

Oracle Life Sciences Site Activate

Release Notes for Configuration Designer



Release 24.2

G11504-04

August 2025

ORACLE®

Copyright © 2024, 2025, 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	i
Diversity and Inclusion	i
Related resources	i
Access to Oracle Support	i

1 Release 24.2.1

What's new	1
------------	---

2 Release 24.2.0.1 (available for this release 13Nov2024)

Stability improvement	1
Deployments	1

3 Release 24.2

What's new	1
Configurations	1
Lifecycles	3
Previously reported known issues	3
Artifacts	4
Bulk delete	4
Configurations	4
Dependencies	4
Deploys	5
Roles	5
Deprecated known issue	5
Dependencies	5

4 Severity definitions

5 Browser support

6 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 of Oracle Health Sciences Customer Support Portal (<https://hsghbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsghbu-jp.custhelp.com/>)

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

1

Release 24.2.1

This release includes enhancements in support of the Oracle Site Activate-Phlex eTMF integration.

- [What's new](#)
We enhanced the artifact configuration form to add two new settings and relabel a field needed for Phlex eTMF integration.

What's new

We enhanced the artifact configuration form to add two new settings and relabel a field needed for Phlex eTMF integration.

Artifacts

Phlex integration

The artifact configuration form now includes two new check boxes labeled "Requires Site Personnel Surname for Phlex integration" and "Include Expiry Date for Phlex Integration" to identify items that need this metadata in Oracle Site Activate. Both new check boxes have Info icons that display a tool tip explaining the setting's purpose.

The artifact configuration form also previously included a "Reference code" field used for Phlex integrations. With this release, we've updated this field label to "Attribute ID."

The screenshot shows the 'Customize an Artifact' form with the following fields and settings:

- Name: 1st Site IP Released
- Type: Document Rule
- Contract Type: None
- Level: Study Country
- Category: Country specific documentation
- IRB/EC Type: None
- Display Order Position: 0
- TMF Identifier:
- Associate with TMF artifact Model Version 3.3: None
- Attribute ID: (highlighted with a red box)
- Requires Site Personnel Surname for Phlex integration: ☐ (highlighted with a red box)
- Description: (text area)
- Enable Discontinue: ☒
- Manage Document Expiry: ☐
- Include Expiry Date in Phlex Integration: ☐ (highlighted with a red box)
- Require expiration date for item completion: ☐

2

Release 24.2.0.1 (available for this release 13Nov2024)

This hotfix includes one correction for a deployment issue.

- [Stability improvement](#)
Learn about the service correction included in this release.

Stability improvement

Learn about the service correction included in this release.

- [Deployments](#)

Deployments

Description	Ticket	Severity
When a configuration deployed to Oracle Site Activate, it did not include decision options that were configured for the TMF Review activity type.	CHK-46363	2

3

Release 24.2

See the enhancements and issue lists published in the 24.2 General Availability release notes.

- [What's new](#)
Learn about new and enhanced functionality in this release.
- [Previously reported known issues](#)
These issues were reported prior to this current release.
- [Deprecated known issue](#)
An issue listed here 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 the item from the known issues list.

What's new

Learn about new and enhanced functionality in this release.

- [Configurations](#)
We added foundational code to support eTMF functionality targeted for a future release.
- [Lifecycles](#)
We enhanced lifecycle functionality to accept TMF review activity type in support of future eTMF functionality.

Configurations

We added foundational code to support eTMF functionality targeted for a future release.

TMF Model Version

With release 24.2, we added a new field in support of functionality targeted for a future release. We added a new “TMF Model Version” field in the Edit Configuration modal below the Name field. By default, for existing configurations, the new field will be null.

When you create a new child configuration, the child will inherit the same TMF Model set on the parent configuration (i.e., a child configuration will inherit the null value for the TMF Model Version field).

However, when you copy a configuration, you may change the TMF Model Version value on the newly copied configuration. When you change the version, all the mapped artifacts have the TMF standardized fields updated using the unique TMF ID. The fields will be null if the unique TMF ID doesn't exist in the new version.

Edit Configuration: copt2.0to3.3

Name: copt2.0to3.3

TMF Model Version: 3.3

Countries: Afghanistan, Albania, Antigua and Barbuda, Australia

Number of Countries: 248

Selected Countries: Afghanistan, Albania, Antigua and Barbuda

If applicable, Configuration Designer will alert you to artifacts affected by a change to the TMF version (i.e., artifacts that you will need to review and update manually). The Copy a Configuration modal lists the affected artifacts along with the Old TMF Mapping ID, and you can copy/paste the list to an external tracking document if necessary.

Copy a Configuration: July29_3.3

Name: Test45466s

TMF Model Version: 2.0

Are you sure you want to update the tmf version for this configuration? The TMF fields for the following items associated with this change will need to be reviewed and updated manually.

Items which will be impacted by this tmf version change, are listed below.

Artifacts and Old TMF Mapping ID

- 1st SIV Conducted | 1.1.20
- ABR Form | 1.4.4
- 1st Site Activated | 1.1.19
- 1st Site Selected | 5.2.20
- 1st Fully Executed Contract | 1.1.20
- BfS - Form A | 5.4.13

Copy to Clipboard

Submit Cancel

When the TMF Version value has been set on the Edit Configuration modal, each artifact in the configuration will include an “Associate with TMF artifact Model Version <#. #>” field in the Customize an Artifact modal. The drop-down list for this field includes values from the configuration's selected TMF Version. The value you select in the drop-down list will be included in the configuration deployed to Oracle Site Activate and will populate the associated field in the Oracle Site Activate Settings area.

Customize an Artifact

Name	1st Fully Executed Contract
Type	Document Rule
Contract Type	None
Level	Study Country
Category	Contract and budgets_Site
IRB/EC Type	None
Display Order Position	0
TMF Identifier	
Associate with TMF artifact Model Version 3.3	1.1.2 - Trial Management Plan
Reference Code	
Description	

Note that if the TMF model is null in Configuration Designer, the deployed configuration in Oracle Site Activate will default to model 2.0. This is expected behavior and will not affect the configuration's artifacts as they will not have an "Associate with TMF artifact Model Version" value.

Epic: CHK-43973

Lifecycles

We enhanced lifecycle functionality to accept TMF review activity type in support of future eTMF functionality.

TMF activity type

We enhanced the Configuration Designer lifecycle functionality with foundational code to support an upcoming eTMF feature targeted for a future release. With this enhancement you can import a CSV containing "tmfreview" in the action column to create a lifecycle with a "TMF review" activity type.

Epic: CHK-43973

Previously reported known issues

These issues were reported prior to this current release.

- [Artifacts](#)
- [Bulk delete](#)
- [Configurations](#)
- [Dependencies](#)
- [Deploys](#)
- [Roles](#)

Artifacts

Description	Ticket	Severity
The budget create and budget edit pages show all collections beyond contract collections.	CHK-22317	3

Bulk delete

Description	Ticket	Severity
Large bulk deletes complete, but the user's browser's request can time out, which results in a continuous spinner icon. Workaround: Refresh the page.	CHK-29927	3
Configuration Designer does not automatically refresh the page as designed when a user performs a Bulk Delete on the last page of the Dependencies or Milestones tab. Workaround: Manually refresh the page.	CHK-44440	4

Configurations

Description	Ticket	Severity
If deploys are in progress when viewing notes for a configuration, the deploy indicator text displays above the note list instead of below and can overlap the note fields and other user interface elements for the duration of the deployment.	CHK-41560	3
A child configuration will inherit a dependency from the parent configuration even when the child configuration already includes an exact duplicate of that dependency.	CHK-42130	3

Dependencies

Description	Ticket	Severity
The dependencies tab displays an inconsistent number of results per page.	CHK-17129	3

Deploys

Description	Ticket	Severity
When deploying a configuration with features not available on the Oracle Site Activate instance, a hard failure occurs instead of an alert.	CHK-8280	3

Roles

Description	Ticket	Severity
When exporting data from the Roles tab, the export includes unexpected permissions fields.	CHK-20240	3

Deprecated known issue

An issue listed here 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 the item from the known issues list.

- [Dependencies](#)

Dependencies

Deprecated issue description	Ticket	Severity
An error occurs if the prerequisite and successor artifacts/activities are the same between the two dependencies and if there is an identical attribute between them. Resolution: We are unable to reproduce this issue.	CHK-21830	3

4

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.

5

Browser support

Use a certified or supported 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 version as of GA)	Supported
Oracle Site Activate Configuration Designer	24.2	Google Chrome	None

6

Revision history

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

Date	Part Number	Description
19Aug2025	G11504-04	Added 24.2.1 Minor release
13Nov2024	G11504-03	Added 24.2.0.1 Hotfix (available for this release 13Nov2024)
30Aug2024	G11504-02	General Availability Release Notes
16Aug2024	G11504-01	Pre-General Availability Release Notes