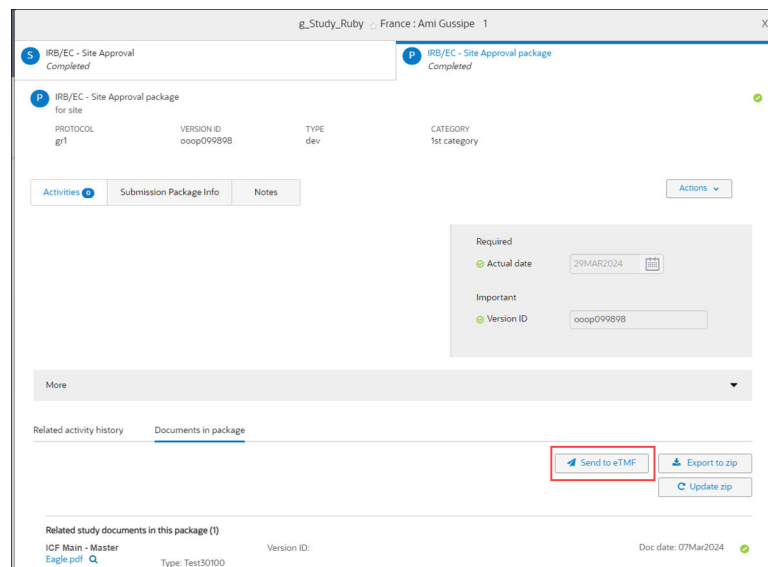
You can publish submission package files to eTMF from within the package if you have a new business role permission, we added a new field in support of Phlex eTMF integration, eTMF publish messages have new fields, and more.

### Publish Submission package files to eTMF

#### New action button on Submission packages

In this release, Oracle Site Activate introduces an enhancement that allows you to trigger sending Submission package documents to an eTMF from within the package itself. When enabled for your organization's account, and when you have a new business role permission, *Enable manual 'Send to eTMF' button on Submission packages*, you'll see a new button on Submission packages. The button "Send to eTMF," will be active only when the submission package is approved. Otherwise, it is inactive (grayed out).

When you click Send to eTMF, Oracle Site Activate sends any files in the submission package to the eTMF endpoint(s) configured for your organization's account or study. You can click the button only once per package; after you send the files, the button no longer displays, and the text "Sent to eTMF" with the date displays instead. If necessary, you can retry messages on the Event Message page or via API if you have a business role permission that allows you to do so.



#### New fields in eTMF messages

We also added new fields to the eTMF publish messages that include information about the submission package itself. This additional information ensures the files in each publish message can be stored in the appropriate eTMF location. When you click the new Send to eTMF button in the approved package, the publish message will include a new element, "submission\_package," with the fields below, which will be populated with values where available:

- package\_name
- protocol\_version (inherited from submission)
- submission\_type

- submission\_category
- package\_version\_id

Note that eTMF messages generated outside of the new manual Send to eTMF flow described above will NOT have the submission\_package element.

*Epic: CHK-43975*

### Oracle Site Activate-Phlex eTMF integration

With release 24.1, we modified Phlex integration to ensure that items sent from Oracle Site Activate can be filed in the correct folder location in Phlex eTMF. To support this change, Oracle Site Activate now uses the Phlex Reference Code value to help match documents between systems. When triggering an eTMF message to a Phlex endpoint or responding to an Artifact GET, Oracle Site Activate will include the Phlex Reference Code for artifacts to support the integration workflows.

We added Reference Code where necessary to support this enhancement:

- Configuration Designer users will add the Phlex Reference Code in the Customize an Artifact modal using a "Reference Code" field added in this release
- After deploying the configuration, Oracle Site Activate users will see the Reference Code value in the Document modal, TMF Data section banner, as well as in Settings > Processes, when editing an artifact.
- Event Messages will include the reference\_code value for eTMF Messages when present
- API users will see the reference\_code field in the Artifact GET responses.

*Epic: CHK-43975*

### Publish message file tokens

To ensure customers can access files when necessary, we enhanced outbound publish messages (e.g., eTMF publish) to allow for the regeneration of file access tokens. Publish message file tokens expire after one hour, and you can now generate a new token when needed by retrying the message from either the Event Messages page or via API.

*Epic: CHK-43975*

### API documentation

We updated the What's new section in Oracle Site Activate API documentation to reflect release 24.1 enhancements to the Artifact Publish, Artifacts GET, and eTMF Publish APIs. Because we also updated several existing API documentation sections, we've included a summary of the updates in a Documentation updates table.

*Epic: CHK-43975*

## Milestones

Milestone replanning functionality now includes an account level setting that requires you to select just one reason for replanning.

### Milestone replanning

In this release, we added a new account-level setting that changes the entity milestone "Reason" for change drop-down list from multi-select to single-select. When this option is enabled for your organization's account and you change an entity milestone's planned date,

you'll see that you can select just one of the reasons listed in the drop-down. You can still add an "Other" reason if that account level setting is also enabled for your organization's account.

This single-select enhancement applies to all areas where you might need to replan a milestone date. For instance, you'll see the updated drop-down lists when you replan from the milestone timelines, on the home page planning tab, etc.

Epic: CHK-43974

## Site experience

We extended the Communication banner feature to Site Experience.

### Communication banner

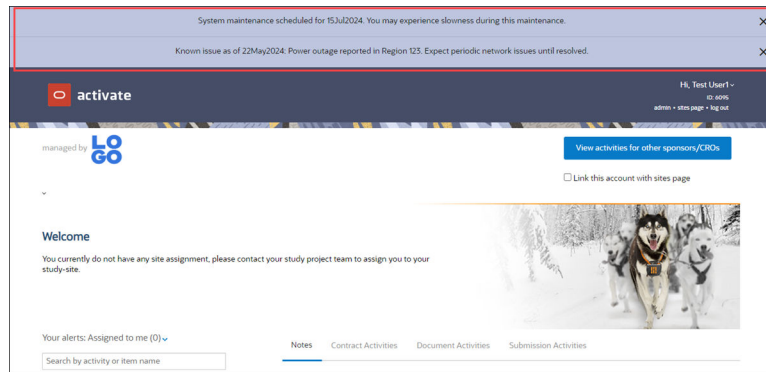
With release 23.2, Oracle Site Activate introduced a Communications banner feature to display up to two text messages at the top of the browser window. With this release, we enhanced the banner feature to now display these messages in Site Experience when configured. Sites will see the same message(s) displayed to CRO or Sponsor users in Oracle Site Activate.

Communication banners provide a convenient option for sharing important messages (e.g., network slowness, a high-impact browser issue, or an upcoming upgrade window). Like Oracle Site Activate users, Site Experience users can optionally dismiss the banner(s) for their current session if preferred.



#### Note:

Please contact your Oracle services representative to discuss enabling communication banners for your organization's account.



Epic: CHK-43974

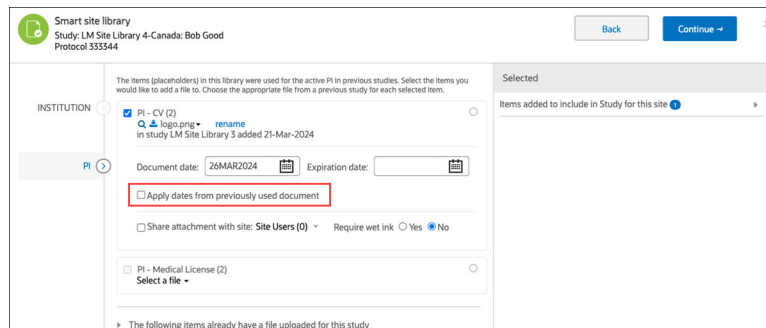
## Smart site library

A new option allows Smart Site Library to automatically apply Document and Expiration dates.

### Document and Expiration dates

We enhanced Smart Site Library to automatically apply the Document date and Expiration date when you reuse documents. When you select a document to reuse from any section (Site, PI, Institution, or Staff), you'll have a new check box option just below the Document date and Expiration date pickers: "Apply dates from previously used document." If you don't check the new option, you can manually enter your preferred dates.

Note that if you check the "Apply dates" box and then uncheck it, the date picker for the Document date defaults to today's date, and the date picker for the Expiration date defaults to blank.



Epic: CHK-43974

## Study management

The Account Overview Studies drawer component now includes Study Progress information, and we made enhancements to updates and display of IRB/EC type values.

### Account overview Studies tab

The Account overview Studies tab now includes study progress data in the study drawer. When you click on a study row, the drawer opens from the right as it did previously, and now:

- The drawer overlays half the screen to provide more room to display data.



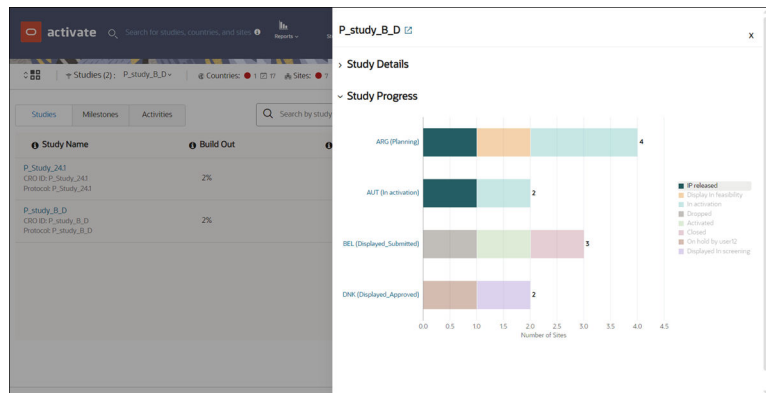
- The drawer's title is the study name. You can access the study in a new tab by clicking the open (🔗) icon.
- The drawer's collapsible Study Details section is closed by default; click the expand toggle icon (➤) to the left of the section name to expand it.

A new Study Progress section displays below the Study Details section, and Study Progress will be expanded by default when you open the drawer component.

The new Study Progress section includes an interactive bar chart, which lists all the countries in the study with country status below the country code. Click the hyperlinked country code to open the country page in a new browser tab.

Each bar in the chart represents the number of sites in different statuses within that country, and the total count of sites in that country shows at the far right of the bar. A dynamic legend displays to the right of the full chart, reflecting only the statuses in the chart (i.e., if two site statuses exist within the entire bar chart, the legend will include only two labels). If your organization has configured a unique “display value” for any status, the Study Progress section will use that value in the chart and its legend.

Hover over a status section on a bar to see a tooltip with Country, Site Status, and Number of Sites in that status. When you hover over a status section in a bar, all sections for the same site status anywhere in the chart are highlighted, and the remaining status sections in all bars will dim. You can also hover over any status in the chart legend to see that status highlighted in the bars.



*Epic: CHK-43974*

## IRB/EC type

### IRB/EC Type in the site list

If your organization adds sites with the Pending IRB/EC type, you can now see the “Pending” status on the site list when it applies to a site.

**Country work** | Dashboard | Notes | Display settings

**Milestones** | Submission dates

	1st Fully Executed Contract	1st SVV Conducted	1st Site Selected	Regulatory Submission - Approval (Country) / Pre v9 28NOV2021	Contract Template Final	1st Essential Document Package Sent	1st Site Activated	Regulatory Submission - Approval (Country) / Pre v9 28NOV2021
<b>Baseline</b>	02SEP2020	25NOV2020	27JAN2021	Initial submit 09SEP2021	01APR2022	01JUN2022	14OCT2022	Final approval Enter a planned date
<b>Planned</b>	09NOV2020	25NOV2020	27JAN2021	09SEP2021	01APR2022	01JUN2022	14OCT2022	Enter a planned date
<b>Actual</b>	28NOV2020	-	-	-	-	At risk	-	-

**Study Sites Table:**

PI/Institution Name	Site number	IRB/EC type	Site network	Status	Action
★ Sitelast, Scarlet Austin Hospital, Melbourne	98765	Pending	SN 1	In activation	<a href="#">Edit</a> <a href="#">Info</a>
★ John, Investigator Charles III Medical Center PI 2	202b1	Central	SN 1	In activation	<a href="#">Edit</a> <a href="#">Info</a>
○ Pea, Eye Institution Alpha PI 1	202b	Central and Local	SN 3	In activation	<a href="#">Edit</a> <a href="#">Info</a>

## Edit IRB/EC Type value

We also enhanced the site page to allow you to edit the IRB/EC type from the main site page instead of navigating to the edit site page. Now, when an IRB/EC Type displays in the upper left of the main site page, you can click this value to select a different value from a drop-down list. Note that you must have rights to edit a site to perform this edit.

**activate** | Search for studies, countries, and sites | Reports | Study library | Bulk work | Team members | More | Hi, Test User1 | Log out

Study: pB 999-9999 | Australia | Scarlet Sitelast | In activation

**IRB/EC Type:** P-IRB/EC (dropdown menu)

**Submission dates:**

Essential Documents Complete	IP Release Ready	Essential Documents Sent	All Contracts Fully Executed	SVV
02SEP2020	25NOV2020	27JAN2021	09SEP2021	01APR2022

*Epic: CHK-43974*

## Submissions

Now you can search for submission Category and Type in Submission modals.

### Search for submission Type and Category

In the Submission modal's Submission Info tab, you can now use type-ahead search to find the submission Category and Type. The search field is at the top of the drop-down lists, and you can type directly into the field label area to add your search text.

Epic: CHK-43598

## Workflow wizard

Your organization can now require you to specify submission Type or submission Category values, and submission Type and submission Category drop-downs now sort alphabetically.

### Submission Type and Category

#### Required to generate submission items

With release 24.1, Oracle Site Activate introduces new options to make submission Type or submission Category required fields in the workflow wizard. If one or both options are enabled for your organization's account, you must enter the required information to generate submission items.

Note that the above enhancement is separate from the account level setting that requires you to select a submission Category or Type before completing an item. That functionality continues to work as it did previously.



#### Note:

Please contact your Oracle services representative to discuss enabling the new setting(s) for your organization's account.

### Alphabetized drop-down lists

Now it's easier to locate submission Category and submission Type values in the workflow wizard. We enhanced the drop-down selection lists to order values alphabetically and added search functionality. The search fields are at the top of the drop-down lists; type directly into the field label area to add your search text.

Epic: CHK-43974

## Impact analysis

See a quick summary of the business and functional impact of enhancements included in the 24.1 release.

Enhancement	Enablement setting	Impact
Document management <a href="#">Associated document versions</a>	<ul style="list-style-type: none"> <li>Feature flip: N</li> <li>Config related: Y (artifact must be enabled with "Enable Add a Version")</li> <li>All studies: Y</li> <li>New role permission required: Y (Enable adding associated document versions)</li> <li>Dependent feature: N</li> </ul>	Allows permissioned users to create associated document versions at study, country, and site levels.
Document management <a href="#">Document description field</a>	<ul style="list-style-type: none"> <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>	Optional Document description field where you can add a free-text description to differentiate the document from others
Integration <a href="#">Publish Submission package files to eTMF</a>	<ul style="list-style-type: none"> <li>Feature flip: Y (Enable manual 'Send to eTMF' button on Submission packages)</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: Y (Enable manual 'Send to eTMF' button on Submission packages)</li> <li>Dependent feature: Y (eTMF integration)</li> </ul>	Send submission package contents to eTMF

Enhancement	Enablement setting	Impact
Integration <a href="#">Site Activate-Phlex eTMF integration</a>	<ul style="list-style-type: none"> <li>Feature flip: N</li> <li>Config related: Y (artifact must have reference code)</li> <li>All studies: N</li> <li>New role permission required: N</li> <li>Dependent feature: Y (Phlex eTMF integration)</li> </ul>	Allows for efficient filing
Integration <a href="#">Publish message file tokens</a>	<ul style="list-style-type: none"> <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 (Access to Event Messages)</li> </ul>	Retried messages will include refreshed token
Integration <a href="#">API documentation</a>	Not applicable	Updated documentation
Milestones <a href="#">Milestone replanning</a>	<ul style="list-style-type: none"> <li>Feature flip: Y (Make dropdown menu single select for entity milestones)</li> <li>Config related: N</li> <li>All studies: Y</li> <li>New role permission required: N</li> <li>Dependent feature: N</li> </ul>	Option for the entity milestone "Reason" for change drop-down list to be multi-select or single-select.
Site experience <a href="#">Communication banner</a>	<ul style="list-style-type: none"> <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>	We enhanced the banner feature to now display messages in Site Experience when configured. Sites will see the same message(s) displayed to CRO or Sponsor users in Activate.
Smart site library <a href="#">Document and Expiration dates</a>	<ul style="list-style-type: none"> <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 (Enable site disambiguation, Enable site disambiguation V2)</li> </ul>	Option to automatically apply the Document date and Expiration date when reusing documents in the Smart Site Library.
Study management <a href="#">Account overview Studies tab</a>	<ul style="list-style-type: none"> <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>	The account overview Studies tab now includes study progress data in the study drawer.

Enhancement	Enablement setting	Impact
Study management <a href="#">IRB/EC type</a>	<ul style="list-style-type: none"> <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 (Enable "Pending" IRB/EC type to trigger site workflows)</li> </ul>	Allows user to view site status "Pending" in the site list.
Submissions <a href="#">Submission Type and Category Search</a>	<ul style="list-style-type: none"> <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 user type-ahead in the search field to find the submission Category and Type.
Workflow wizard <a href="#">Submission Type and Category</a>	<ul style="list-style-type: none"> <li>Feature flip: Y (Enable requiring submission category in workflow wizard, Enable requiring submission type in workflow wizard)</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 users to be required to select submission type and/or submission category.

## Stability improvements

These are the issue corrections included in this release.

- [Document management](#)
- [Integration](#)
- [IP release](#)
- [Milestones](#)
- [Smart site library](#)
- [Study library](#)
- [Submissions](#)

## Document management

Description	Ticket	Severity
Deleting items from the Corrections tab took longer than expected.	CHK-44547	3
When editing an attachment, the Open button on the document's Preview screen did not function.	CHK-44565	3

## Integration

Description	Ticket	Severity
Event messages did not progress as expected and incorrectly remained in Trying status. We corrected this issue and added logging capabilities to help triage future issues.	CHK-44365	2
When a user added an attachment to a placeholder but closed the placeholder without saving the file, the file would be orphaned. If the placeholder was later added to the IP Package, the eTMF publish job could fail.	CHK-44242	3
On the Manage publish endpoints > Custom eTMF attributes page, the Save button was enabled even when a user made no change to the page. Additionally, subsequent edits were not saved as expected after creating a new attribute and the removal confirmation message failed to display as designed. We corrected each of these issues in this release.	CHK-44579	3
On the Custom eTMF attribute page, the Save button was not updated to disabled after a user saved a change to the page.	CHK-44733	4
On the Manage publish endpoints page, the Category field label for custom eTMF attributes incorrectly included an asterisk to indicate that the field was required. The field is not required, and we removed the asterisk in this release.	CHK-44710	4

## IP release

Description	Ticket	Severity
When reviewing documents in an IP Release package, the Cancel button was misaligned and displayed against the modal's right margin.	CHK-44175	4

## Milestones

Description	Ticket	Severity
When a new site was added to a study with the Initial Protocol Received/Sent milestone completed, the prediction API call did not generate Contract Executed and IP Release predictions for the new site as designed. We corrected this issue, so the predictions for the newly added sites are now showing.	CHK-44287	2
Unplanned milestones for all sites in a Country did not display as expected when viewing the Sites/ Milestones filter in the Dashboard view.	CHK-44467	4
In some cases, successor milestones auto-planned without a qualifying event on the predecessor milestone.	CHK-44483	3

## Smart site library

Description	Ticket	Severity
When a user selected documents on the Institution, PI, and Staff tabs then removed one of the documents using the X option under the Selected section, the document was not removed as expected.	3	CHK-44969
We made an infrastructure enhancement to ensure the site disambiguation service runs as scheduled.	4	CHK-45101

## Study library

Description	Ticket	Severity
When sharing Study library documents for older studies, sharing processes progressed slowly and appeared to stall.	CHK-44698	3



## Submissions

Description	Ticket	Severity
When planning a submission package and setting the Package date, the selected documents area was misaligned.	CHK-44344	4
Default site level documents still appeared on a Submission package even after deselecting them in the package planning step.	CHK-44562	3
Submission Version ID did not display as expected in the milestone timeline.	CHK-44614	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](#)
- [Milestones](#)
- [Site experience](#)
- [Site library](#)
- [Staff documents](#)
- [Study library](#)
- [Submissions](#)
- [Team member assignments](#)
- [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	Severity
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. <b>Workaround:</b> Refresh the page.	CHK-20273	4
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

Description	Ticket	Severity
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	Severity
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

Description	Ticket	Severity
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	Severity
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.	CHK-37777	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.	CHK-16576	3

## Site library

Description	Ticket	Severity
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. <b>Workaround:</b> Site Library is enabled for the sites after an hour elapses. Wait one hour and attempt to access Site Library again	CHK-39683	3

## 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
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 DDMMYYYY, 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

Description	Ticket	Severity
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	Severity
The site status pie chart does not accurately reflect site status if the country status has been changed to "on hold."	CHK-20162	4

## Deprecated known issues

Issues listed here are no longer applicable (e.g., does not occur, will not be prioritized for a fix, working as designed, or does not affect current functionality). We removed these items from the known issues list.

- [Contracts](#)
- [Document management](#)
- [Electronic signature](#)
- [Milestones](#)
- [Site experience](#)
- [Study library](#)
- [Submissions](#)
- [Team member assignments](#)
- [User interface](#)

## Contracts

Description	Ticket	Severity
When editing a contract budget currency value, the updated value is not displayed in the widget until the user refreshes the page.	CHK-23461	3
When a completed date for an activity is deleted, it cannot be reset.	CHK-23697	3
If a user adds a note to a contract placeholder and saves it, the note's Type value and note text are not automatically cleared from the form.	CHK-31536	4
When a user saves a new value in the TMF data section, the Save button remains enabled until the user refreshes the page.	CHK-31568	5

## Document management

Description	Ticket	Severity
When file upload fails due to configuration or a detected virus, the file upload process fails, however, the document status is still updated.	CHK-2898	3

## Electronic signature

Description	Ticket	Severity
If a user is tagged to electronically sign a contract type document, but the user is not assigned to a business role with access to contracts, the user can't open the alert in Oracle Site Activate to complete the electronic signature process.	CHK-20210	3

## Milestones

Description	Ticket	Severity
The icon that indicates that a milestone is at risk does not display.	CHK-7855	3



## Site experience

Description	Ticket	Severity
If a site user replies to an alert email and does not include an attachment, and an Oracle Site Activate user accepts the item within the quarantine area, no activities are completed and the status icon erroneously shows an in progress icon.	CHK-11105	

## Study library

Description	Ticket	Severity
When study library document versions are created in quick succession, documents may cross over into different versions of country level placeholders in lineage.	CHK-5985	3

## Submissions

Description	Ticket	Severity
If a reason is provided, user can only see 1000 of the potentially 3000 characters of the reason.	CHK-3230	3
When adding a new package to a submission, additional sites selected in planning do not have the initial submit dates from the first package or any Final Approval baseline and planned dates that have been specified.	CHK-16825	3

## Team member assignments

Description	Ticket	Severity
Users who do not have study or department administrator system roles can access the Team member and roles assignment page.	CHK-4325	3
Study level assignments only show when you select "For my role" on the home page.	CHK-7925	2

## User interface

Description	Ticket	Severity
When viewing a contract expiration date, the date selection icon is not properly aligned if the browser zoom level is set to any value other than 100%.	CHK-21874	3

# 3

## 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.

# 4

## 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	24.1	Google Chrome and Microsoft Edge (Chromium)	None
Site Experience and Oracle Site Activate LITE	24.1	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

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## Post-upgrade refresh

You may need to complete a hard refresh after upgrade to 24.1 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



### Note:

Please note that Safari is not an Oracle tested browser.

# 6

## 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 24.1.

Date	Part number	Description
15Aug2024	F95246-03	Added 24.1.1 minor release
02May2024	F95246-02	General Availability Release Notes
12Apr2024	F95246-01	Pre-General Availability Release Notes