

Oracle Life Sciences Site Activate

Release Notes



Release 23.2
F84098-07
June 2024

ORACLE®

Oracle Life Sciences Site Activate Release Notes, Release 23.2

F84098-07

Copyright © 2023, 2024, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, MySQL, and NetSuite are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

Contents

Preface

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

1 Release 23.2.0.4 (available for this release 28Jun2024)

Stability improvements	1-1
API integration	1-1
Contracts	1-1

2 Release 23.2.0.3 (available for this release 03MAY2024)

What's new	2-1
Integration	2-1
Stability improvements	2-1
API integration	2-2
Data corrections	2-2
Integration	2-2
Milestones	2-3
Study library	2-3

3 Release 23.2.0.2 (available for this release 12Dec2023)

Stability improvements	3-1
Infrastructure	3-1

4 Release 23.2.0.1 (available for this release 20Nov2023)

Stability improvements	4-1
Milestones	4-1
Submissions	4-1

5 Release 23.2

What's new	5-1
APIs and integration	5-2
Document management	5-3
Milestones	5-3
Reports	5-4
Study management	5-5
Usability improvements	5-6
Impact analysis	5-10
Stability improvements	5-12
API integration	5-13
Contracts	5-13
IP release	5-13
Milestones	5-13
Submissions	5-14
User interface	5-14
New known issue	5-14
Contracts	5-15
Previously reported known issues	5-15
API integration	5-15
Audits	5-16
Bulk work	5-16
Contracts	5-16
CRO and sponsor collaboration	5-17
Document management	5-17
Electronic signature	5-18
Global search	5-18
IP release	5-19
Milestones	5-19
Site experience	5-20
Site library	5-20
Staff documents	5-21
Study library	5-21
Submissions	5-21
Team member assignments	5-22
User interface	5-23

6 Severity definitions

7 Browser support

8 Revision history

Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

Documentation accessibility

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

Diversity and Inclusion

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

Related resources

Product documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

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

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

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

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

1

Release 23.2.0.4 (available for this release 28Jun2024)

Release 23.2.0.4 includes API integration corrections and a contract amendment display correction.

- [Stability improvements](#)
This hotfix release includes corrections to User APIs and contracts.

Stability improvements

This hotfix release includes corrections to User APIs and contracts.

- [API integration](#)
- [Contracts](#)

API integration

Description	Ticket	Severity
We updated the Users GET API to improve response time when the request specifies 50 or greater as page size.	CHK-45465	3
We made an infrastructure update to address application restart issues.	CHK-45380	3

Contracts

Description	Ticket	Severity
A contract amendment incorrectly displayed an exact duplicate in the Oracle Site Activate user interface.	CHK-45424	3

2

Release 23.2.0.3 (available for this release 03MAY2024)

Learn about the enhancements and corrections included in the 23.2.0.3 hotfix release.

- [What's new](#)
Describes API documentation updates included in this release.
- [Stability improvements](#)
This hotfix release includes multiple corrections.

What's new

Describes API documentation updates included in this release.

- [Integration](#)

Integration

API documentation

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

Stability improvements

This hotfix release includes multiple corrections.

- [API integration](#)
- [Data corrections](#)
- [Integration](#)
- [Milestones](#)
- [Study library](#)

API integration

Description	Ticket	Severity
We recently updated the token functionality needed to retrieve a file, generating a new one upon message retry. This fix updated our eTMF PUBLISH and Artifact GET API documentation. Now, the documentation for file URL descriptions include the following: "This is a url for the latest file attached to a document, if a file(s) has been uploaded. The url can be used to retrieve a file from Box. The access token is valid for 1 hour; a new one will be generated when the message is retried via UI or API."	CHK-44692	4

Data corrections

Description	Ticket	Severity
A user could not perform self-corrections as expected when that user was the last person to work on the item, and the last activity was auto-approved.	CHK-44572	2

Integration

Description	Ticket	Severity
A new Document Event message (Artifact PUBLISH) was sent each time a Study library document auto-shared to a country or site, which incorrectly may have led customers to create new document versions in their eTMF system. We resolved this issue, and subsequent auto-shares to countries or sites no longer trigger new Document Event messages unless there is a change to metadata or a file replacement.	CHK-44690	2

Description	Ticket	Severity
A new eTMF Event message was sent each time a Study library document auto-shared to a country or site, which may have created new document versions in customers' eTMF systems. We resolved this issue, and subsequent auto-shares to countries or sites no longer trigger a new eTMF Event message unless there is a change to metadata or a file replacement.	CHK-44860	2
Uploading a file to a Study Library item incorrectly triggered two Document Event messages instead of one message.	CHK-44918	2

Milestones

Description	Ticket	Severity
Successor milestones auto-planned without a qualifying event on the predecessor milestone.	CHK-44539	3
When a new site was added to a study with the Initial Protocol Received/Sent milestone completed, the prediction API call did not generate Contract Executed and IP Release predictions for the new site as designed. We corrected this issue, so the predictions for the newly added sites are now showing.	CHK-45091	2

Study library

Description	Ticket	Severity
When sharing Study library documents for older studies, sharing processes progressed slowly and appeared to stall.	CHK-44859	3

3

Release 23.2.0.2 (available for this release 12Dec2023)

Identifies the correction included in the 23.2.0.2 hotfix release.

- [Stability improvements](#)
This hotfix release includes one infrastructure correction.

Stability improvements

This hotfix release includes one infrastructure correction.

- [Infrastructure](#)

Infrastructure

Description	Ticket	Severity
We made an internal infrastructure change to ensure proper handling of Single Sign On (SSO) SAML certificates. This correction did not introduce any change to Oracle Site Activate features or functionality.	CHK-44255	2

4

Release 23.2.0.1 (available for this release 20Nov2023)

Describes four corrections included in the 23.2.0.1 hotfix release.

- [Stability improvements](#)
This hotfix release includes corrections for Milestone and Submission reported issues.

Stability improvements

This hotfix release includes corrections for Milestone and Submission reported issues.

- [Milestones](#)
- [Submissions](#)

Milestones

Description	Ticket	Severity
The Reason for change drop-down list in the milestone modal and Submission planning page did not display the Done button when there was a long list of reasons.	CHK-44154	3
When a user changed a date on the Corrections Milestones tab and checked the at risk check box, the Risk reasons drop-down list did not properly display all configured reasons or the Done button.	CHK-44155	3

Submissions

Description	Ticket	Severity
When creating submission packages, if users checked the Select All option for site documents, the document list failed to load as expected. Additionally, when planning packages with sites in Post IP release, documents for other sites were displayed.	CHK-44072	2

Description	Ticket	Severity
An error occurred when users selected site documents for inclusion in an EU Part 2 Submission package.	CHK-44153	3

5

Release 23.2

See the new and enhanced features, stability improvements, and issue lists published in the 23.2 GA release notes.

- [What's new](#)
Learn about new and enhanced functionality in this release.
- [Impact analysis](#)
See a quick summary of the business and functional impact of enhancements included in the 23.2 release.
- [Stability improvements](#)
These are the issue corrections included in this release.
- [New known issue](#)
This section identifies an unresolved issue found during the development of this current release.
- [Previously reported known issues](#)
See the unresolved issues reported prior to this current release.

What's new

Learn about new and enhanced functionality in this release.

- [APIs and integration](#)
Oracle Site Activate introduces integration with Phlexglobal, the Manage publish endpoints page now masks sensitive fields, and we deprecated several unused fields from the Study Site API.
- [Document management](#)
On Country and Site pages, users can now export completed documents to a zip file.
- [Milestones](#)
Oracle Site Activate introduces a new prediction for site submissions, and the home page milestone modal now notifies users if there is an update to a predecessor milestone.
- [Reports](#)
Now users who create audit trail reports can generate an audit report for an individual user.
- [Study management](#)
The Account Overview Studies tab enhancements provide searching and study details, and a new optional setting will change an account's closed studies to a read-only state.
- [Usability improvements](#)
Multiple usability improvements introduced in this release improve communication, make navigation easier, and more.

APIs and integration

Oracle Site Activate introduces integration with Phlexglobal, the Manage publish endpoints page now masks sensitive fields, and we deprecated several unused fields from the Study Site API.

Phlexglobal integration

Oracle Site Activate users who manage publishing endpoints can now configure Phlexglobal (Phlex) vendor mapping. When selected for mapping on the Manage Publishing Endpoints page, the following fields are required:

- Authenticate URL
- Username
- Password
- Site-PI Connector – helper text for this field is: "User this connector to combine Site Number and Principal Investigator's Last Name in the required Phlex formatting. For example, '-' creates the value '100-Smith'. Permitted characters include '-', '+', '_', '&', '*'
- Default Transmitter Email – helper text for this field is: "This email address will be included in eTMF messages to Phlex when the package approval email address is null. The email included here should exist in Phlex."

When an eTMF message is triggered in Oracle Site Activate, and Phlex is the configured endpoint, the etmf POST message will be transmitted in a Phlex-specified format. If the email address field is not populated in Oracle Site Activate, the message will use the default_transmitter_email value defined in the Phlex endpoint setup.

eTMF Publish messages created for a Phlex endpoint will include pi_last_name and formatted_site_name fields within Study Site. eTMF messages will contain these new fields only when the endpoint is set to Phlex.

EPIC: CHK-42979

Manage publish endpoints

With release 23.2, we enhanced the Manage Publish Endpoints page to mask sensitive data fields (e.g., Password, Client ID Secret, Token, etc.). Data entered into the fields is now masked while entering, can be made visible using the eye icon until saved, and displays as dots once saved.

This enhancement affects the following:

- **Standard** vendor mapping (Standard, Basic, and OAuth2.0 authorization) – Masks Token, Password, and Password credential fields as appropriate
- **Phlex** vendor mapping – Masks Password field
- **TMMCS** vendor mapping – Masks Token field
- **Trial Interactive** vendor mapping – Masks Password field
- **SIP** vendor mapping – Masks Client ID and Client Secret fields
- **Veeva** vendor mapping – Masks Password field

EPIC: CHK-42690

Study Sites APIs

We deprecated the POST country_abbr and PUT sip user id, pi credentials, pi designation fields from Study Site APIs with the release 23.2. The fields are supported via PI POST/PUT APIs.

EPIC: Not applicable. Information only.

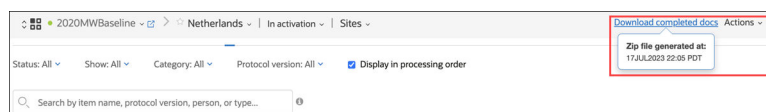
Document management

On Country and Site pages, users can now export completed documents to a zip file.

Export country and site documents to zip file

Users can now download all completed documents to a single zip file on the study country and study site pages. When they click the Export completed documents option on the Actions menu, Oracle Site Activate begins compiling the files associated with the completed artifacts, and a "Preparing documents for export" message displays to the left of the Actions menu. A refresh icon (↻) lets the user check if the download is available.

When the zip has been compiled and is ready for download, the displayed message will change to "Download completed docs," and the refresh icon no longer displays. The download link is specific to the logged-in user and will be available to that user for 24 hours. Additionally, the zip file will include a manifest file.



Oracle Site Activate displays helper messages under the following circumstances:

1. When a user tries to export completed documents, but there are no completed items, the message: "No completed documents with files available for download. Please complete some documents with file attachments and try again." displays.
2. When a user tries to export completed documents, if there are completed items but no files available, the message: "No completed documents with files available for download. Please complete some documents with file attachments and try again." displays.

EPIC: CHK-42692

Milestones

Oracle Site Activate introduces a new prediction for site submissions, and the home page milestone modal now notifies users if there is an update to a predecessor milestone.

Submission to Approval prediction

With release 23.2, Oracle Site Activate introduces a new submission to approval prediction. When the Initial submit activity is completed for site-level submissions, the Final approval now gets a suggested date on the "Submission dates" tab. Users will see the Suggested date symbol on the Final approval when a prediction becomes available.

Users will see "Apply this suggested planning date: DDMMYYYY" and "Prediction is available due to new data" below Final Approval and above Baseline date and the user is able to apply the suggested date as the baseline/planned date. If the Initial submit activity date is updated via correction, then the prediction will retrigger and update the prediction for the Final approval.

Note that this new prediction triggers only when both Initial submit and Final approval activities exist for the submission artifact. If only one is configured, no prediction occurs.

EPIC: CHK-42692

Milestone modal

With release 23.2, we enhanced the milestone modal displayed from the home page Planning tab to include new messaging for predecessor milestone updates. When appropriate, the modal now shows an information icon (i) and helper text to inform users of the update so they know that the successor milestone may also require an update. This enhancement ensures consistent messaging behavior when users display the modal from the Planning tab or milestone timeline.

EPIC: CHK-42691

Reports

Now users who create audit trail reports can generate an audit report for an individual user.

Audit report

With a new User tab, Oracle Site Activate users who have access to audit trail reports can now generate an audit report for a specific user across all studies and within a selected time range. Users can specify a user for the report with the type-ahead user drop-down. The drop-down populates the logged-in user's email address by default. All the users in the account are available for selection in the drop-down which refreshes to display matching email addresses when the user enters at least two characters in the search field. The user can then select a single email address from the resulting list of matching addresses for report generation.

The new Users tab also provides optional filters for Auditable Type (e.g., Activity, Amendment, Artifact, etc.) and Action (e.g., create, update). The Time Line filter, which is required, allows

the user to select a maximum date range of one year. Like data for study audit reports, audit data at the user level is also refreshed weekly on Sundays. Helper text in the user interface recommends that users select dates before the most recent Sunday.

Audit trail

auditable_type	auditable_id	audit_user_name	audit_user	audit_type	audit_action
Activity	3531393	j.smith@example.org	j.smith	User	create
Activity	3531393	j.smith@example.org	j.smith	User	create
Attachment	3531393	j.smith@example.org	j.smith	User	create
AttachmentVersion	3531393	j.smith@example.org	j.smith	User	create
Activity	4462202	a.p@example.org	an.fahel	User	update
Activity	4462204	a.p@example.org	an.fahel	User	update
Note	621734	a.p@example.org	an.fahel	User	create
Note	621734	a.p@example.org	an.fahel	User	update
Activity	4462205	a.p@example.org	an.fahel	User	create
Activity	4462205	a.p@example.org	an.fahel	User	update
Artifact	233006	a.p@example.org	an.fahel	User	update
Attachment	513009	a.p@example.org	an.fahel	User	create

Audit trail
See a chronological record of user-prompted activities for all sites, or for one or more specific sites. View audit records for a study site, country, team member, department, or role.

This report is available only for download in CSV format.
* This report may take a long time to generate.

Study **User**

User
usr_email-21596654...

Auditable Type Filters
None

Action Filters
None

Time Line
(You can select a maximum range of 1 year. Audit data for reports are refreshed weekly on Sundays. Please select dates prior to the most recent Sunday)

28JUL2025 - 29JUL2025

Generate report

Previously generated report

EPIC: CHK-42692

Study management

The Account Overview Studies tab enhancements provide searching and study details, and a new optional setting will change an account's closed studies to a read-only state.

Account Overview Studies tab

With release 23.2, we enhanced the Studies tab functionality in Account Overview to provide search functionality and display study details.

The Studies tab now includes a search field where users can search by study name, CRO ID, or Protocol to filter the displayed study list. To remove filtering and display the full list, the user can click "Clear result" to the right of the search field.

We also made a minor enhancement to the Studies tab to add a new info icon (i) tooltip to the Study Name column. The text is: "The studies shown here are the studies you are directly assigned to. Click on the study row for additional study details."

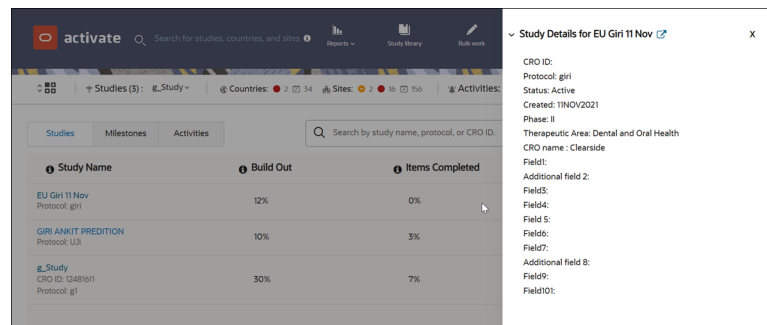
The Studies tab will now display study details in a drawer format. When a user clicks on a study row, the details drawer opens from the right. The collapsible drawer title is "Study Details for [Study Name]." A launch icon (🔗) to the right of the study name allows users to open the study in a new browser tab if preferred.

Below the drawer title, the following study details display:

- CRO ID:
- Protocol:
- Status:
- Created:
- Phase:
- Therapeutic Area:
- Sponsor name: (if CRO account) / CRO name: (if Sponsor account)
- Field1:
- Field2:

- Field3:
- Field4:
- Field5:
- Field6:
- Field7:
- Field8:
- Field9:
- Field10:

The detail drawer displays the field name and any saved value for each field above. By design, only the field name displays if no value exists for a study details field. Additionally, Flex fields 1-10 above will display the system default name, or the configured custom name if any.



EPIC: CHK-42692

Closed study status

In release 23.2, Oracle Site Activate introduces the account level option to make studies in Closed status read-only to prevent any updates. When enabled for the account, Closed studies are viewable but not actionable for most users. A new business role permission, "Enable study status change for closed studies" will allow permissioned users to modify a study's status to return it to an actionable status if preferred.



Note:

Please get in touch with your Oracle services representative to discuss enabling this option for your account.

EPIC: CHK-42692

Usability improvements

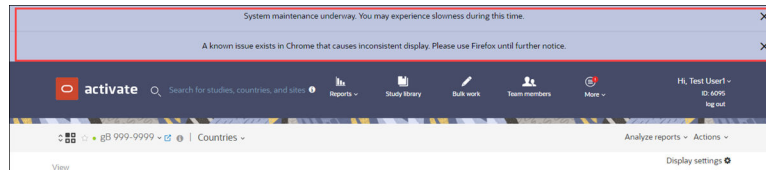
Multiple usability improvements introduced in this release improve communication, make navigation easier, and more.

Communications banner

With release 23.2, Oracle Site Activate introduces communications banner functionality. An Oracle administrator can set a text message at a global and account specific level (i.e., a maximum of two banners could be displayed at one time).

The communication banners, which display at the top of the browser window when enabled, are intended for high priority communications that need to be broadcast to users (e.g., the system is experiencing slowness, a high-impact browser issue, or an upcoming upgrade window).

Banners display only in the Oracle Site Activate application and only for users with a CRO/ Sponsor log in; site users will not see the messages. The banner(s) will display each time users log in; however, users can dismiss them for their current session if preferred.



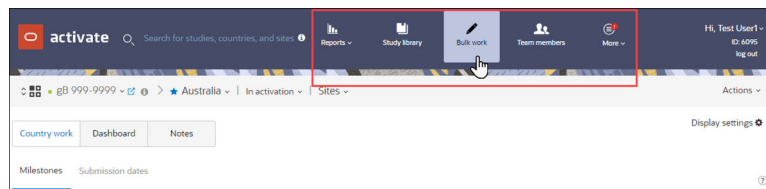
Note:

Please get in touch with your Oracle services representative to discuss enabling a banner at the account level.

EPIC: CHK-42692

Global navigation

The Oracle Site Activate global navigation bar now indicates the focus area with a new light lilac color when users hover the mouse pointer over icons.



EPIC: CHK-42692

Study home page

We added a new Countries drop-down control to the study home page persistent header so users can more easily navigate to a preferred study country home page. All previously available persistent header IDs, symbols, and tooltips are unchanged with this enhancement, with the exception of ">" and "|" symbols, which we updated to clarify the entity relationships. The ">" symbol will now only appear in front of a country name or a site name to indicate the current level. For example, on the country level you will see: study > study country | country status | sites; and on the site level you will see: study | study country > site | site status.



EPIC: CHK-42692

Workflow wizard

When generating contract items, workflow wizard can now enforce contract Type selection. When an account has the setting enabled and contract Type(s) configured, users must select a contract Type to proceed through the workflow wizard if they select a workflow that includes contract items.



Note:

Please get in touch with your Oracle services representative to discuss enabling this setting for your organization's account.

EPIC: CHK-42692

Team Members Role filters

With this release, we enhanced filtering on the Team Members Roles tab to allow users to Save selected roles for automatic display in the team members grid. When saved, the selected Roles will display automatically on the user's subsequent visits to the tab. If the user does not Save and returns to the Roles tab later, the grid displays the default list of five selected Roles.

The screenshot shows the 'Team member assignments' interface with the 'Roles' tab selected. A modal window titled 'Roles displayed' is open, showing a list of roles with checkboxes: Admin, Bdg Esc, Bdg Mgr, Budget Escalateeeee, and Budget Manager. The 'Save' button is highlighted in red.

EPIC: CHK-42692

Submission package planning

We improved submission package planning to ensure packages remain responsive when users add a very high number of documents.

EPIC: CHK-42751

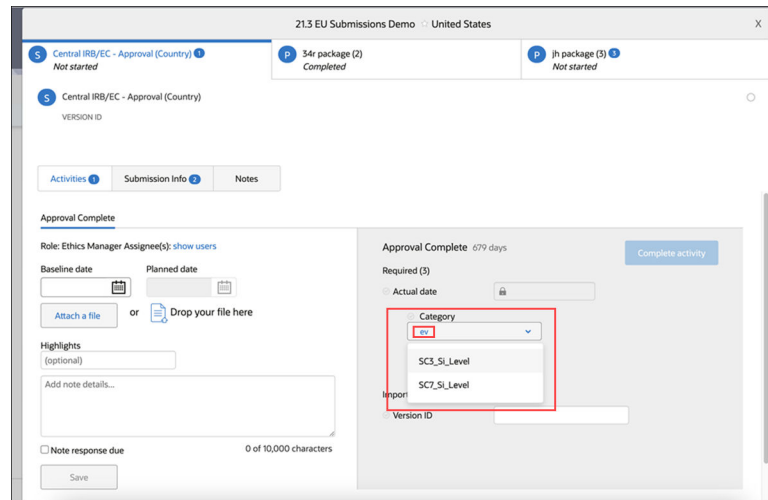
Submission agency upload

Oracle Site Activate now validates agency uploads on the Manage submission agencies page to ensure the CSV format files have the required ASCII or UTF-8 encoding.

EPIC: CHK-42692

Submission Types and Submission Categories

In this release, we improved submission Type and Category list navigation in the submissions modal. For accounts that have submission Type or submission Category enabled, the drop-down lists are now alphabetized. The drop-down control is a type-ahead text search field.

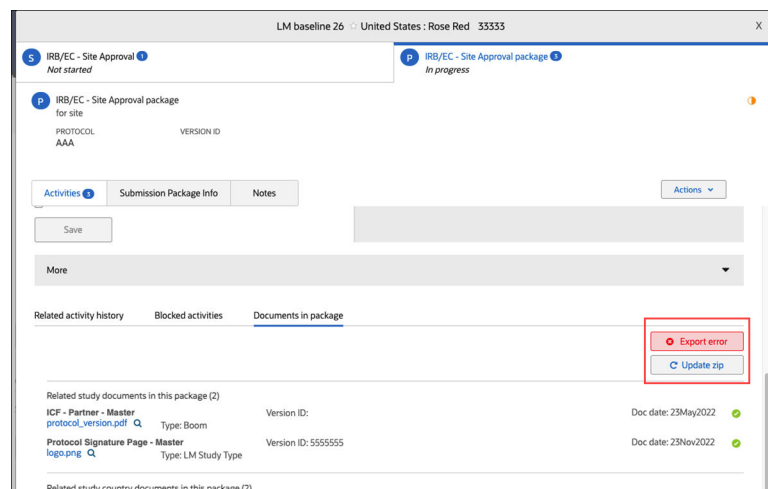


EPIC: CHK-42692

Submission and IP Package export

Users with permission to manually export submission and IP packages will occasionally experience an unsuccessful download attempt. We enhanced export tasks to now allow users to retrigger the export request.

Oracle Site Activate displays an "Export error" message when an export request is unsuccessful. The "Update zip" button now displays if the export error displays. A new export request will be triggered when the user clicks the Update zip button.



EPIC: CHK-43128

Share file with all site users

With this release, we enhanced file sharing logic for an item that does not yet have activities created with an assigned site user. Now in this scenario, when a CRO/Sponsor user uploads a file and selects "Share with all site users," the file will be shared automatically when the site user activity is created and a site user is assigned.

EPIC: CHK-42692

Impact analysis

See a quick summary of the business and functional impact of enhancements included in the 23.2 release.

Enhancement	Enablement setting	Impact
API integration Phlexglobal integration	None	None
API integration Manage publish endpoints	None	None
API integration Study Sites APIs	None	None
Document management Export country and site documents to ZIP	<ul style="list-style-type: none"> • Feature flip: N • Configuration related: N • All studies: Y • New role permission required: N • Dependent feature: Y (file upload) 	Convenience of consolidated zip file
Milestones Submission to Approval prediction	<ul style="list-style-type: none"> • Feature flip: N • Configuration related: Y (smart submission milestones configured) • All studies: Y • New role permission required: N • Dependent feature: Y (prediction enabled) 	Suggested plan for submission approval
Milestones Milestone modal	<ul style="list-style-type: none"> • Feature flip: N • Configuration related: N • All studies: Y • New role permission required: N • Dependent feature: Y (predecessor milestones) 	Planning tab now gives message consistent with elsewhere
Reports Audit report	<ul style="list-style-type: none"> • Feature flip: N • Configuration related: N • All studies: Y • New role permission required: N • Dependent feature: Y (user must have audit report permission) 	Target audit records for a particular user
Study management Account Overview Studies tab	<ul style="list-style-type: none"> • Feature flip: N • Configuration related: N • All studies: Y • New role permission required: N • Dependent feature: Y (account overview) 	View metrics for all studies user is directly assigned to

Enhancement	Enablement setting	Impact
Study management Closed study status	<ul style="list-style-type: none"> Feature flip: Y (Enable studies in closed status to be read-only to all users.) Configuration related: N All studies: Y New role permission required: Y (Enable study status change for closed studies) Dependent feature: N 	Prevent changes in closed studies
Usability improvements Communications banner	<ul style="list-style-type: none"> Feature flip: N Configuration related: N All studies: Y New role permission required: N Dependent feature: N 	Oracle can set message to display
Usability improvements Global navigation	<ul style="list-style-type: none"> Feature flip: N Configuration related: N All studies: Y New role permission required: N Dependent feature: N 	Clarity of selection
Usability improvements Study home page	<ul style="list-style-type: none"> Feature flip: N Configuration related: N All studies: Y New role permission required: N Dependent feature: N 	Easy navigation
Usability improvements Workflow wizard	<ul style="list-style-type: none"> Feature flip: Y (Enable Require contract type in workflow wizard) Configuration related: N All studies: Y New role permission required: N Dependent feature: Y (contract types) 	Contract type is set earlier
Usability improvements Team members Role filters	<ul style="list-style-type: none"> Feature flip: N Configuration related: N All studies: Y New role permission required: N Dependent feature: Y (permission 'Enable managing user roles') 	Persistent filter
Usability improvements Submission package planning	<ul style="list-style-type: none"> Feature flip: N Configuration related: N All studies: Y New role permission required: N Dependent feature: N 	Improved performance

Enhancement	Enablement setting	Impact
Usability improvements Submission agency upload	<ul style="list-style-type: none">• Feature flip: N• Configuration related: N• All studies: Y• New role permission required: N• Dependent feature: Y (permission 'Enable managing agency uploads')	Data validation
Usability improvements Submission Types and Submission Categories	<ul style="list-style-type: none">• Feature flip: N• Configuration related: N• All studies: Y• New role permission required: N• Dependent feature: Y (submission categories/types are enabled)	Easier labeling when in the submission modal
Usability improvements Submission and IP package export	<ul style="list-style-type: none">• Feature flip: N• Configuration related: N• All studies: Y• New role permission required: N• Dependent feature: Y (permission 'Enable manual doc export')	Allows for retrigger of failed export
Usability improvements Share file with all site users	<ul style="list-style-type: none">• Feature flip: N• Configuration related: N• All studies: Y• New role permission required: N• Dependent feature: Y (site users)	File will be shared appropriately

Stability improvements

These are the issue corrections included in this release.

- [API integration](#)
- [Contracts](#)
- [IP release](#)
- [Milestones](#)
- [Submissions](#)
- [User interface](#)

API integration

Description	Ticket	Severity
We updated Milestones PUT to match Oracle Site Activate functionality. When a planned date is revised for a milestone that has been marked at risk, the at risk values, including the at risk check box and at risk reason, will be reset to null.	CHK-43524	3

Contracts

Ticket	Description	Severity
Contracts and sub-contracts with On hold and Terminated status could be corrected when these items should not have been available for correction.	CHK-42819	3
In Budget item metadata, the check mark icon for required fields incorrectly turned from green to gray when a user entered more than two characters.	CHK-38759	3

IP release

Description	Ticket	Severity
The IP package Complete review button was misaligned in some browsers, so the button did not display in the Review column as designed.	CHK-38553	1

Milestones

Description	Ticket	Severity
The milestone timeline did not properly display individual milestones when the account had either the milestone prediction service or the submission milestone prediction service enabled but not both.	CHK-43448	2

Description	Ticket	Severity
When a user updated the milestone planned date for an at risk milestone from within the user interface, the milestone was reset to be no longer at risk from the update, but the at risk reason was not removed as expected.	CHK-43493	3

Submissions

Description	Ticket	Severity
Check boxes to approve sites included in a country submission were not always present as designed.	CHK-41977	3
Submission package activities were not filtered by submission type and category under the Your activities tab.	CHK-42082	3
When the submission package planning wizard included many pages of available documents, the pagination controls were displaced and the page was then unresponsive.	CHK-43145	3

User interface

Description	Ticket	Severity
Protocol information was erroneously displayed in the country page Sites drop-down list.	CHK-41597	3

New known issue

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

- [Contracts](#)

Contracts

Description	Ticket	Severity
Database values for the Account Overview Studies tab "Items completed" calculation do 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

Previously reported known issues

See the unresolved issues reported prior to this current release.

- [API integration](#)
- [Audits](#)
- [Bulk work](#)
- [Contracts](#)
- [CRO and sponsor collaboration](#)
- [Document management](#)
- [Electronic signature](#)
- [Global search](#)
- [IP release](#)
- [Milestones](#)
- [Site experience](#)
- [Site library](#)
- [Staff documents](#)
- [Study library](#)
- [Submissions](#)
- [Team member assignments](#)
- [User interface](#)

API integration

Description	Ticket	Severity
When identifying a site, principal_investigator PUT calls should validate the uniqueness of cros_pi_id and sponsors_pi_id fields, and does not return an error if the call specifies a preexisting value for either field.	CHK-20128	3

Description	Ticket	Severity
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

Audits

Description	Ticket	Severity
Study level artifact discontinue may include a null value instead of the discontinue reason text.	CHK-34230	3

Bulk work

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

Contracts

Description	Ticket	Severity
If contract activities are blocked by budget and contract language activities, and the activities are completed, the "view blocking items" link displays until the page is refreshed.	CHK-18192	3
When editing a completed budget to replace the currency value, the new value does not display after clicking Done in the edit modal. Workaround: Refresh the page.	CHK-20273	4
Creating a new budget version on a contract item successfully adds a new version, but the new version does not include a revision number as expected.	CHK-20631	3
When editing a contract budget currency value, the updated value is not displayed in the widget until the user refreshes the page.	CHK-23461	3

Description	Ticket	Severity
When a completed date for an activity is deleted, it cannot be reset. Workaround: Refresh the page.	CHK-23691	3
If a user adds a note to a contract placeholder and saves it, the note's Type value and note text are not automatically cleared from the form.	CHK-31536	4
When a user saves a new value in the TMF data section, the Save button remains enabled until the user refreshes the page.	CHK-31568	4
Done and Cancel buttons are misaligned when a user adds an amendment to a contract but does not select an amendment reason.	CHK-31581	4

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 the Account Overview page, for contract and subcontracts, the word "Actual" is misaligned in the item heading.	CHK-23409	4
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
When file upload fails due to configuration or a detected virus, the file upload process fails, however, the document status is still updated.	CHK-2898	3

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

Electronic signature

Description	Ticket	Severity
If a user is tagged to electronically sign a contract type document, but the user is not assigned to a business role with access to contracts, the user can't open the alert in Oracle Site Activate to complete the electronic signature process. Workaround: The user can access the contract document via a link in the email notification.	CHK-20210	3
An error message pop-in related to the electronic signature configuration is partially obscured.	CHK-20216	3
When a tagger sends a document to multiple signers, and the tagger uploads a new document before the signers have provided the electronic signature, Adobe Sign does not send an email notification to the recipients that the first document has been cancelled.	CHK-20291	3
After a document has been signed via electronic signature, an Oracle Site Activate user can see the file within the widget under File History, but the file does not display under File History for a site experience user.	CHK-20627	3

Global search

Description	Ticket	Severity
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

Description	Ticket	Severity
Global search does not return results when a search keyword has a dash (e.g., "Study-1068").	CHK-10472	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
The icon that indicates that a milestone is at risk does not display.	CHK-7855	3
On the home page Planning tab, when viewing Milestones a duplicate tooltip displays instead of a single instance.	CHK-24393	4
When planning a study level milestone that does not yet have a configured item to complete, users are erroneously prompted to "Add country documents/submissions to generate items for this milestone."	CHK-29815	3
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

Description	Ticket	Severity
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
If a site user replies to an alert email and does not include an attachment, and an Oracle Site Activate user accepts the item within the quarantine area, no activities are completed and the status icon erroneously shows an in progress icon.	CHK-11105	3
When a site user discontinues a submission, the submission erroneously disappears from Site experience.	CHK-16576	3
When configured for an account, a customer's logo is not displayed in email alert notifications to site users as designed, even when activity completion by email is disabled.	CHK-27912	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. Workaround: Site Library is enabled for the sites after an hour elapses. Wait one hour and attempt to access Site Library again	CHK-39683	3

Staff documents

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

Study library

Description	Ticket	Severity
When study library document versions are created in quick succession, documents may cross over into different versions of country level placeholders in lineage.	CHK-5985	3
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
If a reason is provided, user can only see 1000 of the potentially 3000 characters of the reason. Workaround: See the full description in the submission information section of the submissions widget.	CHK-3230	3
When adding a new package to a submission, additional sites selected in planning do not have the initial submit dates from the first package or any Final Approval baseline and planned dates that have been specified.	CHK-16825	3

Description	Ticket	Severity
On the submissions planning page, the standard date format is DDMMYYYY, but when dates are set or updated, they display in non-standard, hyphenated format: DD-MMM-YYYY.	CHK-22928	4
Users are able to share item level notes with site experience users, which is not by design.	CHK-24766	3
For sites that have a Principal Investigator replacement, no new submission package is generated when a user clicks "Add a new sub-committee."	CHK-29295	3
An assigned define package activity does not display on the assigned user's Your activities list after the activity is completed and later uncompleted.	CHK-37815	3
Additional submission packages created on EU Submissions incorrectly show an open activity even after the item is completed. Additionally, in the modal's item completion panel, there is no Actual date present in the date field even though the date field indicator displays a green check mark (complete).	CHK-37837	3

Team member assignments

Description	Ticket	Severity
Users who do not have study or department administrator system roles can access the Team member and roles assignment page.	CHK-4325	3
Study level assignments only show when you select "For my role" on the home page.	CHK-7925	2
After assigning a site role to multiple users, no "role successfully applied" confirmation message displays.	CHK-22611	4

User interface

Description	Ticket	Severity
The site status pie chart does not accurately reflect site status if the country status has been changed to "on hold."	CHK-20162	4
When viewing a contract expiration date, the date selection icon is not properly aligned if the browser zoom level is set to any value other than 100%.	CHK-21874	3

6

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.

7

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	23.2	Google Chrome and Microsoft Edge (Chromium)	None
Site Experience and Oracle Site Activate LITE	23.2	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

8

Revision history

This book's revision date history and part number list will develop over time as we make any major, minor, or hotfix releases available for 23.2.

Date	Part number	Description
28JUN2024	F84098-07	Added hotfix 23.2.0.4 (available for this release 28JUN2024)
13MAY2024	F84098-06	Corrected release date typo in 23.2.0.3 chapter title
03MAY2024	F84098-05	Added hotfix 23.2.0.3 (available for this release 03MAY2024)
12DEC2023	F84098-04	Added hotfix 23.2.0.2 (available for this release 12DEC2023) and corrected a minor typo in the Browser support chapter
20NOV2023	F84098-03	Added hotfix 23.2.0.1 (available for this release 20NOV2023)
25AUG2023	F84098-02	General Availability Release Notes
11AUG2023	F84098-01	Pre-General Availability Release Notes