
Calyx RIM 7.2.4 Release Notes

Contents

Calyx RIM 7.2.4 Release Notes	1
New in Calyx RIM 7.2.4: Common Functionality	2
New in Calyx RIM 7.2.4: Registrations	3
Entity Fields	4
Entity Fields and Columns Updated: Calyx RIM 7.2.4.....	4
Security Administration Tables	5
Security Administration Tables Updated: Calyx RIM 7.2.4.....	5
Queries	6
Query Fields and Columns Updated: Calyx RIM 7.2.4.....	6
Resolved Issues: Calyx RIM 7.2.4	7
Known Issues	9
Clarification of Behavior: Calyx RIM 7.2	15
Index	18

Calyx RIM 7.2.4 Release Notes

Information about updated files, new functionality, resolved issues, and any open issues or workarounds in Calyx RIM 7.2.4.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation.

Application Updates

Calyx RIM 7.2.4 release introduces the following Application updates:

- The ability to create **Global Project Plan > Clinical Trial** project without a product as mandatory selection with the ability to associate CT Shared Data.
- The ability to create **Global Project Plan > Create Application Registration Package Set** project without a product as mandatory selection.
- The ability to create and manage applications created through wizards without a product and product family association with the specific **NOT DEFINED Application Rights** settings set up in the **Security Administration**.
- Entities: Queries, Wizards, Security Administration

Oracle Updates

Oracle is updated to version 19.18 for Calyx RIM 7.2.4.

New in Calyx RIM 7.2.4: Common Functionality

This table shows new features and enhancements of Calyx RIM 7.2.4 functionality.

Affected Area	Update	Benefit
Wizards	<p>As an application can be created without a product associated, the following wizards are updated:</p> <ul style="list-style-type: none"> — Global Project Plan wizard <p><i>See: Entity Fields and Columns Updated Calyx RIM 7.2.4.</i></p>	The ability to create an application through the wizards to simplify the work of data creation.
Querying	To support the ability to create an application without a product and associate CT Shared Data, Queries now include the updated Product field from required to optional.	Aligned Querying capabilities with the updated data model.
Security Administration	To manage applications without products and product families separately, the access rights for Application Country Rights option are updated. <i>See: Security Administration Tables Updated: Calyx RIM 7.2.4.</i>	The ability to manage not assigned applications with a separate security settings to provide more flexibility.

New in Calyx RIM 7.2.4: Registrations

New features and enhancements for Registration functionality are listed below.

Affected Area	Update	Benefit
Global Project Plan Wizard	<p>The <i>Global Project Plan</i> wizard fields are updated or added when:</p> <ul style="list-style-type: none"> — Creating an application of CTA or IND application type without a product with the ability to associate CT Shared Data. — Creating an application of package set registration type without a product. <p>See <i>Entity Fields and Columns Updated: Calyx RIM 7.2.4</i></p>	The ability to create an application through the wizards to simplify the work of data creation.

Entity Fields

Entity Fields and Columns Updated: Calyx RIM 7.2.4

The following tables describe fields that were modified in this release.

Global Project Plan

Field/ Option Name	Field Type	Description	Business Rules
Products	Multi-select	<p>This field is now optional when selecting Global Project Plan > Clinical Trial:</p> <ul style="list-style-type: none"> — Create New CTA and/or IND Application(s) > Select Products and Countries — Create New CTA Application(s) and Create New Event for Existing IND Application(s) > Select Products, Countries and IND Application Statuses <p>This field is now optional when selecting Global Project Plan > Create New Application Package Set Registration > Select Application Category, Product Family, Products and Countries</p>	The ability to create an application through the wizards to simplify the work of data creation.

Security Administration Tables

Security Administration Tables Updated: Calyx RIM 7.2.4

Security Administration tables, sections, or fields updated in Calyx RIM 7.2.4 release.

Security Administration Section: Application Country Rights

Entity Affected	Column/Field Name	Value List Description
Product Families	Access	This field is updated with the condition that if the access level to Product Families is NOT DEFINED in Application Country Rights, the applications without products and product families can be created from the Create Application, Create Submission > Initial Application wizards if only the NOT DEFINED option is set in Application Country Rights.

Queries

Query Fields and Columns Updated: Calyx RIM 7.2.4

The following table describes fields that were updated with Calyx RIM 7.2.4

Registration Planning and Tracking Queries

Table 1: List of CTA Applications

Field/Column Name	Field Type	Description
Product	Multi-select	This field is now changed to optional on the <i>List of CTA Applications</i> query page.

Table 2: List of IND Applications

Field/Column Name	Field Type	Description
Product	Multi-select	This field is now changed to optional on the <i>List of IND Applications</i> query page.

Resolved Issues: Calyx RIM 7.2.4

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before the release, the hotfix build number is included in the table.

Registrations

Issue	Build Number	Description
DE29688	N/A	An error was displayed when trying to delete a product family that had an application without a product. This issue is resolved. Now, the Delete icon is disabled on the <i>Product Family Attributes</i> page.
DE29563	N/A	It was not possible to delete an application without child entities when the Write access was set for Application Country Rights as the Delete icon was disabled. This issue is resolved. Now, the Delete icon is enabled and the application can be deleted successfully.
DE29266	N/A	When performing the API Post request, if Security Administration > Application Country Rights were set for a particular product family, the application values were not created. This issue is resolved. Now, the application values are successfully created.
DE29264	N/A	When creating an application using the Create Application icon on the <i>Product Family Attributes</i> page, if CTA , IND or CTR was selected as the application type, the fields displayed were different from those displayed while creating an application using the <i>Create Application</i> wizard. This issue is resolved. Now, the correct fields appear as a result.
DE29263	N/A	When performing the API Post request, if NOT DEFINED was selected in Security Administration > Application Country Rights section, the child entities were not created for an application without a product and a product family. This issue is resolved. Now, the child entities are successfully created.
DE29212	N/A	When performing the API Post request, an application that did not have a product was not created under a product family. This issue is resolved. Now, the application without a product is successfully created.

Issue	Build Number	Description
DE29139	N/A	When performing the API Post request to create an event with associated CT Shared Data for EU CTR application, the request failed with an error message. This issue is resolved. Now, the event is created successfully.

Migration

Issue	Build Number	Description
DE28913; [INC0136665]	N/A	After updating Oracle from 19.16.0.0.220719 to 19.17.0.0.221018 version, a column ambiguity error occurred when using the <i>XEVMPD Submission</i> wizard. This issue is resolved. Now, you can use the XEVMPD Submission wizard without errors.
DE29651	N/A	<p>After the Oracle database update to 19.18 version, the following pages were not opened from Calyx RIM left panel and some entities could not be created:</p> <ul style="list-style-type: none"> – Product Families – Registrations – Applications – Events <p>This issue is resolved. Now, these pages are successfully opened and the entities can be created or modified.</p>

Known Issues

The following general issues and module-specific issues were known at the time this document was published, but (due to time limitations) could not be included in the module-specific user documentation packaged with the software product.

Calyx RIM: Common

Issue	Affected Area	Description
DE29048 (Added on the 23rd of December, 2022)	Notifications wizard	The Send to Concerned Parties option includes the Application and Product Family values on the Application Attributes > Notifications > Mail Settings page. This option should display Application only as there is no dependency on Product Family.
DE28641 (Added on the 20th of October, 2022)	Application, Products	When all the products are disassociated on the <i>Application Attributes</i> page, the system allows disassociation. No warning messages informing that at least one product should be associated to the application is displayed.
DE27749 (Added on the 19th of April, 2022)	Application, Country	For individual users, when the <i>Application Country Rights</i> for Product Families is set to All and Countries is set to any rights, navigating to a county from the Application Attributes > Countries tab results in an error. Workaround: Set the <i>Application Country Rights</i> for Product Families and Countries to All .
DE29739	Application, Product Family, Create Submission wizard	The Create Submission wizard does not work for applications without products when selecting Major Update or Amendment options. When it is opened from: <ul style="list-style-type: none"> the <i>Application Attributes</i> page, the error message is displayed. any other pages, for example: Home > Wizards > Create Submission, the applications with products can be only selected.

Issue	Affected Area	Description
DE27309 (Added on the 12th of January, 2022)	Update Product Details Sets, PDS, Substance	When you select Global Project Plan > Modify Substance or Add Substance from <i>Project Attributes</i> page for the Update Product Details Sets project type, not all the fields are displayed in comparison to the Substance page in PDS.
26814	Publishing	Using Prepare for Publishing with the Prepare Cross Reference Leafs option selected results in the <code>Unable to extract checksum</code> error if there is a reference leaf to leaf published to Documentum.
26807 (Added on 20th Aug 2021)	Assembly	When updating a leaf in an assembly, selecting OnLoad for the Actuate option results in an error message. This is because of the default security settings. Workaround: Update the leaf using API.
26799	eCTD Import	After you use the Bulk eCTD Import for TW submission, the Job Status is set to Scheduled instead of Completed . This is because the <code>tw-regional.xml</code> file does not contain the application code. Workaround: Use Import eCTD to Application instead of Bulk eCTD Import . See: <i>Import eCTD to Application</i> .
26728	Global Project Plan wizard, PDS	In the <i>Global Project Plan</i> wizard, when modifying an active ingredient for a PDS the Withdraw Material that is already selected is not shown in the drop-down list.
26699	Assembly	Calyx RIM can incorrectly send a Native .PDF file to for extraction. Also, while a large file can fail extraction, it might not prevent successful publishing.
26642	Assembly	Assembly files created by exporting an assembly to the Assembly File (XML) on versions of Calyx RIM starting with 6.2 CHF 4 cannot be imported to Calyx RIM versions 6.2 CHF 3 and earlier.

Issue	Affected Area	Description
26637; [INC0045216]	Administration	In Data Administration, the Check for Date-based Notifications menu is not available on the Notification Specifications grid.

Calyx RIM Publisher

Issue	Affected Area	Description
DE28730 (Added on 4th of November, 2022)	Assembly	The published output location path for reference leafs is empty.
DE27966 (Added on the 1st of June, 2022)	Assembly	The published output files are not exported to Documentum repository if they have Chinese characters in the file name. Workaround: rename files as per eCTD normalization rules before exporting output.
DE27958 (Added on 1st of June, 2022)	Assembly	After publishing the China assembly, China symbols are present in the name of the STF file. For example: stf- 4.2.1.1 □效学.xml Workaround: rename files as per eCTD normalization rules before exporting output.
25259; [00052856]	Create eCTD wizard	When modifying Applicant Contact Values for M1 in a US 3-3 assembly, if you Deselect a value it does not re-appear in the selection box. As a workaround, you must save an entry with other contact values and then edit M1 again and select the Applicant Contact Value .
25084; [00051037, 00052759, 00056925, 00058862]	Assembly	Deleting large applications or removing multiple sequences from a lifecycle can take much longer than expected to produce results.
20270; [136797FW]	Assembly	Links for External Bookmarks are incorrect for split documents in paper published output.

Calyx RIM Registrations

Issue	Affected Area	Description
26821	Update Application wizard	Trying to update the UUID field in the <i>Update Application</i> wizard resulted in the <code>MetaField [submittorId] does not exist in MetaClass</code> error message. This issue exists for the Applications of MAA type with the EU CTR Procedure type and will be resolved in Calyx RIM 7.2. Workaround: Update the UUID field using <i>Edit on Application Attributes</i> page.
26818	Global Project Plan wizard	When you run the <i>Global Project Plan</i> wizard for the Clinical Trial Project Type with the Create New Event for Existing CTA and/or IND Application(s) option and get to <i>Select CT Shared Data</i> , select a value and click <i>Next</i> , it takes a long time to proceed further. This performance issue will be resolved in Calyx RIM 7.2. Workaround: Wait for the wizard to proceed.

Calyx RIM Outlook add-in

Issue	Affected Area	Description
DE26820	Outlook add-in form	You cannot attach the following items from an e-mail in the add-in forms: <ul style="list-style-type: none"> – Contact - .vcf – Calendar (Event) - .ics – Outlook e-mails - e-mails without an extension (e-mail chain, single e-mail, and composed e-mail)
DE26804	Outlook add-in form	When using the API GET request for retrieving the recipients from Microsoft Graph, if the search criteria contains a space, the following error is shown: <code>500 Internal Server Error</code>
DE26803	Outlook add-in form	In the Add Notification Recipients field, it is not possible to delete any spaces.
DE26782	Outlook add-in form	If more than 50 users try to submit a form, the system fails and an error is displayed.

Issue	Affected Area	Description
DE26781	Outlook add-in form	When an API request with invalid product id is sent for CreateSubmissionAndReference, an incorrect error message is displayed.
DE26738	Outlook add-in form	If Calyx RIM Outlook add-in fails to submit the forms, an incorrect error message is displayed.
DE26731	Outlook add-in form	An auto-populate functionality does not work for the Product field in the Calyx RIM Outlook add-in forms if the product name starts with an article. Example: "The Product 01", "A Product 123" In the Calyx RIM Outlook add-in forms, the auto populate does not work for product unless more than 3 characters are typed.
DE26715	Tool Box and Activity History	When using the Calyx RIM Outlook add-in desktop version on Windows 10, version 2004 and Outlook version 1908, it is not possible to click the Export button on the <i>Activity History Analysis</i> page.
DE26711	Add-in meta overrides	Trying to change the Calyx RIM Outlook add-in icon takes longer time than expected.
DE26704	Outlook add-in form	Empty text files cannot be attached using the Browse File button.
DE26703	Add-in meta overrides	In the Calyx RIM Outlook add-in desktop version, even after restarting the Microsoft 365 Outlook, the system fails to override the "Liquent InSight" launch icon.
DE26702	Outlook add-in form	When trying to attach the files for the Calyx RIM Outlook add-in forms, ToolTips are not displayed for the following: <ul style="list-style-type: none"> – Attach from email button – Browse files button – "No available items to attach" ToolTip when all the attachments are already attached

Calyx RIM Rendering

Issue	Affected Area	Description
DE26968 (Added on the 23rd of December, 2021)	Assembly	The assembly files cannot be published to Documentum if their size is 800 mb and more. The distribute job request fails. Workaround: Ensure that the size of the assembly files is less than 800 mb.
DE28324; [TASK0043134, INC0109855] (Added on the 12th of August, 2022)	Assembly	Publishing to some printers may result in tab text misplacement.
DE26794	Assembly	When eCTD assembly is published, the validation messages from the backbone generator are not displayed in Job Requests Details.

Clarification of Behavior: Calyx RIM 7.2

This section provides an explanation of functionality that may be interpreted as an issue, but is in fact working as designed. All explanations contained here will be added to the product documentation at the earliest opportunity.

Calyx RIM: Common

Issue	Affected Area	Description
N/A	N/A	After migrating to Calyx RIM 7.2, the following user settings are reset to default for the migrated users. <ul style="list-style-type: none"> – Assembly tree width – Product Details Set tree width – Home page side panels width and show/hide condition – Home page widgets show/hide condition – Columns width – Columns order – Columns sort order – Columns show/hide condition – DMS Browse window size
N/A	N/A	After migrating to Calyx RIM 7.2, Public or Private queries saved in the Calyx RIM 6.2 query list will not be available in the Calyx RIM 7.2 query list for the migrated and newly added users.
N/A	Assembly	Performing any actions from Calyx RIM 6.2 CHF 1 against a Veeva repository on limited release version 18R2.2 will result in an exception caused by an unexpected error response from Veeva Vault. If you experience this issue, please contact Veeva Support .
N/A	N/A	If you are using network security products to scan your local intranet hosts for vulnerabilities, be aware that these products have a specific scan used against a JBoss server at TCP/IP port AJP/8009. Scanning the Calyx RIM server with a network security product will cause an outage, requiring a restart. To avoid issues caused by network security scanning products, see <i>Firewall Rule for TCP_IP Port AJP_8009</i> in the Calyx RIM Installation Guide.

Issue	Affected Area	Description
26746	Application	In D2, the application_description attribute value is a concatenation of Application Code, and Application Name and separated by a hyphen. The application_description attribute value does not contain the Family Code. This is because of the decoupling of Product Family and Product from Application.
26740	N/A	With the value for user.device.limit set to 1 in the insight.var file, when a user is logged on to InSight on device one, logging on to a second device terminates the InSight session on device one. However, refreshing the page on device one displays the InSight Home page. This is because of the Azure SSO functionality.
26727	N/A	When a user is not included in the mapping list during the migration process, attempting to reassociate the user with a group can cause an “Invalid Reference” error. The error indicates the user profile is corrupted and Azure AD does not recognize it for synchronization.
26518; [INC0028282, CS0199557]	N/A	When using the Google Chrome or Microsoft Edge web browsers, selecting documents in the <i>Browse Documents > Assign Document</i> window sends the <i>Browse Documents</i> window to the background (behind the Assembly window), making a user activate the window for subsequent document assignment.
26418	N/A	Duplicating Browser Tabs: Prior to Calyx RIM 6.2 CHF 3, duplicating a browser tab of an active Calyx RIM session DID NOT require login for the duplicated session created on the new tab. From Calyx RIM 6.2 CHF 3 onward, duplicating a browser tab of an active Calyx RIM session WILL require login for the duplicated session created on the new tab.
24513	Assembly	When searching against a Veeva repository using DMS Search in Calyx RIM, an error may appear about exceeding the API calls limit. By default, Veeva Vault has an API burst limit of 2,000 API calls within a 5-minute period, and 100,000 API calls daily. These limits help to prevent runaway script scenarios (e.g. where the logic creates an infinite loop that continuously calls the Vault APIs). To request an increase to this limit, please contact Veeva Support .

Calyx RIM Publisher

Issue	Affected Area	Description
N/A	Assembly, Technical Administration	When an assembly is created from an assembly file, the locations included in the assembly file that do not match the repositories in Calyx RIM Technical Administration will not be saved.
DE28529	Data Administration (SPOR Master List)	For Calyx RIM 7.2, after the migrated build is installed, the values for the new SPOR Master Lists tables may not appear. This was determined to be a data setup error. This issue can be resolved by starting the synchronization process from the beginning. The architecture requires that the database and blob data are in sync and replacing a database or blob from another environment will cause issues.
DE27968	Assembly	When the length of the output path exceeds the limit allowed by the operating system, publishing fails. This issue can be resolved by shortening the folder or leaf output names in assembly.
26732	Publishing Settings library	In Internet Explorer only, the <i>Link Inspector</i> report page is not refreshed when Edit Link Output Channel is performed. The change is reflected after clicking the Refresh button in the report. The <i>Link Inspector</i> report page refreshes as expected in Microsoft Edge or Google Chrome.

Index

C

Clarification of Behavior [15](#)

N

New Features [1–6](#)

R

Release Notes [9](#)

Resolved Issues [7](#)