

# Oracle Life Sciences Site Activate

## Release Notes



Release 25.1

G24881-02

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Oracle Life Sciences Site Activate Release Notes, Release 25.1

G24881-02

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# 1

## What's new

With release 25.1, Oracle Site Activate introduces feature, user interface, and navigation enhancements that improve user experience and conform to Oracle design standards. We've described the improvements in the feature area descriptions in these release notes.

### Global improvements

In this release, you'll see significant user experience enhancements that improve navigation and simplify your work.

#### Release 25.1 overview

Release 25.1 introduces enhancements that align with Oracle design standards, including a modern color palette, updated fonts, new icons, and improved input controls. These updates create a more consistent, intuitive, and visually appealing user experience and align Oracle Site Activate with other Oracle products. In addition, we made the following application-wide improvements and updates:

- Vertical global navigation at the left side of your screen replaces the former top menu design. See details of this enhancement in the [Global and user badge navigation](#) section.
- Tables now use a progressive loading design and rows will load as you scroll down to the bottom. See the [Tables and item selection](#) section for additional details.
- All pages show the current view in the browser tab (for example, "Activate – Study home"). See details of this enhancement in the [Page titles](#) section.
- Contracts, Documents, Submissions, and IP release packages have a new full-screen artifact drawer design that replaces the previous modals. The drawers provide familiar functionality with improved navigation. See details of this enhancement in the [Artifact drawers](#) section.
- Minor text updates (e.g., changing the label on the "Submission dates" tabs to "Submissions") improve the user interface but do not change functionality.
- Minor navigation updates include relocating table legends and some input fields where necessary. These minor design element changes did not remove functionality.
- Enhanced accessibility powered by Oracle JET (OJET) ensures consistent design principles, making navigation intuitive and layouts predictable. OJET provides comprehensive keyboard navigation on every page and improved color contrast, resulting in greater readability and a more inclusive user experience.

**Note**

These release notes highlight key updates, including improved navigation, new features, and redesigned pages; however, they do not provide a comprehensive list of every change. Some updates in this release altered the appearance of certain features (such as colors, fonts, or icons) without changing their functionality. Visual-only changes are not included here, but remaining functional changes and new enhancements are described in detail in the sections that follow.

**Global and user badge navigation menus**

With release 25.1, vertical global navigation replaces the previous top header navigation. Now, at the top left of any page, click menu  to expand a list of navigational links to Oracle Site Activate and Oracle eTMF functional areas (TMF is available in the menu only if Oracle eTMF has been licensed by your organization). When you sign into Oracle Site Activate, the Study home page displays by default, as it did previously.

Navigation options in the left menu reflect your Oracle Site Activate business role permissions. For example, the Event Messages option in the menu's Oracle Site Activate section will be available only if you have been granted business role permission to manage Event Messages. Also, when unreviewed files are available in the Quarantined Files area, the global menu icon as well as the expandable More section and the Quarantined Files sections will update to display an attention  icon.

When expanded to include all available options, the global navigation menu will be organized as follows:

**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
- View Tasks for All Studies

**Activate**

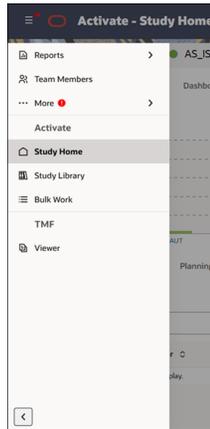
- Study Home
- Study Library

- Bulk Work

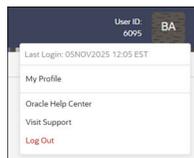
## TMF

- Viewer

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



We also made minor updates to the user menu at the upper right of each page. We removed the "Hi, <username>" text and replaced it with a badge showing your initials (or your full name if this option is enabled for your organization's account). Click the badge to access links to your user profile, the Oracle Help Center, Support, etc. Note that now you'll also find the Log Out option in the user badge menu.



## Page titles and browser tabs

We improved navigation in this release with updated page titles and matching browser tab titles. Browser tab text is dependent upon your organization's licensing and use of Oracle Site Activate and Oracle eTMF.

### Oracle Site Activate + Oracle eTMF

- Study, country, and site homepages have explicit titles with a matching tab titles:
  - Activate - Study Home
  - Activate - Country Home
  - Activate - Site Home
- Oracle eTMF pages (i.e., TMF Viewer) uses "TMF" as the prefix with a matching tab title

### Oracle Site Activate only

Browser tabs for the study, country, and site home pages and major functional areas (e.g., Team Members, Study Library, Bulk work) have explicit page and tab titles with the "Activate -"

prefix before the page name. By design, other functional areas (e.g., Quarantine, Submission Details, Event Messages, etc.) show the page name in the browser tab, but don't include the "Activate -" prefix.



## Global search

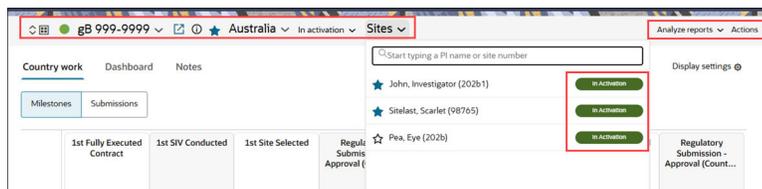
In addition to styling updates for Global search, release 25.1 includes a minor functional update. Now, instead of the search field displaying by default, you'll click search  next to the page title to expand the search field. Enter two or more leading characters to begin your search.



## Study Country Site navigation and controls

With release 25.1, you'll see familiar navigation and other information in the persistent study, country, and site navigation bar. For instance, you'll see the Accounts icon, drop-down selectors, the favorite icon, Actions drop-down, etc. We made a minor styling update to Study, country, and site text so that it is now more prominent. You'll also see new status badges in the country and site drop-downs.

The Analyze reports drop-down and the Actions drop-down have a minor functional change; these links now open when you click, rather than on hover.



## Tables and item selection

### Progressive loading

With the design updates introduced in this release, tables now use progressive loading to fill the available space on initial display and then load additional rows as you scroll down. Most tables feature a pulse loading animation. Pagination is no longer supported, so the forward, back, and page count controls have been removed.

### Selected rows

When you select a table row, it appears with a blue background. If you use the "select all" check box at the table's upper left, all visible rows are selected, and as you scroll down, the item count automatically updates to include each new row, which is selected by default. Select all mode will be disabled if you initiate a search or sort which refreshes the table.

### Show/clear selected

Previously, selecting items in some tables created a subset table above the main table. Subset tables are no longer supported. Instead, tables in the following areas now include “Show only selected” and “Clear selection” controls:

- Home page (Planning > Milestones and Submissions tabs)
- Bulk work (Activities, Items, and Planning tabs)
- Team members (Roles tab)

The screenshot shows the Oracle Roles management interface. At the top, there are tabs for 'Roles' and 'Business Partners'. Below the tabs, there is a section for 'Apply roles to the 3 selected users.' with a 'Select Roles' dropdown and an 'Apply roles' button. Below that, there are filters for 'User Type', 'User Status', 'Business Partner', and 'Roles Displayed'. A search bar is also present. The main table displays a list of users with columns for 'User name', 'Roles', 'Admin', 'Admin: All', '2222', 'Activate eTMF', and 'access unblinded'. Three users are selected, indicated by checkboxes in the first column. A red box highlights the 'Show only selected' toggle and 'Clear Selection' button.

	User name	Roles	Admin	Admin: All	2222	Activate eTMF	access unblinded
<input checked="" type="checkbox"/>	1742 Tester yesd@ake1magnitest.com	18	✓	⊖	✓	⊖	⊖
<input checked="" type="checkbox"/>	172005AB Testing_update 172005ab@test.com	17	✓	⊖	⊖	✓	✓
<input checked="" type="checkbox"/>	555 555 salresign555@oracle.com	16	⊖	✓	✓	⊖	⊖

## API integration

The Artifact Attachment APIs support two new attributes, Event Messages Retry PUT includes new time ranges, and Phlex eTMF integration has multiple enhancements.

### Artifacts Attachment API

You can now include `document_date` and a new `complete_open_activity` attribute in the Artifacts Attachment POST and PUT APIs, with `complete_open_activity` defaulting to false. When the attribute is set to true: if the artifact has only one activity, the artifact lifecycle completes; if there are multiple activities, only the open or current activity is completed, and the artifact progresses to the next activity as usual.

The API will return error messages if the open activity has a decision option, is the final activity and is missing required fields, or if the activity does not accept uploads. These rules make it easier for you to update artifact status through the API while ensuring key requirements are met.

### Event messages

Event Messages Retry PUT now includes two additional time ranges: `twoWeeks` and `month`.

### Manage publish endpoints

The 25.1 release enhances several fields on the Manage publish endpoints page to align user interface character restrictions with database character limits. This change affects the maximum allowed characters for following fields:

- **Token:** Limit increased from 128 to 256 characters
- **custom\_token\_name:** Limit increased from 128 to 256 characters
- **Username:** Limit decreased from 128 to 64 characters

- **auth\_url**: Limit increased from 128 to 1024 characters
- **auth\_type**: Limit decreased from 128 to 32 characters
- **auth\_domain**: Limit decreased from 128 to 32 characters
- **auth\_exp\_freq**: Limit increased from 128 to 1024 characters
- **base\_url**: Limit increased from 128 to 1024 characters
- **study\_sites\_url**: Limit increased from 128 to 1024 characters
- **staff\_url**: Limit increased from 128 to 1024 characters
- **get\_exp\_freq**: Limit increased from 128 to 1024 characters
- **site\_pi\_connector**: Limit decreased from 128 to 1 character
- **default\_transmitter\_email**: Limit increased from 128 to 512 characters
- **url**: Limit increased from 128 to 1024 characters

### eTMF Publish messages

Any customers currently using effective date in eTMF publish messages (actually populated by expiry date) should update their integrations. There will now be an expiry date (all documents) and an effective date (applicable contracts only) in eTMF publish messages.

### Phlex eTMF integration - Configuration

#### 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.

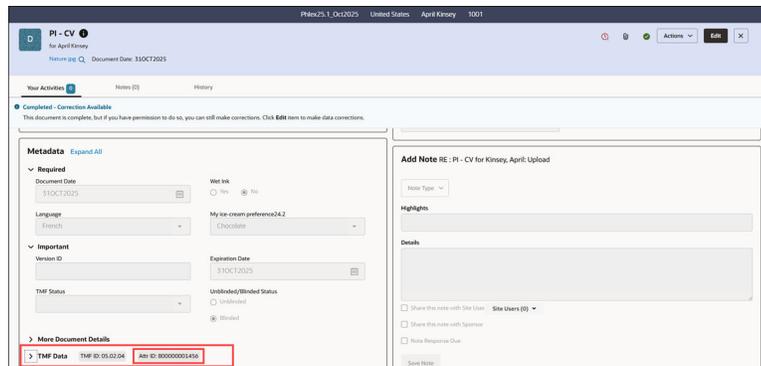
#### Note

Any customers currently using effective date in eTMF publish messages (actually populated by expiry date) should update their integrations. There will now be an expiry date (all documents) and an effective date (applicable contracts only) in eTMF publish messages.

### 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 item drawer will label the Attribute ID as “Attr ID” in the TMF Data section, and in the new Ad Hoc document page, the field is labeled “Attribute ID.” eTMF messages will include the Attribute ID field as `attribute_id`.



## Phlex eTMF Integration - Supported file types and languages

### 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.

#### **Note**

Oracle Site Activate allows upload of the following additional file types; however, they are not supported in Phlex eTMF integration: xlsx, gz, 7z, 7zip, bz2, rtf, txt, csv, tab, pps, pot, pptm, potx, potm, xlsx, 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

Language	Language code
French	fr
German	de
Hebrew	he
Hungarian	hu
Italian	it
Lithuanian	lt
Polish	pl
Slovak	sk
Spanish	es

### Phlex eTMF Integration - API enhancements

As part of this release, we made the following updates to 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

#### Note

For customers that want to include the Phlex IP Release attribute in eTMF messages, please talk to your Oracle team to enable this account level setting.

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.

## Artifact drawers

Artifact drawers replace modals and provide a more streamlined user experience.

### General artifact drawer enhancements

The new artifact drawers introduced in this 25.1 release replace legacy modals for Documents, Contracts, Submissions, and IP Release Packages. The General enhancements described below apply to all drawers, including Document drawers. Please review the [Contract drawer](#),

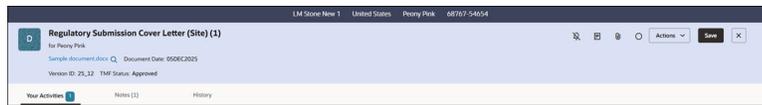
[Submission drawer](#), and [IP Release package drawer](#) sections in these release notes to learn about unique drawer functionality for those artifact types.

### Drawer header

The drawer's header shows a square avatar next to the artifact name to indicate the type (e.g., document "D," submission "S," contract "C," amendment "A," etc.). The header also includes the artifact's name, file name (if present), study, country, and site names when applicable. For site-level artifacts, the PI, site, or staff name displays just below the artifact name. When key metadata fields are set (e.g., version ID, protocol, category, type, reason, and TMF status), they also display in the header.

Lineage documents display the master document's version ID and a blue flag with the artifact name. The metadata for these documents appears in the same format as for standard artifacts.

Artifact icons display at the upper right and have descriptive tool tips. Icon order follows previous standards. Hover over the icons to view the descriptions. You'll also see Save and Edit buttons, as applicable, at the header's upper right.



### Tabbed and accordion organization

Artifact drawer tabs always show in this order: Your Activities, Notes, and History. The Your Activities and Notes tab labels are dynamic and show the count of available activities and the number of notes saved for the artifact.

The new drawer design separates Metadata (panel to the left) and activity-related actions (panel to the right). The Metadata panel includes collapsible accordion sections (e.g., Required, Important, More Document Detail, etc.). The accordions include the fields configured for that artifact (e.g., Version ID, Wet Ink, Expiration Date, TMF Status, etc.). When applicable to the artifact, additional accordion sections for "Documents Included In" and/or "Blocked Activities" display at the bottom of the drawer on the Your Activities tab.

### Your Activities tab

#### Activity train and navigation

At the top of the tab, an activity train shows all activities for the artifact.

- Completed activities have a green check mark and a completion date.
- Open activities are interactive, with the first open activity loading by default.
- Blocked activities are grayed out for you and aren't clickable, but you can view the train and completed activities/dates.

For completed artifacts, you still see the activity train, but the activity panel is not available in the drawer.

#### File handling and sharing

The File panel on the left lets you upload attachments via drag-and-drop or by using the attach button. If a file is attached, you'll see its name, a preview icon (if applicable; not all types can be previewed), and options to share with site users or sponsors, add electronic signature requests, and use a Replace button when relevant.

#### Activity panel and controls

On the right, you see the activity name, assigned user role, “Show Users” or “Assign to me” links, and the Complete button, which activates when all required fields are set. If you don't have the required user role to work on this activity, you'll see the message, “This item is blocked because you do not have the [RoleName] role.” In this case, you can edit the artifact's metadata if you have write permissions (i.e., your user role is not a read-only role).

Just above the Activity panel, you'll also see a toggle control to pause email alerts. When you enable the optional control, it will pause alerts for that specific activity, and you can schedule a preferred date when you want alerts to resume.

### Saving and alerts

You can save changes only after you make edits. Some fields, such as Completed Date and the artifact Decision Options (if configured), save only when the activity is completed. If you attempt to navigate away from the drawer and you have unsaved changes, you'll be prompted to save or discard them.

### Package detail and Blocked activities

At the bottom of the drawer, “Documents Included In” and “Blocked Activities” accordion sections provide quick access to package details, actionable dependencies, a display filter, and role-based guidance. These accordions are included only when applicable to the artifact.

### Special states: Completed, Discontinued, and Read-Only

For completed artifacts, you can view all metadata, files, activities, and notes; however, editing is possible only if you have correction permission. If you can correct, an Edit button replaces Save, letting you enter correction mode to update fields and save or cancel as needed. If your organization allows, you may add missing attachments to completed artifacts that are not in a completed or approved package.

When an artifact is discontinued, the drawer appears in read-only mode, shows a discontinued icon, and disables all activity actions. The Notes tab is still accessible, but it will prevent new entries.

Read-only users can view all content but cannot make any changes (e.g., add, edit, or save any metadata) or add notes.

The screenshot displays the Oracle artifact drawer for a Regulatory Submission Cover Letter (Site) [1]. The interface includes the following sections:

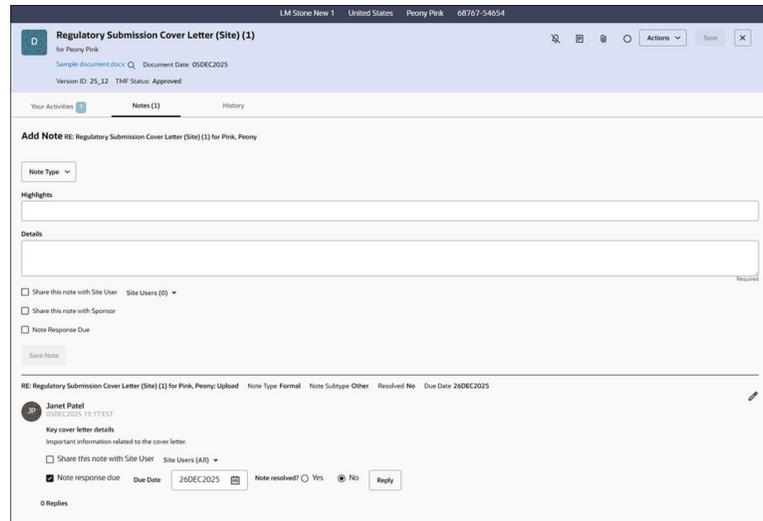
- File Upload:** A file named "Sample document.docx" is uploaded. Options include "Share this file with Sponsor", "Add Electronic Signature Request", and "Share this attachment with site".
- Metadata:**
  - Required:** Document Date: 05DEC2025. Web risk: Required.
  - Important:** Version ID: 25\_12. TMF Status: Approved.
  - More Document Details:** TMF Data: TMF ID: 05.01.01.
- Activities:** An "Upload" activity is shown with a "1 minute" duration. It includes a "Share email alerts for this item" toggle and a "Become email alerts on" field set to 05DEC2025. A "Complete" button is visible.
- Add Note:** A section for adding a note with fields for "Note Type", "Highlights", and "Details". Sharing options include "Share this note with Site User", "Share this note with Sponsor", and "Note Response Due".
- Blocked Activities:** A table listing activities that are blocked. The table has columns for Item, Contract Type, Activity, Level, Assignee, Actionable?, and Status.
 

Item	Contract Type	Activity	Level	Assignee	Actionable?	Status
Regulatory Submission Cover Letter [Site] [1]		Upload	Pink, Peony	Site Coordinator	Yes	○
Regulatory Submission Cover Letter [Site] [1]		Review	Pink, Peony	Regulatory Manager	No	○

## Notes tab

At the top of the Notes tab, you can add a new note that specifies note type, a [note subtype](#) (new in this release), highlight, content, optional response due date, and sharing options with sponsors. The note count in the tab label updates automatically as you or your team add additional notes for this artifact. Existing notes are listed at the bottom of the Notes tab. You can view existing notes and edit them if you have the required permission (e.g., adjust the note response due date, mark notes as resolved, and reply with comments or file attachments).

If an artifact is discontinued or you have read-only access, you may view notes but not add new ones.



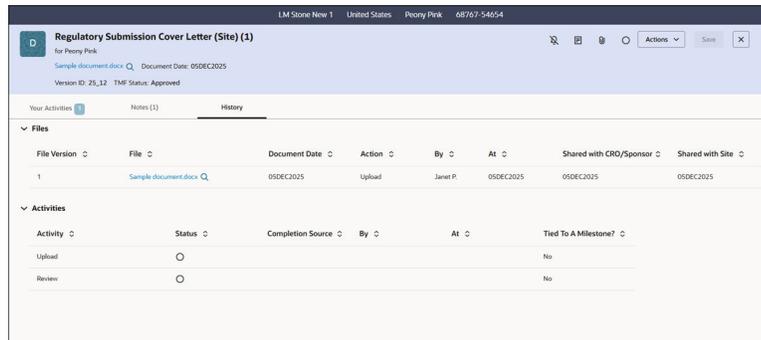
## History tab

The History tab can display the following three sections:

**Lineage:** If applicable, a Lineage section appears at the top of the tab, displaying lineage details such as the master document, master file, document date, version ID, status, and description.

**Files:** All file versions related to the artifact are shown. Details include file name, preview link, document date, action taken, user who performed the action, time of action, and sharing information for CRO, sponsors, or sites.

**Activities:** The Activities section records the complete activity history, including the activity name, status, completion source, user, time, and relationship to milestones. With the appropriate user role permission, you can edit the completion date for any activity not tied to a milestone by using a correction dialog to update the date and record the reason.



## Bulk work

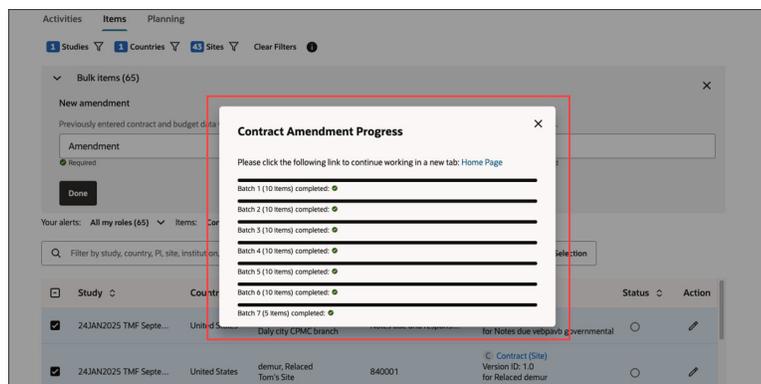
This release introduces a new drawer layout for contract artifacts.

### Batch amendment processing

When you select "Add amendments for all contracts in a country," the Bulk Work page opens pre-filtered to the relevant country, displaying Contracts and Items that can be amended, with all items selected by default. This is previously existing functionality designed to streamline your workflow and save time.

With enhancements in this release, the list now uses progressive loading, so you can scroll to access additional contracts as needed and include them in the group requiring the amendment.

A new modal will display after you complete the New amendment fields and click Done. The modal displays processing in batches of up to 10 items, and you'll see each batch marked as Done when completed. You cannot close the modal until all batches are finished, but the modal includes a Home Page link that lets you continue working in a new tab if preferred.



## Contract management

This release introduces a new drawer layout for contract artifacts.

### Contract artifact drawers

### Contract drawer layout and navigation

When you open the artifact drawer for contracts, a button set shows below the contract name in the artifact header, which makes it easy to navigate directly to available budget and contract language artifacts under the main contract. Each button shows the subcontract name, its version number when applicable, the open activities count, and the current subcontract status.



## Metadata and activity panels

Within the Metadata panel on the drawer's left side, you'll find general details like the document description and version ID at the top, followed by contract-specific metadata. Some fields, such as contract type, may be set as required according to customer preference. These fields are prominently displayed under Metadata details, and for the final activity, required fields move to the Required section to ensure accuracy when the artifact is finalized.

A Tracking Dates section will be included in the Metadata panel whenever scheduled activities are present. It provides fields for baseline, planned, and actual dates and remains visible regardless of which activity is currently open. Completed artifacts lock these fields unless you have correction permission.

The activity panel on the right side of the drawer contains the activity-specific metadata and attributes, including the activity name and age, assigned role, and a link to assign the activity to yourself. The activity panel also includes a Completed date field and the Complete button.

## Amendment management

When you work with amendment artifacts, you'll see the artifact title and button name based on the defined artifact configuration (e.g., "Amendment," "Budget Amendment," etc.). Relevant metadata sections, such as "More Amendment Details," "More Budget Amendment Details," or "More Contract Language Amendment Details," appear depending on the contract type. Only one of these amendment metadata sections is displayed for each artifact.

## Contract and subcontract actions

You can click the Actions button in the artifact header to: discontinue or reinstate a contract or its subcontracts, put items on hold, terminate them, add a new budget when enabled, or create a new amendment. Actions available to you are the same actions available in the legacy contract modals and they depend upon you having the appropriate user role permission and the artifact's configuration.

The screenshot displays the Oracle Clinical Budget (Site) interface. The main content area is titled 'Template Upload' and includes a 'Drag and Drop' section for file uploads. Below this, there are several form sections:

- Metadata:** Includes fields for Version ID (22), TMF Status (Approved), and a 'Required' checkbox.
- More Budget Details:** Contains various financial and operational fields such as Artifact ID (742314), Category (Contract and Budgets\_Site), Hubback Percentage, Per Subject Cost, Per Subject Cost Deviation, Allocated Number of Patients, Total One Time Up Front Fees, Institutional Overhead, Patient Stipend?, Patient Stipend Amount, Negotiation is complete?, Currency, and Total One Time Up Front Fee Breakdown.
- Tracking Dates:** Includes fields for Baseline Date, Planned Date, and Actual Date.
- Document Included in:** A table with columns for Package, Protocol Version, Type, and Category.

On the right side, there is a 'Template Upload' summary card showing '57 days' remaining and a 'Complete' button. Below it is an 'Add Note' section with a dropdown for 'Note Type', a 'Highlights' field, a 'Details' field, and checkboxes for sharing the note with Site Users and Site Users (S). A 'Save Note' button is at the bottom.

## Infrastructure

A new internal table captures user and activity data for downloads and exports.

### Export data

With release 25.1, we added new internal table that captures who initiated an export and when. We now capture the following export actions:

- Submission/IP Package: Export to Zip
- Country, or Site: Export completed documents

For each export, we can provide the following data if needed:

- Date and time the export was initiated
- Study ID
- Country ID
- Site ID
- Artifact ID
- User email
- Items included in the export
- Action type (download or export)

# IP release package

This release introduces a new drawer layout for IP release packages.

## IP release package drawers

### IP review package header and activities

When you access the artifact drawer for an IP package, you'll see the activity train at the top of the Your Activities tab shows the activities applicable to the artifact, and it updates as the package progresses from compile, to review, to approval.



### Compile package activity flow

If the open activity is Compile Package and you have the appropriate user permission, click the "Plan package" button in the Metadata panel. You can select documents to include in the package using the package planning wizard; all previously available package compiling functionality remains. With release 25.1 you'll see new columns we added in the PI/Site Documents tab for PI (lastname, firstname) and Site number.

### Review Package activity and initial review management

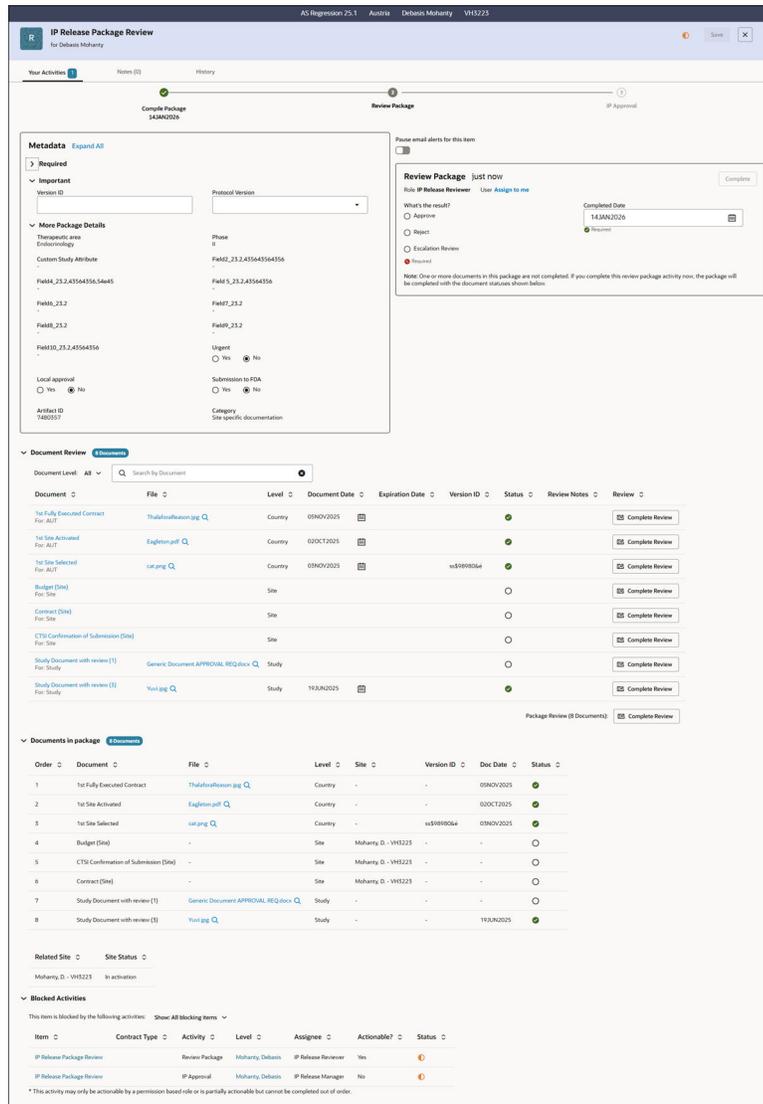
When the Review Package activity is open, you may edit all relevant metadata, preview or download files, open artifact drawers for included documents, and make review decisions on both documents and the package. Additional features include the ability to add or view dependency notes and manage expiration dates, if these settings are enabled for your account. Completion of the review activity moves the workflow forward to the next stage.

### Manage rejected packages and corrections

If the initial IP package is rejected, the artifact drawer opens a new Compile Package activity. You need to confirm corrections for all rejected documents before completing compilation. The Document Review section switches to Document Correction, displaying only those documents that still need attention. Marking documents or the package as corrected updates their status, and you can add or review notes for each item. The Edit IP Package button allows you to manage package contents in real time, reflecting document status and counts, and tracking new or removed items. Once you complete compilation, all documents become visible in the Review Package section for further evaluation.

### Track document corrections and approvals

Within subsequent review cycles, you'll see each document's review and approval state, and you'll use Edit and Complete Review controls. The drawer always displays the number of documents included, helping you keep track as you update the package.



## Milestones

You can now easily adjust your view of the Milestones Timeline chart for better visibility and navigation using new zoom and scroll controls.

### Milestones Timeline

When you view the Milestones Timeline chart on Account overview and home page > Dashboard you can now use a control at the upper right to zoom in or out as needed. To adjust the chart zoom to your preferred level, hover over the Timeline chart to display the control, and click the plus button to zoom in or the minus button to zoom out. When you zoom out, you can use the horizontal scroll bar below the chart to move the timeline left or right for easier navigation.



## Notes

Notes now indicate the study, country, and site as applicable; you can now save a note sub-type if enabled for your account; and notes now have a reportable Resolved at field.

### Note for Study, Country, Site

Now when you click the Notes tab on the study, country, or site home page, the top of the note shows what it is in regards to. Following the Add note title, the "Re:" text specifies the study, country, and site information depending where you launched the note from. The text follows this format:

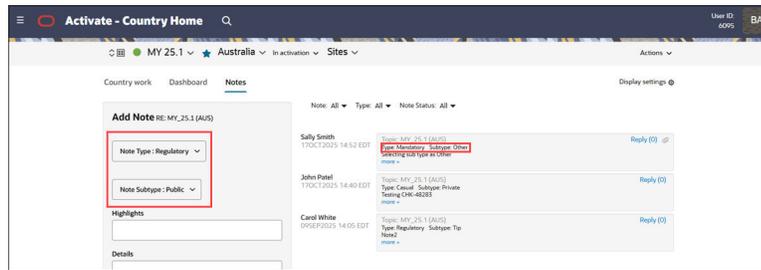
- Study home: "Re: <study name>"
- Country home: "Re: <study name> (<countrycode>)"
- Site home: "Re: <study name> (<countrycode>, <sitenum>)"

### Note sub-type

Now, when you choose a Note Type, you can also specify a Note Subtype if this option is enabled and configured for your organization's account. When multiple Note Types share a similar theme, a subtype field can give you a more detailed way to categorize notes, making it easier to organize and search within the system.

Note Types can include "Other" as a selectable value if your organization enables this option. By design, the "Other" option does not provide a free text field.

When you view a note with a saved Subtype value, it will be listed to the right of the note Type.



### 📘 Note

Please contact your Oracle services representative to discuss enabling Note Subtypes for your account.

### Resolved at

When you mark a note as resolved by changing the “Note resolved” setting from No to Yes and saving it, Oracle Site Activate now records the time in a new “resolved\_at” field. If you change the setting back from Yes to No, the “resolved\_at” field is cleared. This field is blank by default and only gets filled in when you first resolve the note.

The Data Export Utility Study Level Notes cube also now has a “Resolved at” column. If you have permission to access the utility, you can include the column in a report to review the timestamp for when each note was marked as resolved.

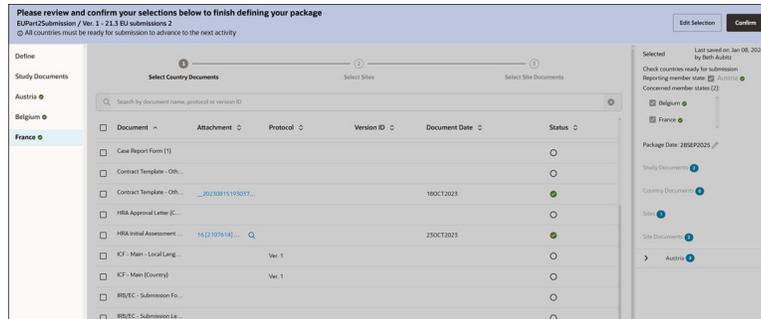
## Package planning

EU submission and IP package planning wizards allow you to use left navigation tabs on the Confirm step.

### EU submission package and IP package planning

With this release, we updated left side navigation for the EU submission package and IP package planning wizards so that the tabs are enabled on the Confirm screen. This enhancement allows you to access the tabs and view selections in read-only mode. If necessary, click Edit Selection to return to edit mode and adjust the selected documents.

Depending upon your choice to enter back into the Edit mode, actions buttons displayed at the upper right will be in the following order: Cancel, Save, Back Continue, Done. Note that the Submission validation package does not have the Continue button, as the process ends at the Study Documents step. Additionally, an IP Package will have the following buttons: Cancel, Back, Continue OR Done.

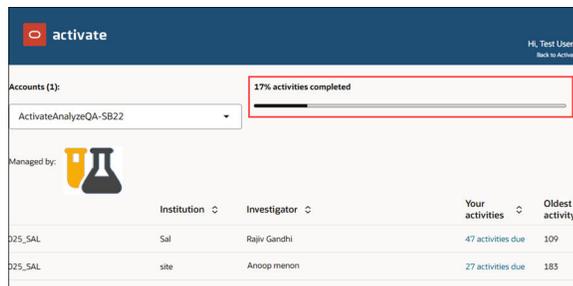


## Site experience

This release includes minor styling updates, a horizontal percentage completion bar that replaces a legacy pie chart, and a new counter for notes saved on Submission Activities.

### Site experience

Site users who have enabled the option to link their accounts under one login will see minor styling updates on the activities landing page in this release. For instance, the page previously had a pie chart above the activities table that showed completion progress. Now the page shows progress in an activities completed bar that shows the percentage (e.g., "17% activities completed"). All previously available functionality and data shown in the activities table is still available.



Additionally, when viewing Submission Activities, the "View all notes for this submission" now includes a count to show the number of saved notes.

# Study management

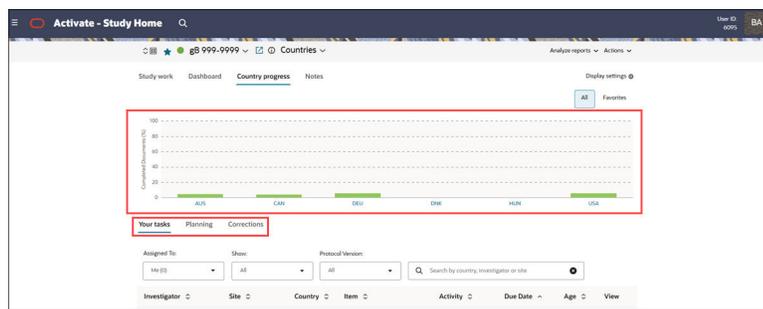
The Your tasks | Planning | Corrections sub-tabs now display only on the Dashboard and Country Progress pages and the Country Progress chart has usability improvements.

## Study home page

Previously, the Your tasks | Planning | Corrections sub-tabs appeared on every Study home page main tab (i.e., on the Study work, Dashboard, Country Progress, and Notes pages). To make navigation clearer and reduce unnecessary controls, we removed the Your tasks | Planning | Corrections tabs from Study Work and Notes pages and they display only on the Dashboard and Country Progress pages.

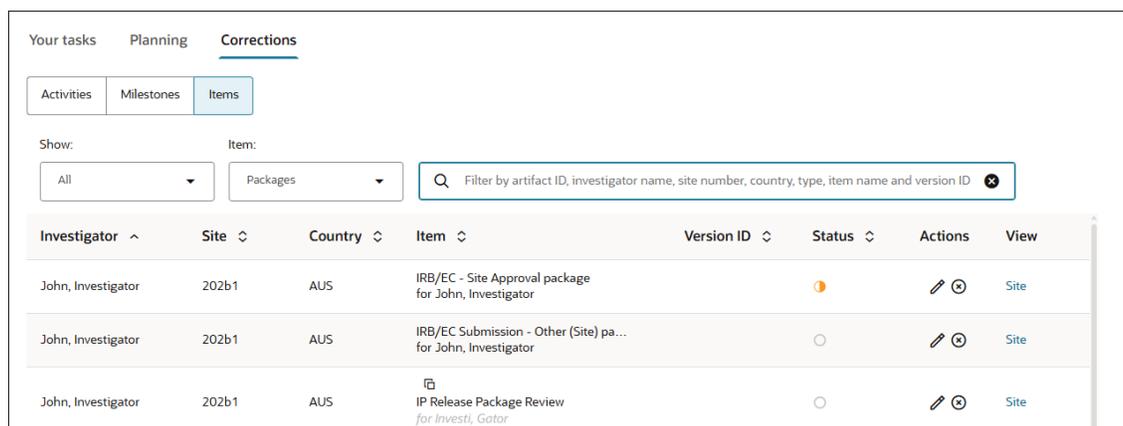
On the Country Progress tab, you'll also see the following usability improvements to the bar chart:

- The chart now displays completion in 20% increments
- The y-axis (vertical) has a new “Completed Documents (%)” label
- Country codes shown below each bar are now styled as clickable links



## Artifact ID search in Corrections

Now you can search by Artifact ID on the study home page Corrections > Activities and Items subtabs. This enhancement makes it easier to locate and resolve issues related to specific Artifact IDs shared by other teams or systems. We've also updated the helper text in the Items tab search field to indicate that you can search by Artifact ID.



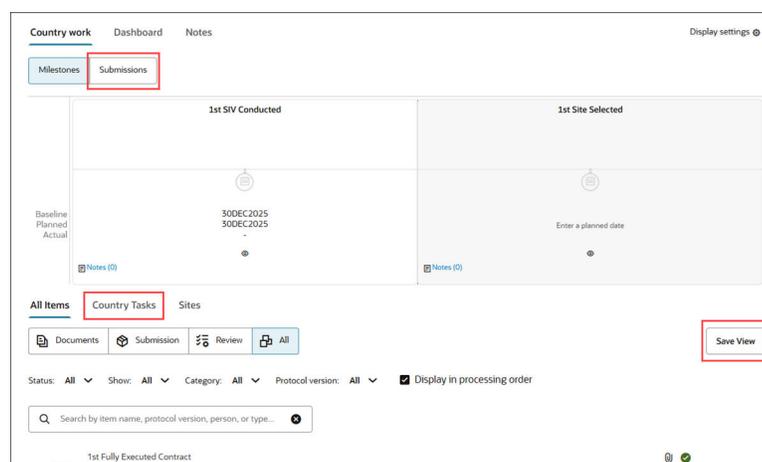
## Study country management

Updated tab and button labels align the study country home page with the study and site home pages.

### Study countries

On the Study country home page, we made minor text changes to align with updates on the Study home and Site home pages:

- On the Country work tab, the Submission dates sub-tab is now labeled Submissions
- The former Your activities tab is now labeled Country Tasks
- The Save Filters button is now labeled Save View

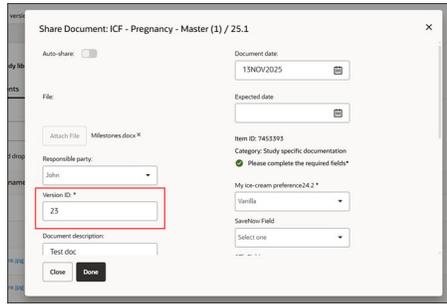


## Study library

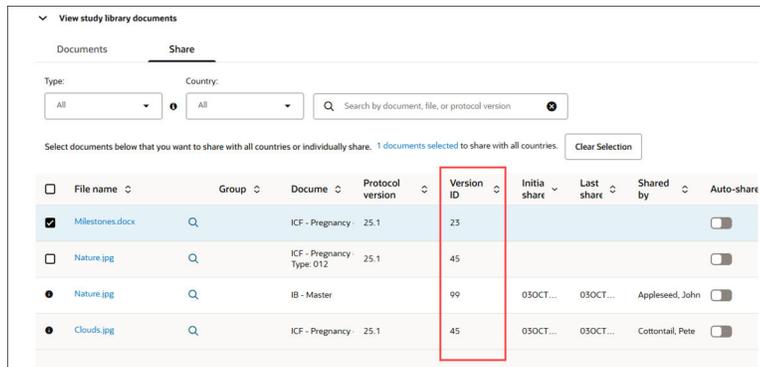
The document edit modal now requires the Version ID field for configured items, and the Share details tab has a new Version ID column.

### Required Version ID

The document edit modal will now require you to populate the Version ID field when "Require version ID for item completion" is configured for the item. When you create the item in the Study library, the Version ID field label has an asterisk to indicate it is required. Provided all other required fields in the modal have been populated, entering a Version ID enables the modal's Done button, allowing you to complete the process.

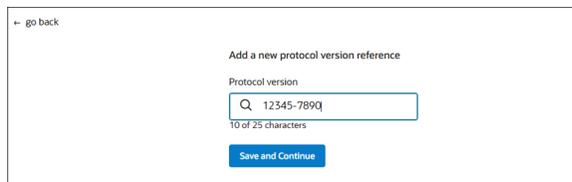


With this enhancement, we also added the Version ID column to the Share details tab.



### Add/Edit Protocol version

Now when you add or edit a protocol version from the Study library, you'll see a new character counter below the Protocol version field to help you stay within the 25-character limit. If you enter more than 26 characters, the counter below the field changes to red text and the Save and Continue button will be disabled until you reduce the text to 25 characters or below.



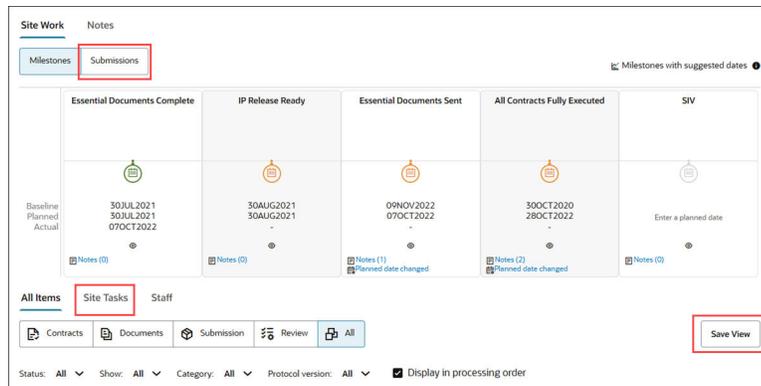
## Study site management

On the Site home page, tab and button labels have been updated for consistency.

### Study sites home

On the Site home page, we made minor text changes to align with updates on the Study home and Country home pages:

- On the Site work tab, the Submission dates sub-tab is now labeled Submissions
- The former Your activities tab is now labeled Site Tasks
- The Save Filters button is now labeled Save View



## Submissions

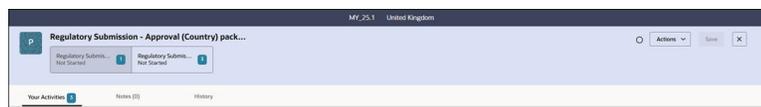
A new drawer layout for submissions activities replaces the previous modal design, and the IRB/EC/RA Name drop-down display of both the Agency name and ID if this option is enabled for your account.

### Submission artifact drawers

#### Submission drawer layout

For submission artifacts, the drawer includes a button set just below the submission name to provide easy navigation between available packages, custom-named packages, or the overall Submission Package. Each button provides the package name, current version (if applicable), the number of open activities, and artifact status to indicate progress and outstanding work. Study and EU Submission Packages also show the Protocol, Category, and Type values just below the button set when these values are known. At the far right, you'll also see the artifact status icon, Actions drop-down, and the Save and Close options. The Save button will enable only after you've made changes to the drawer.

When you have the correct role permissions, you may add either a submission package or a subcommittee package directly from the drawer, streamlining workflow for complex multi-package submissions. These options are available in the drawer's Actions menu as they were previously.



### Metadata fields

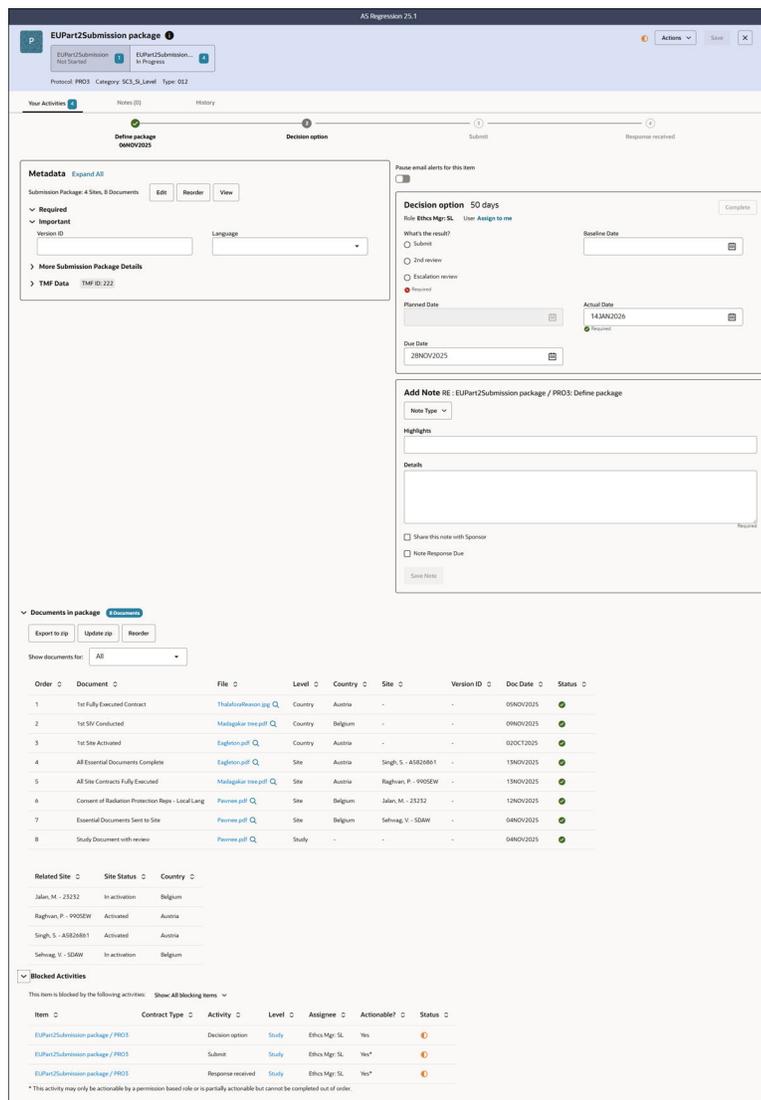
On the Your Activities tab, the Metadata panel on the left side of the drawer uses accordion sections, which you can expand or hide individually or use the "Expand All" or "Collapse All" controls. For country submissions, the top of the panel highlights the number of sites and countries approved from the submission. The "More Submission Details" section captures descriptive metadata not covered elsewhere, and the "Submission Dates" area lets you set both the initial submission and final approval dates.

The right side of the submission drawer presents all activity-specific metadata, including details like activity name, age, role, links to assign yourself, and the Complete button. If your

organization has enabled settings for additional timeline information, you'll also see baseline, planned, and completed dates in the activity section.

### Submission package view

For each submission package, the Metadata panel describes the count of sites and documents included. During an open compile package activity, this is displayed as "Submission Package: 0 Sites, 0 Documents." When the activity is complete, the description updates to show the actual count and to offer actions such as Edit, Reorder, or View. Click View to jump to the lower section of the drawer where you can access additional accordion sections. The "Documents in Package" section, when expanded, presents sortable tables for both documents and related sites, along with options to export or update the package as a zip file. If you select a country, it will exclude study level documents. Show documents for All to include study level documents. You can reorder documents using drag-and-drop tools; the interface enables Save and Cancel controls that respond to your changes in order.



### Study and EU Submissions management

For study and EU submissions, you have granular control over approval selection. At the country level, you can select approved countries and designate one country as the Reporting Member state. At the site level, you may select approved sites within each country and edit

those selections as necessary. Any update to the country or site selection, or reporting member state, enables the Save button. You'll be prompted to save or discard changes if you attempt to exit the drawer without saving.

**EUValidationSubmission** SampleStudy1

EUValidationSubm. Not Started | EUValidationSubm. In Progress

Protocol: Gaskara Category: CAT2 Type: dev

Your Activities | Notes (0) | History

**Approval Complete**

Drag and Drop: Select or drop file here

Metadata: Expand All

▼ Countries Approved from this Submission (3 Countries Selected)

Reporting Member	Country	Country Status
<input checked="" type="checkbox"/>	Belgium	In activation
<input checked="" type="checkbox"/>	Denmark	In activation
<input type="checkbox"/>	Italy	In activation
<input checked="" type="checkbox"/>	Austria	In activation
<input type="checkbox"/>	France	In activation

Required

Type: dev | Category: CAT2

IRB/EC/RA Name: | Expiration Date: |

Important

Version ID: |

More Submission Details

Submission Dates

TMF Data: TMF ID: 44

Blocked Activities

Item	Contract Type	Activity	Level	Assignee	Actionable?	Status
EUValidationSubmission / Gaskara	Approval Complete	Study	Document Manager	Yes*	<input type="radio"/>	
EUValidationSubmission package / Gaskara	Submit	Study	Ethics Mgr. SL	Yes*	<input type="radio"/>	

\* This activity may only be actionable by a permission based role or is partially actionable but cannot be completed out of order.

Approval Complete 28 days

Role: Document Manager | User: Assign to me

Baseline Date: | Planned Date: |

Actual Date: |

Add Note RE: EUValidationSubmission / Gaskara: Approval Complete

Note Type: |

Highlights: |

Details: |

Share this note with Sponsor

Note Response Due

Save Note

For EU Submissions, when the submission approval activity has been completed, you can still access the drawer to take limited actions on the Your Activities tab:

- Discontinue this version using the option in the Actions drop-down
- Drag and drop a file attachment
- Make Initial and/or Final approval dates visible on the activity calendar (eye icon)

Additionally, you can add a note on the Notes tab.

**EUValidationSubmission** AS-Regression\_25.1

EUValidationSubm. Completed | EUValidationSubm. Completed

Protocol: PRD5 Category: CAT3 Type: LM Study level

Your Activities | Notes (0) | History

**Approval Complete**

Drag and Drop: Forget attachments? Select or drag file here

Metadata: Expand All

▼ Countries Approved from this Submission (3 Countries Selected)

Reporting Member	Country	Country Status
<input type="checkbox"/>	Belgium	In activation
<input type="checkbox"/>	Austria	In activation
<input type="checkbox"/>	France	Submitted

Required

Type: LM Study level | Category: CAT 3

IRB/EC/RA Name: MAL-E-SHPY16112232 (ED: LENA5) | Expiration Date: 14JAN2026 |

Important

Version ID: |

More Submission Details

Submission Dates

TMF Data: TMF ID: 44

Approval Complete 08/04/2024

Role: Anyone | User: None

Baseline Date: | Planned Date: |

Actual Date: 14JAN2026 |

Add Note RE: EUValidationSubmission / PRD5: Approval Complete

Note Type: |

Highlights: |

Details: |

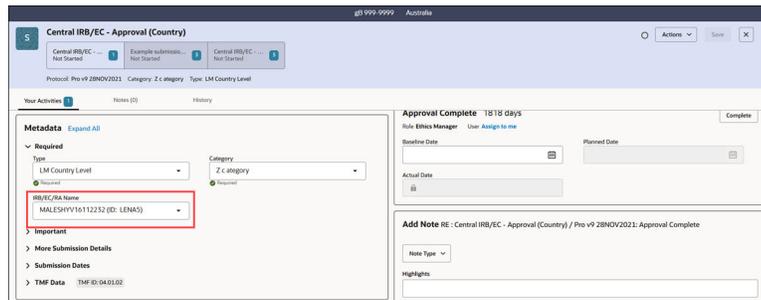
Share this note with Sponsor

Note Response Due

Save Note

## Submission Agency and ID

To make it easier to find the correct agency when managing submission items, we enhanced the IRB/EC/RA Name drop-down list to support display of both the Agency name and ID. When this feature is enabled for your organization's account, you'll see the agency name and the corresponding ID in the following format: Agency Name (ID: <AgencyID>).



## User interface

Now the list of languages displayed in Oracle Site Activate can be tailored to your organization's requirements and Version ID fields show character counts.

### Displayed languages

With this release, we made an infrastructure improvement that provides greater control over languages displayed in Oracle Site Activate. This update allows for hiding unused languages so only those designated as “active” will appear or be available for selection in the user interface.

#### **Note**

Please contact your Oracle services representative to discuss requirements for showing and hiding languages in your account.

### Version ID field character count

For artifacts at the country and site levels, we added character counters to Version ID fields. As you type in the Version ID field, the counter updates in real time; you can enter up to 255 characters if needed. This enhancement gives you clear visibility into total character counts to help you avoid issues when sending data to external systems with character limits.

**Metadata** [Expand All](#)

Submission Package: 4 Sites, 222 Documents Edit Reorder View

▼ **Required**

▼ **Important**

Version ID

12345

5 of 255 characters

> **More Submission Package Details**

> **TMF Data** TMF ID: 02.02.03

## User profile

A new tool tip clarifies time zone usage for email alerts.

### My time zone

You'll now see a new info icon next to "My time zone" in the Email Content section of your profile page. When you hover over this icon, a tool tip appears explaining that your time zone is only used for sending email alerts. This enhancement helps clarify how your time zone setting is applied within the system.

**My Profile**

Email address  
testuser1@example.org

Settings for email reminders  
Receive email notifications about work that is due for me (Monday - Friday). > Roles assigned to me (41)

**Email Content\***

New alerts for me.  
Only email me when there are new alerts that were not previously sent to me.

Once a day  Twice a day  Every hour (9 am - 6 pm)

All alerts due for me.  
Email me when there are alerts that are currently assigned to me.

Once a day  Twice a day  Once a week

at 9 am

**My time zone** ⓘ

(GMT-05) Timezone only used for sending email alerts

Set to my current time zone.

Done Cancel

# 2

## Impact analysis

A quick summary of the business and functional impact of enhancements included in the 25.1 release.

Enhancement	Enablement setting	Impact
Global improvements - <a href="#">Global and user badge navigation menus</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>	With release 25.1, vertical global navigation replaces the previous top header navigation.
Global improvements - <a href="#">Page titles and browser tabs</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 improved navigation in this release with updated page titles and matching browser tab titles.
Global improvements - <a href="#">Global 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>	For Global search, instead of the search field displaying by default, you'll click  next to the page title to expand the search field.
Global improvements - <a href="#">Study Country Site navigation and controls</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 made a minor styling update to Study, country, and site text so that it is now more prominent. You'll also see new status badges in the country and site drop-downs.
Global improvements - <a href="#">Tables and item selection</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>	With the design updates introduced in this release, tables now use progressive loading to fill the available space on initial display and then load additional rows as you scroll down.
API integration - <a href="#">Artifacts Attachment API</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>	N/A
API integration - <a href="#">Event messages</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>	N/A

Enhancement	Enablement setting	Impact
API integration - <a href="#">Manage publish endpoints</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>	N/A
API integration - <a href="#">eTMF Publish messages</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>	N/A
API integration - <a href="#">Phlex eTMF integration: Configuration</a>	<ul style="list-style-type: none"> <li>• Feature flip: N</li> <li>• Config related: Y</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: N</li> </ul>	We made updates in Oracle Site Activate to support our Oracle Site Activate-Phlex eTMF integration.
API integration - <a href="#">Phlex eTMF integration: Supported file types and languages</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>	N/A
API integration - <a href="#">Phlex eTMF integration: API enhancements</a>	<ul style="list-style-type: none"> <li>• Feature flip: Y</li> <li>• Config related: Y</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: Y "Enable IP Release attribute for Phlex eTMF integration messages" (specific feature flip for eTMF message including the phlex_requires_iprelease)</li> </ul>	We made the updates to eTMF messages to support our Activate-Phlex eTMF integration. They are visible when an endpoint has vendor = Phlex.
Artifact drawers - <a href="#">Artifact drawer</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 new artifact drawers introduced in this 25.1 release replace legacy modals for Documents, Contracts, Submissions, and IP Release Packages, to provide a more streamlined user experience.
Bulk work - <a href="#">Batch amendment processing</a>	<ul style="list-style-type: none"> <li>• Feature flip: N</li> <li>• Config related: Y</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: N</li> </ul>	Batch amendment processing now uses progressive loading for the item list.

Enhancement	Enablement setting	Impact
Contract management - <a href="#">Contract artifact drawers</a>	<ul style="list-style-type: none"> <li>• Feature flip: N</li> <li>• Config related: Y</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: N</li> </ul>	New drawer layout for contract artifacts.
Infrastructure - <a href="#">Export data</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>	A new internal table captures user and activity data for downloads and exports.
IP release package - <a href="#">IP release package drawers</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>	This release introduces a new drawer layout for IP release packages.
Milestones - <a href="#">Milestone timeline</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>	You can now easily adjust your view of the Milestones Timeline chart for better visibility and navigation using new zoom and scroll controls.
Notes - <a href="#">Note for Study, Country, Site</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>	Notes now indicate the study, country, and site as applicable.
Notes - <a href="#">Note subtype</a>	<ul style="list-style-type: none"> <li>• Feature flip: Y (Select note subtype when creating a note)</li> <li>• Config related: N</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: Y (Select note type when creating a note)</li> </ul>	You can now select a note subtype if enabled.
<a href="#">Notes - Resolved at</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>	Oracle Site Activate now records the time in a new "resolved_at" field, which also appears in the Data Export Utility Study Level Notes cube.
Package planning - <a href="#">EU submission package and IP package planning</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>	Planning wizard allows you to use left navigation on the confirm step of EU Submission and IP package.

Enhancement	Enablement setting	Impact
Site experience - <a href="#">Site experience</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>	Legacy pie chart is replaced with horizontal percentage completion bar.
Study management - <a href="#">Study home page</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 removed the Your tasks   Planning   Corrections tabs from Study Work and Notes pages and they display only on the Dashboard and Country Progress pages.
Study management - <a href="#">Artifact ID search in Corrections</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>	Now you can search by Artifact ID on the study home page Corrections > Activities and Items subtabs.
Study country management - <a href="#">Study countries</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>	Updated tab and button alignment.
Study library - <a href="#">Required Version ID</a>	<ul style="list-style-type: none"> <li>• Feature flip: N</li> <li>• Config related: Y</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: N</li> </ul>	The document edit modal in the Study library will now require you to populate the Version ID field when "Require version ID for item completion" is configured.
Study library - <a href="#">Add/Edit Protocol version</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>	A new character counter below the Protocol version field has been added.
Study site management - <a href="#">Study site home</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>	Updated tab and button alignment
Submissions - <a href="#">Submission artifact drawer</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>	A new drawer layout for submissions activities replaces the previous modal design.

Enhancement	Enablement setting	Impact
Submissions - <a href="#">Submission Agency ID</a>	<ul style="list-style-type: none"> <li>• Feature flip: Y (Enable Agency ID in IRB/EC/RA name drop-down on submissions)</li> <li>• Config related: N</li> <li>• All studies: Y</li> <li>• New role permission required: N</li> <li>• Dependent feature: Import Submission Agencies</li> </ul>	We enhanced the IRB/EC/RA Name drop-down list to support display of both the Agency name and ID.
User interface - <a href="#">Displayed languages</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 list of languages displayed in Oracle Site Activate can be tailored to your organization's requirements.
User interface - <a href="#">Version ID field character count</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>	For artifacts at the country and site levels, we added character counters to Version ID fields.
User profile - <a href="#">My time zone</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>	A new tool tip clarifies time zone usage for email alerts.

# 3

## Service notice

Review product announcements and change notices.

### **Deprecated reports**

With release 25.1, we deprecated the unused Standard reports and Operational reports from Oracle Site Activate. The Audit report, Analyze reports link, and Data export options remain available in the Reports menu for users who have permission to access these features.

### **Upcoming feature deprecation notice**

With patch release 25.1.1, we will deprecate the Study Planning and Business Partner Collaboration features from Oracle Site Activate. These features are not in use and this change will not impact your organization.

# 4

## Stability improvements

These are the issue corrections included in this release.

### Alerts

Description	Ticket	Severity
Hourly Oracle Site Activate email notification alerts were not sent as expected.	CHK-46736	2
Users with over 1,000 alert notifications did not receive email alerts as expected.	CHK-46591	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 date time format. We corrected this issue and Milestone Publish messages now use ISO date time format. Note that this correction also updated Activity Change messages to ISO date time format.	CHK-46499	2
Intermittently, response time for Artifacts GET messages was longer than expected and could result in timeout errors.	CHK-46531	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-46575	1
Event messages did not trigger as expected for completed study library items.	CHK-46656	2
The Users GET API response did not include a user's study, country, or site assignments as expected.	CHK-46685	2

Description	Ticket	Severity
The Artifact GET API failed when a page size greater than 99 was specified; this issue has been resolved, and the API now supports page sizes from 1 to 200, with a default of 30 as designed.	CHK-46834	3
In SharePoint migrated environments only, Artifact GET calls for staff level items were not successful for items with files attached.	CHK-46862	1
We corrected an issue that prevented Artifacts API users from creating an item that already existed for a site under a country.	CHK-49570	3
API documentation for POST artifacts incorrectly showed "artifact_level" instead of "level" inside the example request.	CHK-49571	3
We made a service correction to address an issue where users could not attach documents in a study if a study and country were created via API.	CHK-49967	3
Caching for Artifact, Site, and SiteSurname attributes is now disabled to prevent errors when sending a known site in a different study.	CHK-50489	3

## Audit trail

Description	Ticket	Severity
We fixed an issue where audit logs for workflow-related changes, such as artifacts, activities, workflow definitions, and dependencies, sometimes kept the wrong user name after a delete action. Now, logs accurately display the correct user name for subsequent activities, so actions are no longer incorrectly tagged with the name of the user who performed the delete action.	CHK-48330	3

## Bulk work

Description	Ticket	Severity
Bulk work did not always return results as expected.	CHK-47509	2
When searching for lineage items using a keyword, no results were found even when documents matching the keyword were available.	CHK-47532	3
No results were returned when searching a long text string on the Items or Activities tabs even when matches were available.	CHK-48650 CHK-48662	2

## Contracts

Description	Ticket	Severity
Artifact modals for contracts and sub-contracts did not open as expected from the Corrections tab.	CHK-46535	2

## Document management

Description	Ticket	Severity
Files that included non-ASCII characters in the file name did not upload and migrate to SharePoint as expected.	CHK-46655	2
When discontinuing or reinstating a document placeholder, you could click Done multiple times, which incorrectly generated multiple Event messages and audit records. In this release, we changed the Done button behavior so you can click the button just once.	CHK-46987	3
When a site was created immediately after the study country via API, site-level document auto-sharing failed and the site did not receive the document as expected	CHK-47496	3
Duplicate items could be created if you created a site through the user interface or API and then shared an item from the Study library to that site.	CHK-48049	3

Description	Ticket	Severity
IP package exports did not include the most recent files uploaded to the items.	CHK-49762	2
If there were multiple files present on an item, the PI/Site documents section in the submission package and IP package wizards showed incorrect documents after you sorted the Attachment column.	CHK-50013	2

## Electronic signature

Description	Ticket	Severity
Oracle Site Activate did not recognize mixed case email addresses.	CHK-46818	3

## Exports

Description	Ticket	Severity
We corrected a database memory issue that caused CSV extract errors.	CHK-46276	2
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-46588	2
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-46693	2
CSV extracts incorrectly reflected Boolean values as "1" or "0" instead of "true" or "false." We corrected this issue and Boolean values now show as true, false, or null as expected.	CHK-46733	2
An export error occurred if you attempted to export a ZIP file from a package's Selected documents tab.	CHK-46929	2
We made an infrastructure update to ensure CSV queries will retry if an interruption or error occurs.	CHK-46974	2
An export error occurred if you attempted to export a package larger than 250MB.	CHK-48101	3

## Global search

Description	Ticket	Severity
Global search did not return results even when matching results were available.	CHK-46312	2

## Infrastructure

Description	Ticket	Severity
We made infrastructure enhancements to ensure proper access to the Data Export Utility, Study Planning, and Configuration Designer in multi-tenant environments.	CHK-47821 CHK-47822	2
An error occurred if you attempted to export documents to a zip file.	CHK-48655	1

## Milestones

Description	Ticket	Severity
Duplicate milestones were incorrectly created for one site.	CHK-45505	3
Updating a milestone at the site level did not update the study Dashboard Chart view or allow you to filter the chart by Category as expected.	CHK-47249	3
Country and site milestones that were newly added to an existing configuration were not created as expected.	CHK-50440	3

## Notes

Description	Ticket	Severity
A note Highlight was not saved as expected if you created the note by clicking Complete activity in the item modal.	CHK-46280	3
The Add a note section in the notes modal was incorrectly enabled for a user with view only permission.	CHK-46172	3

Description	Ticket	Severity
A user with view only permission was incorrectly allowed to create a Reply note in an item with an existing note and in the Notes history table on the Notes tab.	CHK-46215	3
Notes where no reply is expected were incorrectly included in results if you filtered Note Status by Unresolved.	CHK-47400	4

## Oracle Site Activate LITE

Description	Ticket	Severity
After loading assignments for the site user, the loading progress icon continued to display.	CHK-47816	2
The Notes column header incorrectly included a sort control when sorting is not supported for the icon-only Notes column.	CHK-49181	4

## Single Sign On (SSO)

Description	Ticket	Severity
Oracle Site Activate SSO to Oracle Site Analyze did not route users to Oracle Site Analyze as expected.	CHK-46467	2

## Site experience

Description	Ticket	Severity
A site experience user's assigned activities did not load as expected for a linked account.	CHK-50060	3
An error occurred when a site user attempted to navigate to a linked account to view assigned activities for other sponsors or CROs.	CHK-50434	2

## 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-46019	2
When changing the site IRB type using the editable IRB drop-down list on the site page, the site's Network value and IRB name were incorrectly removed when the page was refreshed.	CHK-46741	3

## Study home

Description	Ticket	Severity
Oh the home study home page Your tasks tab, the Role filter's total activities number did not match the sum of activities for individual roles.	CHK-46173	1
An error occurred when the study home page Your tasks tab took longer than expected to load.	CHK-46641	4
The study home page Planning tab for Submissions did not load as expected for large studies with a high number of submissions and packages.	CHK-50486	1

## Submissions

Description	Ticket	Severity
When planning a submission package, the Selected section on the right side of the page showed scroll arrows even when scrolling was not applicable.	CHK-49716	4

## 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-46536	2

## User interface

Description	Ticket	Severity
If your computer was set to London time zone (UTC +0:00), the calendar date picker did not work correctly if you selected a future expiration date by clicking the year first rather than moving through the months one at a time.	CHK-46976	3
Time zone differences between your 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-46767 CHK-46772 CHK-48267 CHK-48372	4
In the vertical global menu (i.e., hamburger icon), there was no exclamation mark to indicate when files were held in quarantine after being sent through Oracle Site Activate LITE or email reply.	CHK-47982	3

# 5

## New known issues

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

### Account overview

Description	Ticket	Severity
When you search on the Account Overview Your Tasks tab, the results may include items that do not exactly match your search term; for example, searching for "PI – CV" might also return "Sub-I CV."	CHK-49264	2

### API integration

Description	Ticket	Severity
The Studies POST API can create a study without a process/ configuration even when the account setting requires that a process be present when creating a study.	CHK-50315	2

### Audit trail

Description	Ticket	Severity
P and Submission ZIP exports and exports of completed documents at both levels did not create audit trail entries as expected.	CHK-50216	3

### Bulk work

Description	Ticket	Severity
On the Bulk Work Activities tab, you can't search for artifacts by Type or Category, even when that metadata is set in the document or submission.	CHK-49155	2

Description	Ticket	Severity
If you complete a document activity after discontinuing its milestone, the milestone disappears from Bulk Work, and you cannot reinstate it.	CHK-50316	3
When the "Enable studies in closed status to be read-only to all users" setting is on for your organization's account, a closed study's name incorrectly appears in the Studies/Countries/Sites filter on the Bulk Work page. Instead of showing the closed study's name by default, the filter should display the word "Study" and have no study selected.	CHK-50771	3

## Contracts

Description	Ticket	Severity
If you enter a disallowed value into a percentage field for a contract item, such as 101% in the Per subject cost deviation field, the error message does not clearly explain why your entry is invalid.	CHK-50930	2
When you create amendments in bulk for contracts that have an associated protocol, the new amendments do not inherit the protocol version from the original contracts as expected.	CHK-51183	2

## Corrections

Description	Ticket	Severity
On the home page under Corrections > Items, the delete "X" icon is missing from the Actions column. Instead, you see an ellipsis, which suggests there is more content, but the delete option does not appear as designed. <b>Workaround:</b> Drag the Actions column's right side border to the right to view the X icon.	CHK-51186	3

## Document management

Description	Ticket	Severity
When multiple artifacts are created for the same site by triggers that call the same artifact creation, the revision number is not incremented correctly, resulting in duplicate artifacts with revision "0" instead of sequential numbering. The system should assign the next available revision number to each duplicate artifact, such as "1" or "2," to ensure proper versioning.	CHK-50479	3

## Electronic signature

Description	Ticket	Severity
If you try to add an eSignature request for an unsupported file type, such as .jpg, you should see an error message explaining the file type is incompatible with eSignature; however, no error message appears.	CHK-46956	3
If your Adobe access was created in a different system, you may lose the ability to sign in Oracle Site Activate, and the Complete eSign button no longer appears for you as the signer.	CHK-47151	2

## Exports

Description	Ticket	Severity
If two exports start around the same time for the same item with minor updates, the first one is not cancelled as expected.	CHK-51113	3
Study level package export logs and audits do not include study ID as expected.	CHK-51174	2

## Milestones

Description	Ticket	Severity
The Save filters option on the study milestones Tabular view will not save your filters if there are more than 64 milestones selected.	CHK-51150	2
The info icon hover text on an auto planned milestone is incorrect; it currently says, "Your predecessor milestone has a new planned date. Please review." It should say, "This milestone was automatically planned based on the predecessor milestone."	CHK-51229	3

## Oracle Site Activate LITE

Description	Ticket	Severity
When you sort the Age column by clicking the arrow, the sorting is reversed: ascending incorrectly shows ages from highest to lowest, and descending incorrectly shows ages from lowest to highest.	CHK-49206	4

## Site experience

Description	Ticket	Severity
The page footer containing links to policies, terms of service, copyright, and the release version number does not stay fixed at the bottom of the page as designed; instead, it moves as the page content changes.	CHK-49719	3

## Study countries

Description	Ticket	Severity
Some study countries created via integration do not have the number of planned sites. You can update the value in the Edit a study country modal; however, the modal does not properly validate that the required "Number of planned sites" field is populated, and it will allow you to click Done without entering a number.	CHK-50443	3

## Study library

Description	Ticket	Severity
If you open the Share now dialog in Study Library, exit without sharing, change the selected study, and repeat the process, you encounter a server error. This issue appears after you open the Share now modal following a change to the selected study.	CHK-49260	3

## Submissions

Description	Ticket	Severity
If your organization's account does not have the "Enable Pending IRB/EC type to trigger site workflows" option enabled, you should not be able to select "P – IRB/EC" in the IRB/EC drop-down on the site page. If you attempt to choose this option, an error occurs and your selection is not saved.	CHK-50069	3

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Description	Ticket	Severity
When you plan an EU submission part 2 package and select documents for a site, selecting another site without first deselecting the original site causes your previous document selections to be cleared and the count to reset to zero. Previously selected documents for the first site should remain selected, and the selected document count should not be lost when you choose additional sites.	CHK-50389	3

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## Team member assignments

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Description	Ticket	Severity
When a user is newly assigned to a role on the Teams tab, that user automatically becomes the Primary for the role.	CHK-50943	2

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## User interface

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Description	Ticket	Severity
When an activity has a due date setting enabled with “Expected days for completion” specified (e.g., Due Date + 1 day offset), the due date shown in the artifact’s Due Date field may be incorrect by up to one day.	CHK-50737	4
In the global navigation menu, clicking the word “More” does not open the menu as expected. <b>Workaround:</b> Click the arrow to expand the More section.	CHK-50855	4

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# 6

## Previously reported known issues

See the unresolved issues reported prior to this current release.

### Contracts

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

### Document management

Description	Ticket	Severity
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

### Study library

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
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

# 7

## Deprecated known issues

An issue listed in this section is 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 all issues in this section from the known issues list.

### 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

Description	Ticket	Severity
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
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

## 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

## 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.	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

## 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
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

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

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## User interface

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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

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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.

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## Browser support

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

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

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

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

Product	Release	Certified (Latest versions as of GA)	Supported (Latest version as of GA)
Oracle Site Activate	25.1	Google Chrome and Microsoft Edge (Chromium)	None
Site Experience and Oracle Site Activate LITE	25.1	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

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## Post-upgrade refresh

You may need to complete a hard refresh after 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

### Note

Please note that Safari is not an Oracle tested browser.

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## 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 25.1.

<b>Date</b>	<b>Part number</b>	<b>Description</b>
10Feb2026	G24881-01	General Availability Release Notes