
Calyx RIM Release Notes

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Calyx RIM 7.0

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Calyx RIM 7.0.

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

Note: Unless stated otherwise, this platform release provides the same functionality and regulatory updates as Calyx RIM 6.2 CHF 6 and Rendering 4.4 CHF 2.

New Brand: Calyx RIM

Calyx RIM was formerly Liquent InSight suite. While the rebranded names of products and components may appear in the user documentation, the rebranded software user interface will appear in future releases.

SSD Updates

- All IdPs are supported only via federation with Azure AD
- Introduction of SCIM support
- Azure Files/Sync support provides the ability to connect to an on-premises fileshare for seamless transfer of files (bi-directional) and optimal publishing performance.

Calyx RIM 7.0 introduces support for the following versions of Documentum REST API:

- 7.2
- 16.4
- 20.2

Note: Registrations Forms integration with D2 uses DFS 16.4.

Calyx RIM on Microsoft 365

Calyx RIM 7.0 introduces the Outlook add-in, a separately licensed, subscription-based add-in that integrates with Microsoft Outlook. This integration enables workflows to help you create submission and reference records in Calyx RIM directly from Microsoft 365 Outlook.

Analytics with Power BI

Calyx RIM 7.0 provides updated reporting schema supporting datasets for reports using Power BI. The following OOTB reports and datasets are available with this release:

- Associate Licenses Marketing Status
- RMP Report
- PSMF Annex H Report
- PSUR WMAS Report

- Worldwide Registrations & Events Reports
- XEVMPD Status

Queries

The following queries are moved from WebFocus Analytics to Querying in Calyx RIM 7.0:

- XEVMPD Submissions - QC Verification and Audit
- XEVMPD Submissions and Acknowledgements

Product Family Enhancements

With Calyx RIM 7.0, Applications can be associated to Products from different Product Families enabling the tracking of all relevant Products within a single application. This change enables you to capture the process, product, and submission data under a single application.

Publishing

Performance improvements	<ul style="list-style-type: none"> — Increased speed when preparing a publishing ticket for a submission that has many leafs without content — Increased speed when preparing a publishing ticket for a submission that has many Native leafs
Usability and functional improvements	<ul style="list-style-type: none"> — Ability to select multiple volumes and delete them in bulk — Ability to select which indication section to add a study to via Study Report wizard — Support for Extended Range Unicode Characters for publishing requests, rendering, and text recognition <p>Publish request screen:</p> <ul style="list-style-type: none"> — Default values can be configured via overrides — Only Default values can be configured via overrides — Only options applicable to a selected Publish type (Electronic/Paper) are available for selection — Selected options are preserved for an assembly and auto-populated next time publish request is invoked

Functionality and Technology Removed

- Analytics module based on WebFocus.
- SharePoint and Open Text Content Server (Livelink) DMSs support.
- Integration with Documentum via DFC.
- Ability to toggle Kendo/non-Kendo pop-up windows.
- Rendering support for Microsoft Project and Microsoft Visio.
- Rendering from the Documentum queue. Rendering from within Calyx RIM UI is still available.
- Validation against dtd/xsd during publishing.

- Add User/Group Wizard is removed. (Azure Active Directory is the supported Identity Provider Type for Calyx RIM. PingOne, Okta, and LDAP IdPs are supported via federation with Azure AD only.)

All IdPs are supported only through federation with Azure AD. The following functionality is removed:

- Direct integration with Okta, PingOne, LDAP
- Change password

Additional Components

These components are available via the Calyx RIM 7.0 platform or as on-premises installations:

- Rendering 5.0 - *formerly InSight Rendering*
- Viewing 5.5 CHF 6 (5.5.0.6.0015) - *formerly InSight for Viewing*
- Validator 5.1 CHF 9 (5.1.0.117) - *formerly InSight Validator*
- Linking plug-in (PDF) 1.8 CHF 1 + (hotfix 1.8.1.4) - *formerly SmartLink for PDF*
- Linking add-in (Word) 1.8 CHF 1 + (hotfix 1.8.1.4) - *formerly SmartLink for Word*
- Cumulative View Builder 2.3 (2.3.0.2)
- Authoring and QC plug-in (PDF) 4.2 CHF 1 (4.2.0.42) - *formerly SmartDesk for PDF*
- Authoring add-in (Word) 3.2 CHF 2 (3.2.022) - *formerly SmartDesk for Authoring*

Prerequisites

The users and groups who will be using the Calyx RIM 7.0 system should have their accounts created in Azure AD and provide the User Object IDs for the User migration phase.

Note: For data migration and installation assistance, please contact your Business Development Representative.

API Updates

The Calyx RIM 7.0 includes multiple API updates including the update for Product Family decoupling. Changes between the InSight 6.2 API and the Calyx RIM 7.0 API are documented in the *Calyx RIM 7.0 Administration* and *Calyx RIM 7.0 Data Exchange* guide. See: *Calyx RIM 7.0 Administration > Technical Administration > Calyx RIM API Documentation* and *Calyx RIM 7.0 Data Exchange > Data Exchange API > Data Exchange API Document > Calyx RIM 7.0 Data Exchange Change*

New in Calyx RIM: Common Functionality

This table shows new features and enhancements of common Calyx RIM functionalities.

Decoupling Product Families and Products from Applications

Product Families and Products are decoupled from Applications. This change provides the ability to create and maintain an application for products residing in different product families.

Affected Area	Update	Benefit
<p>Home page:</p> <ul style="list-style-type: none"> – Search menu results – Find menu results <p>Navigation:</p> <ul style="list-style-type: none"> – Product Family tree – Countries tree 	<p>Based on the relationship updates between an Application and Product Family, the menus are updated with additional columns and fields, some existing columns and fields are renamed or removed.</p>	<p>Additional context is provided when the user selects Products for the Application.</p>
Entity Product tabs	New columns are added for Family Code, Family Type, and Family Name.	Updated functionality provides additional context when records are shown.
Wizards	<ul style="list-style-type: none"> – Since the Create Application icon was removed from the Applications tab on the Product Family, you can only create an Application from the <i>Create Application</i>, <i>Create Submission</i> (Initial Application) or <i>Global Project Plan</i> (Create Application) wizards. – The Product Families filters are removed from the following wizards: <i>Create Submission</i> (Initial Application) and <i>Create Application</i>. – The Global Project Plan wizard (Create Application) still enforces creation of an application within one Product Family. 	<p>The system presents a variety of efficient wizard alternatives to replace creating an Application under the Product Family.</p>
Global Project Planning	Global Project Plan wizards still support the Product Family Type filter for all project types.	Bulk creation and update of entity records.
Product selection widget	<ul style="list-style-type: none"> – New columns are added for Family Code, Family Type, and Family Name. – You can associate any Product to an Application, regardless of the Product Family, except for products with the status of Not Approved or Withdrawn. 	<p>This change provides additional clarity and flexibility when associating Products.</p>

Affected Area	Update	Benefit
Entities	<p>A new rule enforces Product Family uniqueness from the Family Name.</p> <p>A new rule is added to enforce Application uniqueness when you create, update, or copy an application in the Calyx RIM system.</p> <ul style="list-style-type: none"> – CTA Application type: <i>Application Code + Study Number</i> – Non-CTA Application type: <i>Application Code + Application Name</i> 	<p>With the ability to associate any Product to an Application, this change provides new uniqueness rules to identify entities within the new data model.</p>
Querying	<p>To conform to Product Family decoupling, Queries now include:</p> <ul style="list-style-type: none"> – Updated Product Family field names – Additional Product Family and Product columns – Changes to security logic in the database 	<p>Aligned Querying capabilities with the updated data model.</p>
Security Administration	<p>For a user to have access to an Application that is associated with multiple Product Families, that user should be configured to have access to at least one Product Family associated with the Application.</p> <p>An administrator can now grant user access to Entity Security > Products for SPT, ELP, and PRP users.</p> <p>Azure Active Directory is the supported Identity Provider Type for Calyx RIM 7.0. PingOne, Okta, and LDAP IdPs are supported via federation with Azure AD only.</p>	<p>Security Administration functionality is updated to align with the updated data model.</p>
Security enhancement	<p>The full exception error messages will not be shown on the screen. For more information about security errors, check the <code>server.log</code> file.</p>	<p>This change enhances security and prevents potential infringement of vulnerable data.</p>

Affected Area	Update	Benefit
Technical Administration	Superuser credentials saved in the database are now encrypted when: <ul style="list-style-type: none"> – A new repository is added (Technical Administration > Repositories) – An existing repository is updated 	Repository passwords are now stored securely.

New for Analytics and Reports

Starting with Calyx RIM 7.0, Calyx RIM provides Analytics with Power BI for analytics and reporting. You can access any data source and unify data from these sources to create interactive, multi-directional dashboards and reports. See: [Power BI](#) website.

Affected Area	Update	Benefit
I Want To Go To	<ul style="list-style-type: none"> – My Reports – Favorite Reports 	These menu options are no longer needed and are removed.
Security Administration	Entity Security section <ul style="list-style-type: none"> – Ad hoc Reports – Reports 	These configuration settings are no longer needed and are removed.
	Home Page access <ul style="list-style-type: none"> – Reports 	This configuration setting is no longer needed and is removed.
Technical Administration	Your administrator can create the link to the Analytics with Power BI system in the Calyx RIM user interface for access to the out-of-the-box reports.	You can access out-of-the-box Analytics reports and provide a visual representation of Calyx RIM data.

New in Publishing

This table shows new features and enhancements of publishing functionality.

Affected Area	Update	Benefit
Publish Request	<p>The <i>Publish Request</i> window now shows options based on the publishing output channel value (Electronic or Paper) and the assembly type.</p> <p>The <i>Publish Request</i> window shows the publishing output channel options based on the last selected publishing output value. For example, if you select Electronic as the publishing output channel value, the next time you initiate the <i>Publish Request</i> window, the Electronic output channel options are shown by default.</p> <p>If you have permission for only one publishing output channel, only those options that are relevant to that output channel are available.</p> <p>In the <i>Publish Request</i> window, the Selected Leaf Elements option is now selected by default for the Publish eCTD/Electronic section. It is now possible to override default values for some of the fields. See: <i>Entity Fields and Columns Updated: Calyx RIM</i></p>	<p>The contextual design minimizes redundant actions that were required to be performed previously. This improves the efficiency of working with the application and provides a better user experience.</p>
DMS Repository	<p>When different versions or renditions of a document in a DMS Repository are assigned to assemblies, the rendition identifier of each document is considered for displaying specific content, page count, links, and bookmarks of the assigned document in Calyx RIM.</p>	<p>This change lets the system maintain a separate set of extractions for each rendition of the source document.</p>
Create Study Reports	<p>The option Update the sub-folder structure for 5.3.5 Reports of Efficacy and Safety Studies is now included in the <i>Create Study Reports</i> wizard.</p>	<p>This option lets you add study reports to specific Indication folders.</p>
Volumes	<p>In an assembly, you can select multiple individual volumes or select a volume range to delete them simultaneously. You can use the context menu to delete the selected volumes in bulk.</p>	<p>The bulk delete functionality improves the efficiency of deleting multiple volumes.</p>
Rendering	<p>Extended Range Unicode Characters for publishing requests, rendering, and text recognition are now supported.</p>	<p>Calyx RIM can now process Extended Range Unicode Characters.</p>

New in XEVMPD

New features and enhancements broadly categorized under XEVMPD are listed in this table.

Affected Area	Update	Benefit
Reporting	The query XEVMPD Submissions - QC Verification and Audit has been added under <i>Registration Planning and Tracking</i> .	The XEVMPD Submissions - QC Verification and Audit query provides XEVMPD data associated with a particular Authorised Product for QC assessment. You can now access this report directly from within Calyx RIM.
	The query XEVMPD Submissions and Acknowledgements has been added under <i>Registration Planning and Tracking</i> .	The XEVMPD Submissions and Acknowledgements query provides XEVMPD acknowledgement files information, including 3rd Acknowledgement Types with the description of the proposed changes from EMA. You can now access this report directly from within Calyx RIM.

New in Calyx RIM on Microsoft 365

Calyx RIM 7.0 introduces the Outlook add-in, a separately licensed, subscription-based add-in that integrates with Microsoft Outlook. This integration enables workflows to help you create submission and reference records in Calyx RIM directly from Microsoft 365 Outlook.

Affected Area	Update	Benefit
Calyx RIM Add-in for Outlook	The Add-in displays the following: <ul style="list-style-type: none"> — Create Submission Workflow — Create Submission and Reference 	Enables automation of common business processes from Outlook to Calyx RIM, such as creating a sequence and reference for an application.
Calyx RIM API integration	Calyx RIM Outlook add-in is integrated with, and consumes information about overrides via, the API. For more information, contact your Business Development Representative to consult with our Client Enablement team.	Calyx RIM entity meta data is available via Outlook.

Affected Area	Update	Benefit
Overrides	Calyx RIM Outlook add-in integrates with the API to support overrides applied to Calyx RIM. Dynamically rendered forms can contain fields specified in the Create Submission Workflow/Create Submission and Reference sections, along with the overridden required fields. For more information, contact your Business Development Representative to consult with our Client Enablement team.	Supports configuration of overrides to include extra fields, data types, required/not-required information, possible values, and any other applicable data customization. The dynamic user interface makes it possible to display specific UI elements for each customer based on the configured overrides.

New in Data Exchange

This table shows new features and enhancements of Data Exchange functionality.

Affected Area	Update	Benefit
Data Exchange	The Application Name field size is increased to VARCHAR2(2000) for the Data Exchange API and the Calyx RIM API.	The Application Name field can now accommodate longer names.

List of Enhancements: Calyx RIM 7.0

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Calyx RIM: Common

Issue	CHF/Hotfix Build	Description
26698	6.2.0.6.0022	This change enables the selection of the EU National 3.0.3 template for the Great Britain and United Kingdom regulatory regions when using the Create eCTD Wizard.
26688	6.2.0.6.0022	The Application UUID is now unique within a regulatory region, instead of being unique within the system.
26682	6.2.0.6.0022	The XEVMPD Wizard is updated to support the EMA XEVMPD requirement for BREXIT to generate 'XI' as the Authorisation country code in the EVPRM message for all United Kingdom registrations.
26681	6.2.0.6.0022	The UUID field is now visible on the application page for the countries of Great Britain and United Kingdom regions.
26674	6.2.0.6.0022	The United Kingdom country is now available for selection in the Country field in the Authorized Product Selection tab of the <i>XEVMPD Submission</i> wizard.
26644	6.2.0.6.0007	It is now possible to withdraw a country from Centralized Procedure (CP) applications via the Product Details Set . The withdrawn country is not available to associate with a subsequent Event (Countries list) created for the same Application.
26542	6.2.0.5.0055	For EAEU submissions, you can now auto-populate the Output Folder with metadata values from Solvent and Drug Substance extensions.
26541	6.2.0.5.0055	You can now include Solvent metadata for EAEU submission XML.
26519; [PRB0040530]	6.2.0.5.0055	When diagnosing issues that required a restart, the <code>data_exchanger.log</code> and <code>server.log</code> files were cleared out after the restart. The configuration has been modified to prevent the log files from being cleared out after restart, and messages are continually added to the existing log files.

Issue	CHF/Hotfix Build	Description
26512	6.2.0.5.0055	Mass Update Properties was available for Calyx RIM with the Submission Planning and Tracking (SPT) license, but not with the Electronic Lifecycle Publishing (ELP) license. Mass Update Properties functionality is now available for clients with ELP licenses.
26496; [INC0025048]	6.2.0.5.0055	When creating a new working assembly using the Create eCTD wizard in an EU MRP application, the country metadata for the subsequent countries is copied as the default country metadata from the first country page except for the Agency name, Applicant, and Invented Name values even if a new country was added to the application.
26480; [INC0023770]	6.2.0.5.0055	In Data Administration > Other Maintenance > Indications/Intended Use Values , you can use the Mass Update feature to update a MedDRA Version for multiple Indication/Intended Use values.
26450; [CS0092205]	6.2.0.5.0055	Memory usage is optimized when publishing very large submissions in Calyx RIM.
26437	6.2.0.4.0079	To prevent instances when Calyx RIM could freeze due to an unstable connection to the Veeva DMS, the following timeout values have been added to the <i>insight.var</i> file for connections to the Veeva DMS: <ul style="list-style-type: none"> veeva.api.connect.timeout - The maximum number of milliseconds the application will wait when attempting to establish a connection to a Veeva vault. veeva.api.read.timeout - The maximum number of milliseconds the application will wait for a response from Veeva after a connection has been established to a Veeva vault. <p>If these parameter values are not included in the <i>insight.var</i> file, the respective timeouts will be equal to 30 seconds (veeva.api.connect.timeout) and 60 seconds (veeva.api.read.timeout).</p>
26421	6.2.0.4.0079	The updated 510k and PMA assembly templates are included in this release.
26416	6.2.0.5.0055	The new List of Events with Change Details query enables you to view events that are associated with change, change details, and event change details.

Issue	CHF/Hotfix Build	Description
26387	6.2.0.5.0055	The uniqueness constraint for the EudraCT Number on a protocol is removed. A study or the clinical trial shared data can now include a redundant EudraCT Number.
26380	6.2.0.4.0079	<p>Job Request messages include these updates:</p> <ul style="list-style-type: none"> – The Job Message text is formatted with line breaks. – Errors displayed in the Job Message column are presented in bold text. – The descriptions of rendering errors are presented in bold text. – The Backbone Generator text that starts with <code>ERROR:</code> is presented in bold text, starting from <code>ERROR:</code> up to the line break.
26360	6.2.0.4.0079	On the home page, you can choose to show or hide specific product families from the Product Family navigation tree.
26359	6.2.0.5.0055	You can automate the inactivation of registration attachments once the corresponding acknowledgment is received via the XEVMPD Acknowledgement wizard. This option can be configured through application setup. By default, the option is disabled. These updates will not appear in the XEVMPD Audit Report .
26356	6.2.0.5.0055	Extra fields can be updated in bulk on the Event Change Detail when the Details are associated to the Event via the Project > Associate Change Detail(s) to Events wizard. For details, please contact your Business Development Representative to consult with our Client Enablement team.
26355	6.2.0.4.0079	On the Entity Audit Trail of the Administration tab, you can now query the following entities: <ul style="list-style-type: none"> – Change – Change Details – Event Change Details
26354	6.2.0.5.0055	The new System Process Default Flag provides the ability to assign multiple display statuses to the same Internal System Status in <i>Data Administration</i> for Application, Event-Change Detail, Product, Product Detail Set, and Sequence. You can now see the assigned status after running the wizard or when the Event is closed manually.

Issue	CHF/Hotfix Build	Description
26353	6.2.0.4.0079	The Event-Change Detail associations logic is changed. Now, the logic is based on the individual Event-Change Detail Status . If there are multiple Change Details associated with one Event and one of the Change Details has a status of Not Approved or Withdrawn , it will be available for selection even if the overall Event is closed as Approved .
26348	6.2.0.4.0079	The number of Veeva API calls has been significantly reduced for Expand Tree , Assign Binder , and Assign Document actions in DMS Browse/Search .
26345; [INC0014459]	6.2.0.4.0079	The performance of the <i>XEVMPD Submission</i> wizard is improved.
26321; [INC0013546]	6.2.0.5.0055	It is now possible to create a folder or a leaf with an extension other than Default and extended attributes populated using a single API call.
26315, 24020, 22557; [00063191, 00041781, 00053012]	6.2.0.4.0079	When assigning documents from DMS, the leaf name and the output file name used for documents required revisions. It is now possible to define customized leaf and document attributes in the <code>propertyMappings.xml</code> file and use them when documents are assigned from DMS or File Share.
26314; [00064910]	6.2.0.4.0079	The ability to create, update, activate, or deactivate Package Category and Package Type values in Data Administration using the API is added.
26289; [INC0012144]	6.2.0.4.0079	Assigning Veeva sections caused the API burst limit to be exceeded. The number of Veeva API calls for assigning the Veeva document sections has been significantly reduced.
26265	6.2.0.5.0055	You can identify when any SPOR Maintenance value was created and by whom. These fields are added: <ul style="list-style-type: none"> — Created By — Created Date
26264	6.2.0.5.0055	You can identify when any Data Administration value was created/last modified and by whom. These fields are added: <ul style="list-style-type: none"> — Last User Updated — Last Changed Date
26204; [00064468]	6.2.0.5.0055	The full field value can be viewed in Data Administration when you create or modify the pick list.

Issue	CHF/Hotfix Build	Description
26200; [00064469]	6.2.0.4.0079	The RMS Term Name field now appears as a column in the grid view for these <i>Data Administration</i> tables: <ul style="list-style-type: none"> – ATC Values . – Compendial Designation/Source Values. – Concentration Measure Type Values. – Country Values. – Denominator Unit Values. – Numerator Unit Values. – Dosage/Pharmaceutical Form Values. – EMA Authorisation Status Values. – Language Values. – Legal Basis Values. – Medical Device Values. – Medicinal Product Type Values . – Procedure Type Values – Route of Administration Values – Unit of Measure Prefix Values
26181; [00063727]	6.2.0.4.0079	Calyx RIM 7.0 enables you to configure a field of comma-separated values for use as search criteria in DMS Search , for Documentum only. This configuration can be applied to most of the text-like document attributes for Documentum. Please contact your Business Development Representative to consult with our Client Enablement team.
26158; [00064073]	6.2.0.4.0079	The Calyx RIM API authentication process is enhanced to incorporate the LDAP configuration parameters defined in the <code>insight.var</code> file.
26136; [00063706]	N/A	The List of Events with Change Details report is introduced to support querying of Change/Change Detail/Event Change Detail entities with extra fields. Also, the Entity Audit Trail report now supports querying of Change/Change Detail/Event Change Detail.
26099; [00063341]	6.2.0.4.0079	When a new working assembly is created under an application that includes unlifecycled assemblies, the warning message: "An unlifecycled working Assembly already exists for this Application under the following sequences:" shows the sequence codes for the working assemblies (with hyperlinks).

Issue	CHF/Hotfix Build	Description
26081; [00063116]	6.2.0.4.0079	Calyx RIM 7.0 supports the International Medical Device Regulators Forum (IMDRF) assembly templates for Health Canada.
25991, 24795, 23817; [00060791, 00060643, 00047556, 00039935]	6.2.0.4.0079	When working with Study Tagging Files (STF), generic updates to extensions and extension attributes had to be made for each STF individually. It is now possible to update extensions or extension attributes for STFs in bulk using the Mass Update Properties feature.
25963 [00060633, 00054727]	7.0.0.0.0100	The Calyx RIM error messages are revised to make them accurate and easy to follow. When Calyx RIM displays an error, you can go to the <code>server.log</code> file to get more details.
25954; [00060145]	6.2.0.4.0079	In the <i>XEVMPD Submission</i> wizard, the Authorised Product section error messages have been revised for clarity. See: <i>XEVMPD Error Messages for Authorised Product</i> in the online help.
25795; [00058695]	6.2.0.4.0079	To improve the user experience, the XML Definitions field is added to the Publish Request window.
24532, 20873; [00044627, 00037898]	6.2.0.5.0055	New job statuses are introduced for Job Requests: <ul style="list-style-type: none"> – Completed with Errors – Completed with Warnings
24325	6.2.0.5.0055	Calyx RIM now retains the site folders in M5 after importing the study reports as node extensions.
24222 [00041913]	7.0.0.0.0100	In the <i>Publish Request</i> window, the Selected Leaf Elements option is now selected by default for the Publish eCTD/ Electronic section.
23946, 23842; [00039378, 00039725]	6.2.0.4.0079	When modifying the metadata (for example, 2.3.S, 2.3.P, Node Extension) in an assembly, each node had to be revised and updated individually. With the Mass Update Properties feature you can revise and update the metadata revisions in bulk.
23632; [00038044]	N/A	The option Update the sub-folder structure for 5.3.5 Reports of Efficacy and Safety Studies is now included in the <i>Create Study Report</i> wizard, to add study reports to specific Indication folders.

Issue	CHF/Hotfix Build	Description
23803 [00039687]	6.2.0.5.0055	In an assembly, you can now update the Folder or Leaf extension value from the Change Type > Extension without switching to the Default value.
22824; [00030514, 00043876, INC0013821]	6.2.0.4.0079	When assigning multiple documents from DMS or a File Share, leafs were created with the name of the file along with the file extensions. It is now possible to define leaf and document attributes without extensions in the <code>propertyMappings.xml</code> file and use them when documents are assigned from DMS or a File Share.
22581; [00026219]	6.2.0.4.0079	When assigning documents, if the leaf title field was blank, the value for it was not retrieved from a DMS. It is now possible to define a leaf title value that is taken from a source document in the <code>propertyMappings.xml</code> file.
20209 [131037FW, 00041581]	7.0.0.0.0100	You can now delete more than one Volume at a time from an Assembly using the Ctrl or Shift key.
20108; [129625FW]	7.0.0.0.0100	To improve the user experience, the <i>Publish Request</i> window now shows only the required fields that are related to the selected Publishing Output Channel . You can now view/select all the Publishing Output Channel settings without scrolling.

Rendering

Issue	CHF/Hotfix build	Description
4977	4.4 CHF 2	A new method of Retrieve request and two new methods of backbone-generator request are introduced with this release to support: <ul style="list-style-type: none"> — eCTD import of EAEU submissions with PDFs embedded into XML — the process of EAEU submissions generation with PDFs embedded into XML

Resolved Issues: Calyx RIM 7.0

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 previously released certified hotfix (CHF), that CHF build number is included.

Calyx RIM: Common

Issue	CHF/Hotfix Build	Description
26738; [INC0056197]	N/A	For some of the OOTB and extra fields of the newTextAreaView and adminTextAreaView types, the length limit was broken in the UI and after entering, the system showed only 50 characters in the UI. This issue is resolved. Length in the UI is fixed and corrected for the OOTB and extra fields to show more than 50 characters.
26675	6.2.0.6.0022	Timeline/Event Plans did not work as expected when adding or removing a country from an existing Event Plan for MRP, DCP, or CP Procedure Types. Countries already associated with the existing Timeline/Event Plan were incorrectly listed in the Countries Available box and were not available in the Copy Default Lead Times from the following Country drop-down list. Also, when deleting countries from an Event Plan, no countries were listed in the Associated with Plan area. These issues are resolved to support the EMA XEVMPD requirement for BREXIT.
26673	6.2.0.6.0022	When Northern Ireland (XI) was added to the EU Region in Data Administration, the XEVMPD wizard did not recognize it and showed a warning message. This issue is resolved. The new Northern Ireland country is recognized as an in-scope country with a country code of XI for an XEVMPD submission to support the EMA XEVMPD requirement for BREXIT.
26672	6.2.0.6.0022	Northern Ireland could not be associated as a Registration Package set entity when added to the Product Detail Set, so country package set marketing information can be entered for EU CP Applications. This issue is resolved. Northern Ireland is associated as a Registration Package set entity when added to the Product Detail Set to support the EMA XEVMPD requirement for BREXIT.

Issue	CHF/Hotfix Build	Description
26620	N/A	The security issues related to the following vulnerabilities are addressed in this release: <ul style="list-style-type: none"> – XSS (Cross Site Scripting) – SSRF (Server Side Request Forgery) – FPT (Field-programmable Technology)
26619	6.2.0.6.0007	The System Process Default Flag was not available for Registrations > License Status . A workaround required you to use only one display status (not multiple) mapped to one Internal System Status value. This issue is resolved.
26617; [INC0037885]	6.2.0.4.0079	Some words could not be saved, for example <code>monkey</code> in a text field, and an error message about invalid characters appeared. This issue is resolved. Words now can be saved to any text field in Calyx RIM 7.0 when <code>enableXssFilter</code> is set to <code>true</code> in the <code>securityConfiguration.xml</code> file.
26608; [INC0038408]	6.2.0.5.0055	After migrating to Calyx RIM 6.2 CHF 4, clicking the Concerned Parties icon resulted in an error. This occurred if the domain of a user was changed and there was a NULL value for that user in the Domain column in the SEC.USR table. This issue is resolved.
26604; [INC0037291]	7.0.0.0.0100	When a session was timed-out, trying to perform an activity resulted in the error message <code>You do not have the appropriate privileges to access the requested resource</code> . This issue is resolved. Now, if you try to perform an activity when a user session is timed-out, the user session will be restored.
26565; [INC0033560]	6.2.0.5.0055	Calyx RIM did not recognize some users as members of their assigned Active Directory (AD) groups. This issue is resolved.
26486; [INC0024081]	6.2.0.5.0055	If an application had an <code>Active</code> or <code>Not Approved</code> or <code>Withdrawn</code> status, and the application had a registration with a status other than <code>Withdrawn</code> , it was not possible to update an event with <code>Withdrawn</code> status. This issue is resolved.

Issue	CHF/Hotfix Build	Description
26477; [INC0023763]	N/A	After Product Family information with its metadata was updated and then moved from Calyx RIM to D2 LSRD, subforms on the <i>Properties</i> tab were empty for the Application in D2 LSRD. When the Application information was updated separately in Calyx RIM, subforms on the <i>Properties</i> tab contained the appropriate information. This issue is resolved. The <i>Properties</i> tab of D2 LSRD Application shows correct information when you update a Product Family or an Application in Calyx RIM.
26476; [INC0029689]	6.2.0.6.0007	After the Product Family information and metadata were moved from Calyx RIM to D2 LSRD, making changes to Product Family Indications/Intended Use in Calyx RIM resulted in the deletion of the Submission Country value from D2 LSRD. In Calyx RIM, the application continued to display the Reviewing Country . This issue is resolved and the D2 LSRD shows all of the necessary information.
26449	6.2.0.5.0055	An InSight API request to retrieve a list of assemblies for assembly types other than templates did not work. This issue is resolved.
26402; [INC0017878]	6.2.0.5.0055	When an event was closed with a reason using the Specify Reason for Termination/Withdrawal option, the same reason was applied to the parent application. This issue is resolved.
26397, 24517; [INC0017263, 00044443]	6.2.0.5.0055	When deleting an assembly, there was no indicator to show the progress of the deletion process. This issue is resolved. A progress indicator shows that the deletion is in progress.
26388; [INC0016307]	6.2.0.4.0079	In the Create Submission wizard Sequence Code field, despite entering a code of four digits as recommended, this message showed: <code>If this is an eCTD submission it is recommended you enter a four digit sequence code.</code> This issue is resolved. There are no messages when four digits are entered.
26367	6.2.0.4.0079	Calyx RIM retrieved only the first 999 groups when authenticating a user in Azure. As a result, users not in one of the first 999 groups were unable to log on. This issue is resolved. Calyx RIM now authenticates all users in Azure.
26346; [INC0014465]	6.2.0.5.0055	Notifications were not sent even when the <code>mail-service.xml</code> file included a valid SMTP server name and port number. This issue is resolved.

Issue	CHF/Hotfix Build	Description
26339; [INC0014292]	6.2.0.4.0079	<p>Calyx RIM failed to update the following via the API:</p> <ul style="list-style-type: none"> – Historical or future dates in the Event Country Status Schedule – Projected and actual dates in the Sequence Status Schedule <p>These issues are resolved. You can now insert historical or future dates in the Event Country Status Schedule and the current actual date in the Sequence Status Schedule.</p>
26323; [INC0013607]	6.2.0.4.0079	<p>If an assembly was created from another assembly, and the source assembly was removed from the system, manually adding an event to the Approved view resulted in the error: <code>The object you are acting on has been deleted or modified by another user.</code> Refresh your object to view the current information. In the Update Status wizard, trying to add an event to the Approved view caused Calyx RIM to freeze and the same error to be registered in the log file. These issues are resolved.</p>
26316; [INC0012933]	6.2.0.4.0079	<p>Starting from Calyx RIM 6.1 CHF 4, the migration to 6.2 and CHFs failed with an ORA error in logs for some customers. This issue is resolved by removing the <code>select * from dv_user_workflow_secure</code> query from the migration package.</p>
26307; [CS0027071]	6.2.0.4.0079	<p>When Calyx RIM was configured to use Single Sign-On via Microsoft Azure, a user disassociated from an Azure group added to Calyx RIM could not be re-associated back to that group. This issue is resolved.</p>

Issue	CHF/Hotfix Build	Description
26287; [00012133]	6.2.0.4.0079	<p>The New menu on the Calyx RIM home page displayed the following options only when access was enabled to more than one of the options in Security Administration. When access was enabled to only one of these options, that option failed to appear under the New menu:</p> <ul style="list-style-type: none"> – System Alert – Publishing Settings Library Template – Change – Registration Attachment <p>This issue is resolved. Now, the New menu shows the option for which the access is enabled in Security Administration.</p>
26278	6.2.0.4.0079	<p>When e-signature was enabled for Azure AD users, the system accepted any user credentials for e-signature instead of the logged-in user credentials. As a result, anyone (including Read-only users) could sign in and save changes. This issue is resolved. Now, only logged-in users can sign in and save the changes.</p>
26210, 25081; [00064119, 00064088, 00063968, 00050671]	6.2.0.4.0079	<p>Veeva users configured to use Single Sign-On (SSO) were unable to access DMS Browse because of authentication issues. This issue is resolved. Configuration for SSO authentication is now added to Calyx RIM for Veeva users. Veeva users can access DMS Browse without authentication errors.</p>
26122; [0063208]	6.2.0.4.0079	<p>A role was not accessible on the Security Administration page if the role had all License Modules settings set to None/Select. This issue is resolved. Now, the No Module Users role is displayed as expected.</p>
25941; [00060258]	6.2.0.4.0079	<p>Unauthorized remote users were able to access Red Hat JBoss EJBInvokerServlet. This issue is resolved by commenting the JBoss <code>EJBInvokerServlet</code> code block in the <code>web.xml</code> file. For more information, see Disabling Unauthorized Users from Accessing Red Hat JBoss EJBInvokerServlet.</p>

Publishing

Issue	CHF/Hotfix Build	Description
26670; [INC0045661]	N/A	When an EAEU submission was published, the output file contained incorrect values in the <code><hcsdo:RegistrationFileIndicator></code> tag. This issue is resolved.
26625	6.2.0.6.0007	In the EAEU v 1.0 assembly template, some output folder values were missing and some output file names were incorrect. This issue is resolved. Now, output folder values and output file names are updated as required.
26606; [INC0038763]	6.2.0.5.0055	The Submission Readiness report took longer to generate than usual, and sometimes the report failed to generate. This issue is resolved. Now, the Submission Readiness report generates successfully in less time.
26597	6.2.0.5.0055	When EAEU submissions were published after performing a Delete operation on one or more leafs, incorrect leaf attributes and DocID values were included in the output XML. This issue is resolved. The output contains correct values.
26592	6.2.0.5.0055	The Export Published Output process did not support Cyrillic symbols in filenames when choosing to embed PDF files into the EAEU XML file. This issue is resolved.
26588	6.2.0.5.0055	The Export Published Output process failed intermittently when choosing to embed PDF files into the EAEU XML file when the processed file path included spaces. This issue is resolved.
26583; [INC0023438]	6.2.0.5.0055	If a workflow was associated to the assembly root, a folder, or a document in an initial sequence assembly, and the Synchronize with the Submitted View option was applied, the workflow was lost. This issue is resolved. Associated workflows are kept for each node after the option is applied.
26582	6.2.0.5.0055	The <code>mediaTypeCode</code> attribute was missing from the embedded PDF nodes of the EAEU XML output file. Although this attribute is not required per the schema, the agency validator requires it. This issue is resolved. The <code>mediaTypeCode</code> attribute is now included in the EAEU XML file for embedded PDF nodes.

Issue	CHF/Hotfix Build	Description
26556; [INC0033264]	6.2.0.5.0055	When using the Synchronize with the Submitted View option, the time to synchronize the documents sometimes took longer than usual. This issue is resolved.
26537; [INC0030024,INC0033088]	6.2.0.5.0055	All leaf Titles should have appeared in XML under the following conditions: <ul style="list-style-type: none"> – If a user published all XML from root assembly. – If an assembly had two leafs and one leaf is selected, Title for both leafs had to be published, not for only one. This condition did not work. <p>This issue is resolved. If all the XML is published from the root assembly, or if one of two leafs is selected and published, the system generates equal results in both cases.</p>
26533; [INC0029832]	6.2.0.5.0055	Errors were found when the Publishing Readiness Query was run for the China eCTD. This issue is resolved.
26530; [INC0029543]	6.2.0.5.0055	The Document Creation Date showed the current date, even though no value was specified for that field in the modify mode. This issue is resolved. Now, Document Creation Date displays a date only when the field is populated.
26527, 26226, 25965; [INC0029460, 00064445]	6.2.0.5.0055	The options For this Element and Document were not available on the <i>Update Overlay Settings</i> page invoked from the Document . This issue is resolved.
26502; [INC0025226]	6.2.0.5.0055	Applying the eCTD Import to an AU-3-0 assembly where the Sequence Description attribute had a code values different from those provided by the agency caused the import to fail. This issue is resolved. Now the import ignores the mismatches and takes the code value.
26487; [INC0024292]	6.2.0.5.0055	After importing published GCC submissions, some folders were renamed or missing. This issue is resolved. Now, the imported assembly keeps the original structure.
26469; [INC0023438]	6.2.0.5.0055	If a Workflow was associated to a leaf in an initial sequence assembly and the Synchronize with the Submitted View option was applied, the Workflow was lost. This issue is resolved. Associated Workflows are kept for each leaf after the option is applied.

Issue	CHF/Hotfix Build	Description
26458; [INC0022479]	6.2.0.5.0055	Publishing failed for the 2.3.S, 2.3.P, and 2.7.3 folders of ICH Module 2-5 v3.2 when the metadata field contained a single quote character. This issue is resolved.
26455; [INC0022252]	6.2.0.5.0055	Variables with spaces in the Variable Name field did not resolve in the published output. This issue is resolved.
26452; [INC0015705] 26383; [INC0015705]	6.2.0.4.0079	In an application containing single or multiple sequences, using the Create eCTD wizard from the Sequence page resulted in the Concerned Parties values getting deleted. This issue is resolved. The information of the Sequence Concerned Parties is displayed properly.
26444; [INC0021105]	6.2.0.5.0055	Incorrect Folder/Leaf names were observed in sections 1.08, 1.09, and 1.12 in JP eCTD Module 1 v1.0 assembly template. This issue is resolved. The JP eCTD Module 1 v1.0 assembly template is updated.
26401; [INC0017630]	6.2.0.5.0055	When deleting leaves in bulk using Delete (Withdraw) lifecycle operation in the Working assembly, the assembly tree refreshed and the deletion symbol (crossed leaf) appeared only on one of the leaves instead of all of them. This issue is resolved.
26438; [INC0020386]	6.2.0.4.0079	The <sequence> value in published .xml output was not the same as the value defined for Sequence on the regional or envelope Folder Attributes page. This issue is resolved. The value defined under the Folder Attributes page is displayed in the <sequence> tag for the versions of EU 3.0.1/3.0.3, JO-1.0 and GCC-1.5.
26434; [INC0020054]	6.2.0.5.0055	In Internet Explorer, when using the Delete (Withdraw) option on multiple leaves from subfolders of a Working assembly, the process would run for a long time with no result. This issue is resolved. The method used to communicate with the server is changed and now you can select any number of leaves to withdraw.
26425; [INC0376737]	6.2.0.5.0055	In a Working assembly with documents assigned from Documentum, the links created to bookmarks in other documents using Calyx RIM Linking plug-in (PDF) resolved to incorrect pages after publishing. This issue is resolved.

Issue	CHF/Hotfix Build	Description
26422; [INC0019310]	6.2.0.4.0079	Links with "Application" applicability were mixing (appeared where not necessary and disappeared where necessary) after DMS synchronization if the new minor version of the same document had been created in Documentum. This issue is resolved.
26409; [INC0018167]	6.2.0.4.0079	The search function did not work in the Approved Views of an assembly. This issue is resolved.
26404; [INC0018012]	6.2.0.4.0079	When a link was created to a bookmark in a document from a previous sequence, the link created targeted to the first page of the document, instead of the bookmark. This issue is resolved. Now the links target to the correct page.
26395; [INC0016670]	6.2.0.4.0079	Folders in the approved view were out of order. This issue is resolved.
26386; [INC0016091]	6.2.0.4.0079	A first request to create the <code>parexel__c</code> rendition for a PDF document from Veeva failed. This issue is resolved. The source document is retrieved instead of the <code>parexel__c</code> rendition if Standard Rendition is selected for a Veeva PDF file. For another Rendition Identifier value and non-PDF documents, the corresponding rendition is used. Now, in some cases two calls instead of three are sent to Veeva.

Issue	CHF/Hotfix Build	Description
26370; [INC0015274]	6.2.0.5.0055	<p>The pagination formulas using Reverse and Bates types did not resolve properly for paper publishing. Example: <code>\$Bates (\$Reverse (\$Calculate (\$ {ATP} - \$ {ARP} + 1) , "-1") , 5)</code>.</p> <p>This issue is resolved. The formula works when an intermediate variable is used as the first one in alphabetical order according to Variable Code. Example:</p> <ul style="list-style-type: none"> – Variable Name = <code>someTestName</code>, Variable code = <code>calcRevPage</code>, Variable Value = <code>\$Reverse (\$Calculate (\$ {ATP} - \$ {ARP} + 1) , "-1")</code> – Variable Name = <code>someTestName</code> , Variable code = <code>revBates</code>, Variable Value = <code>\$Bates (\$calcRevPage, 5)</code> <p>To experience better performance, we recommend to minimize the formulas usage and set up them in Publishing Settings Library, not in Data Administration.</p>
26361; [INC0014994]	6.2.0.4.0079	Leaf attributes were missing from a leaf in the Approved View when that leaf was replaced in a previously lifecycled sequence. This issue is resolved.
26344; [INC0014379]	6.2.0.4.0079	On the Add or Edit Page Marker menu, changing the Page Number to more than 3 characters caused the error message: <code>Page Number cannot exceed 3 characters</code> . This issue is resolved. Now, it is possible to enter 5 characters in the Page Number field.
26340; [INC0014300]	6.2.0.5.0055	After reordering leaves in a Working Assembly using Reorder Child Leafs option, users observed empty folders in Publishing and Sequence views. This issue is resolved in InSight 6.2 CHF 4 as a result of other fixes.
26328; [INC0014090]	6.2.0.4.0079	When the lifecycle operation on the same leaf across different sequences was performed and those events were added to the Approved View , using the Change Status Wizard resulted in an error. This issue is resolved.
26320; [CS0042776]	6.2.0.4.0079	Users authenticating with Azure AD were unable to access Veeva using Single Sign-On (SSO) when Veeva was configured to authenticate using ADFS. This issue is resolved.

Issue	CHF/Hotfix Build	Description
26310, 19440; [INC0012460]	6.2.0.5.0055	After performing a DMS Synchronization on an assembly with an assigned document that was versioned, the document attributes and assembly tree were not automatically refreshed by Calyx RIM. This issue is resolved. Now, the icon 'Newer version available' is displayed without having to manually refresh the assembly tree.
26300; [00063883]	6.2.0.4.0079	After an EU MRP assembly with an updated folder structure different from the template order was lifecycled, the Sequence view displayed empty folders in the next Working assembly after Create eCTD wizard was launched. This issue is resolved. Now, the Sequence view does not include any empty folders.
26291, 26410; [INC0012181, INC0018227]	6.2.0.4.0079	In a working assembly, performing a Replace operation on a reference leaf failed to load the assembly tree. This issue is resolved.
26286; [INC0012051]	6.2.0.4.0079	Retrieving a list of assembly templates via API requests failed. This issue is resolved. Now, the list of assembly templates via API requests can be accessed successfully.
26276; [INC0011104]	6.2.0.5.0055	The assembly templates for CH 1.3 and CH 1.4 contained errors that caused validation issues. This issue is resolved.
26255; [00065020]	6.2.0.4.0079	Creating a standalone assembly using the JO 1.0 assembly template and then executing the Create Study Reports wizard failed with the <code>cannot determine region based on dtids</code> error. This issue is resolved. The Create Study Reports wizard now runs successfully, and you can create a standalone assembly using the JO 1.0 assembly template without error.

Issue	CHF/Hotfix Build	Description
26247, 26405; [00064107, 00016162, INC0018046]	6.2.0.4.0079	When a document from a Veeva repository was assigned, the rendition information was recognized incorrectly by Calyx RIM. This resulted in an unnecessary extract request. If a TOC had Calyx RIM bookmarks that were edited, the edit changes did not appear in the generated TOC. Also, an extraction request was sent with each rendition, even when the rendition parameters were not changed. These issues are resolved. When documents are assigned from a Veeva repository, the rendition information is recognized correctly and edits appear correctly in the generated TOC. If rendition parameters are not changed, no extraction request is sent.
26245; [00065009]	6.2.0.4.0079	Calyx RIM authentication via API failed when an application server was configured with multiple domains. This issue is resolved.
26240; [00064944]	6.2.0.4.0079	When replacing a leaf in a subsequent sequence associated with a new event, closing the event and creating an approved view, both the new leaf and the replaced leaf were displayed in the approved view. This issue is resolved. Only the replaced leaf is displayed in the approved view.
26221; [00064631]	6.2.0.5.0055	In EU Submissions with MAA in Submission Type and with the initial value in Submission Unit Type , the users were able to save the empty INN in EMA Envelope Information . This issue is resolved. Now, the users are required to populate it when needed.
26199; [00064147]	6.2.0.4.0079	After updating a template and running Render Generated TOCs and Special Sheet Templates , extractions were generated for each assembly element containing a special sheet if it pointed to the same template and there were multiple settings profiles with the same template file. This issue is resolved. Now, the extraction request is sent for each special sheet template.
26163; [00063867]	6.2.0.4.0079	The folder structure of study reports created when importing an eCTD application was incorrect. This issue is resolved. The folder structure of study reports is now created correctly when importing an eCTD application.

Issue	CHF/Hotfix Build	Description
26142; [00063604]	6.2.0.4.0079	When using the Volumize feature on an assembly that contained a volume with a TOC attached to it, there was an error. This issue is resolved. Now, using the Volumize feature on an assembly containing a volume with a TOC attached to it does not display an error.
26139; [00063733]	6.2.0.4.0079	Creating a new assembly, or importing using an existing assembly, took longer than expected. This issue is resolved. The performance of creating a new assembly, or importing an assembly using an existing assembly, is improved.
26137; [00062685]	6.2.0.4.0079	An invalid reference error occurred when changing the XML definition file in the publishing settings from U.S. 2.0.1 to U.S 3.3, if more than one application type with the same us-3-3 Application DTD/Schema and eCTD code existed. This issue is resolved. Now, no error shows when changing the XML definition file in the publishing settings from U.S. 2.0.1 to U.S 3.3.
26120; [00063566]	6.2.0.4.0079	When an assembly section was selected in the Import Assembly Wizard , or when an assembly was created from an existing assembly, the corresponding assembly tree sections at the bottom half of the page were not displayed. Also, the full length of the scroll bar was not displayed, even on a maximized browser window. These issue are resolved. When an assembly section is selected in the Import Assembly Wizard . or when creating an assembly from an existing assembly, the corresponding assembly tree sections are displayed. The full length of the scroll bar shows on the browser window.
26057; [00063029]	6.2.0.4.0079	The Reset TOC Content button was not enabled in assemblies unless the Standalone Assemblies value for home page access under Security Administration was set to Yes . This issue is resolved.
26046; [00062700]	6.2.0.4.0079	The performance of refreshing the Link Inspector took several hours. This issue is resolved. The performance has been improved in sequence assemblies with: <ul style="list-style-type: none"> — External links in documents when source and target are within the same tree — Internal links in documents — In-Process links in documents

Issue	CHF/Hotfix Build	Description
25979; [00060743]	6.2.0.4.0079	When the screen resolution was set lower than [X]x1050 format, users were not able to send a publish request because the OK and Cancel buttons on the <i>Publish Request</i> and <i>Job Details</i> windows were not visible. This issue is resolved.
25862	6.2.0.4.0079	In an assembly tree, after running Prepare to Publish, deleting a leaf containing a source document linked to a target document resulted in a warning: <code>ORA-02292: integrity constraint (ODS.R_339) violated - child record found</code> . This issue is resolved. A leaf is deleted successfully.
25831	6.2.0.5.0055	When using the API to convert a leaf to reference, it could not be targeted to a leaf from a Sequence view. This issue is resolved.
25566; [00054314]	6.2.0.4.0079	When using the eCTD Import process to import an assembly containing reference leafs and assigned documents in the assembly tree, the reference leafs and the documents were switched in the imported assembly. This issue is resolved.
25487; [00055381]	6.2.0.5.0055	The Find and Replace option did not function as expected in the Publishing view of an assembly and the updated leaf names were not available in the current sequence in the Working view. This issue is resolved. Now, in the Publishing view, the Find and Replace option updates the nodes as expected in the current sequence in the Working view.
25263; [00052834]	6.2.0.5.0055	GCC submissions containing multiple Cover Letters could not be imported to Calyx RIM. This issue is resolved.
23864; [00039884, 00054020, 00055522, INC0016252]	6.2.0.5.0055	Using the Change Submittal Status wizard after changing a folder extension in a later sequence caused a reference error. This issue is resolved.

Issue	CHF/Hotfix Build	Description
25325; [00053635, 00055122, 00059463, 00062975,INC00162 53, INC0016254, INC0017802]	6.2.0.5.0055	GCC sequences failed an eCTD import because of missing language folders in <code>xlink:href</code> . This issue is resolved. Now, the eCTD import is completed with no errors in the Job Requests even if language is missing for some folders. The system takes the English language as the default one and the language folder name is the same as in GCC template.
23864; [00039884, 00054020, 00055522, INC0016252]	6.2.0.5.0055	Using the Change Submittal Status wizard after changing a folder extension in a later sequence caused a reference error. This issue is resolved.

Registrations

Issue	CHF/Hotfix Build	Description
26447	6.2.0.4.0079	On the <i>Product Family Attributes</i> page, the following attributes were incorrectly listed after the Development Sponsor attribute. This issue was specific to the Pharmaceutical, Veterinary and Flu Vaccine product family types. This issue is resolved. Now, these attributes are listed after the Approved Trade Names attribute. <ul style="list-style-type: none"> – Product Family Concerned Parties – Product Family Keywords – Product Family Description – Product Family Comments
26419; [INC0019054]	6.2.0.4.0079	When a Package Set was associated with a Registration instead of with a Full Product Presentation (FPP), the information from the PDS Active Ingredients of the Package Set was included in the submission XML. This issue is resolved. Only Active Ingredients from Package Sets associated with a Full Product Presentation are now included in the XEVMPD submission XML.
26417; [INC0018864]	6.2.0.4.0079	An Application was not updated with the Withdrawn status despite the Registration License Status value being internally mapped to Withdrawn . This issue is resolved.

Issue	CHF/Hotfix Build	Description
26398; [INC0017367]	6.2.0.4.0079	When using the Copy Registration Wizard, trying to copy a registration in a multiple country application such as an MRP or DCP resulted in an error. The error was due to the constraint on the Medicinal Regulatory Agency field. This issue is resolved. After using the Copy Registration Wizard, the field Medicinal Regulatory Agency becomes blank and the value must be updated manually.
26227; [00064595]	6.2.0.4.0079	If the time of the Approved status was set to a time that was earlier than that of the Submitted status, the status in the Event attributes page in the Countries tab changed to Submitted. This issue is resolved. Now, the calculation of Event Country Statuses is corrected. The current status shows the latest actual date.
26193; [00064402]	6.2.0.4.0079	In the Registration Attachment page, selecting a file that had an extension in upper case (such as .DOC or .PDF) failed to populate values for the Attachment Name and the File Name fields. This issue is resolved. Values for Attachment Name and File Name fields are populated as expected.
26127; [00063568]	6.2.0.4.0079	The URL in the e-mail that was sent to concerned users when an Event-Country Status was changed, failed to resolve to the expected target. This issue is resolved. Now, clicking the URL navigates to the event country where the status was created or updated.
26063; [00062715]	6.2.0.4.0079	The query for the List of Product Registrations with Application and Product Detail Properties report failed to show the results on the screen. This issue is resolved. Now, the query for the List of Product Registrations with Application and Product Detail Properties report shows the results on the screen.
25996; [00060206]	6.2.0.4.0079	In the Global Project Plan (GPP) wizard, selecting multiple events that exceeded the query limit resulted in the disappearance of the Update Project Event Country Status field, in some cases. This issue is resolved. The SQL query limit is increased for Event Country Status field in GPP wizard Update Project Event Country Status flow.

XEVMPD

Issue	CHF/Hotfix Build	Description
26336; [INC0014237]	6.2.0.4.0079	The XEVMPD Submission wizard worked incorrectly for the Invalidate MA operation type on an Authorised Product when there was more than one Event and this resulted in the error: <code>No Active Ingredient was specified</code> . This issue is resolved. For the Invalidate MA operation type on an Authorised Product , when there are multiple Events for the same PDS, the XEVMPD Submission wizard works correctly.

Workflows

Issue	CHF/Hotfix Build	Description
26195; [00064087]	6.2.0.4.0079	When an activity name was longer than 255 characters, trying to complete that activity resulted in an error. This issue is resolved. Now, an activity name can contain up to 1000 characters.
25990; [00060779]	6.2.0.4.0079	When creating an Event-Country Status under a closed Event that was created via a workflow, there was an error. This issue is resolved. Now, there will be no error when creating an Event-Country Status under a closed Event that is created via a workflow.

Rendering

Issue	CHF/Hotfix Build	Description
4999; [INC0040253]	4.4.1.1	Inserting a metafile (.emf) conflicted with the Amyuni printer driver and caused the rendition to fail. This issue is resolved. It is recommended that you convert any .emf file to a different format before inserting to prevent rendition issues.
4998; [INC0037216]	5.0.0.17	When a large file from Veeva DMS was assigned to an assembly and published, the publishing process failed with the <code>System out of memory</code> error. This issue is resolved. Now, large files from Veeva DMS assigned to an assembly publish successfully.
4997	4.4.1.1	After rendering Word documents, some links in the rendered PDFs were sometimes split into multiple link boxes. This issue is resolved. Now the links are displayed correctly.

Issue	CHF/Hotfix Build	Description
4991; [PRB0040598]	4.4 CHF 2	Some native links could disappear under certain conditions, such as splitting a document in an assembly into several page ranges. This issue is resolved. Now the links are displayed and navigate to the correct locations.
4988	N/A	The Business Service Retrieve re-authenticated with Veeva on each request processed and caused the Veeva API burst limit to be reached. This issue is resolved. Rendering now includes a cache that saves login data so that it does not have to authenticate each time it needs to get a document or information from Veeva.
4979	4.4.1.4	Publish jobs failed when attempting to publish two documents assigned from Veeva with Publishing Output Channel = Paper . This issue is resolved.
4975, 4928, 4895; [00056617, 00062932, INC0016169, INC0021914]	4.4 CHF 2	Print jobs using the Lipient PS Printer option failed due to memory management issues in the third-party component responsible for converting PDF to Postscript. This affected Postscript-based printers only. This issue is resolved.
4958; [00056740, INC0013561]	4.4 CHF 2	Watch requests failed if the server they belonged to was down or suspended. This was caused by a problem with the repository backup algorithm. This issue is resolved. Now a backup repository will properly execute watches that belong to a down or suspended repository.
4946; [00064768]	4.4.0.49	Rendering was not able to communicate back to the application server on networks that did not allow TLS 1.0 encryption. This issue is resolved.
4945; [00064279]	N/A	Thai and other scripts that depend on combining diacritics had those diacritics incorrectly placed on printed tabs. This issue is resolved. Thai text is correctly printed on tabs.
4929; [00062908]	4.4 CHF 2	Issues with the Auto Text Wrap option for tabs caused improper line breaks, which required the manual override of tab text. This issue is resolved by an expanded list of line break symbols.
4889; [00055307,00058062, 00060015, 00060371]	N/A	The maximum file size that could be retrieved for publish or render is 2 GB. To publish or render successfully, it was recommended to divide the files larger than 2 GB to smaller files and save. This issue is resolved. Now, you can retrieve files that are larger than 2GB for publish or render.

Issue	CHF/Hotfix Build	Description																												
4850; [00052462]	4.4.1.1	<p>Rendering limited the number of sub-jobs to 25 per workflow and would not start the next workflow until all 25 sub-jobs had completed. This issue is resolved. Now, the total MaxConcurrent for the Workflow Business Service on all servers is multiplied by 3 to control the number of jobs in progress, with 10 as the minimum and 40 as the maximum. Examples:</p> <table border="1" data-bbox="688 585 1469 1056"> <thead> <tr> <th data-bbox="688 585 867 674">Servers</th> <th data-bbox="867 585 1073 674">Maximum concurrent</th> <th data-bbox="1073 585 1268 674">Formula value</th> <th data-bbox="1268 585 1469 674">Jobs in progress</th> </tr> </thead> <tbody> <tr> <td data-bbox="688 674 867 726">2 servers</td> <td data-bbox="867 674 1073 726">3</td> <td data-bbox="1073 674 1268 726">10 (low limit)</td> <td data-bbox="1268 674 1469 726">3</td> </tr> <tr> <td data-bbox="688 726 867 779">2 servers</td> <td data-bbox="867 726 1073 779">15</td> <td data-bbox="1073 726 1268 779">10 (low limit)</td> <td data-bbox="1268 726 1469 779">10</td> </tr> <tr> <td data-bbox="688 779 867 831">4 servers</td> <td data-bbox="867 779 1073 831">5</td> <td data-bbox="1073 779 1268 831">12 (4*3)</td> <td data-bbox="1268 779 1469 831">5</td> </tr> <tr> <td data-bbox="688 831 867 884">4 servers</td> <td data-bbox="867 831 1073 884">15</td> <td data-bbox="1073 831 1268 884">12 (4*3)</td> <td data-bbox="1268 831 1469 884">12</td> </tr> <tr> <td data-bbox="688 884 867 968">20 servers</td> <td data-bbox="867 884 1073 968">5</td> <td data-bbox="1073 884 1268 968">40 (high limit)</td> <td data-bbox="1268 884 1469 968">5</td> </tr> <tr> <td data-bbox="688 968 867 1056">20 servers</td> <td data-bbox="867 968 1073 1056">50</td> <td data-bbox="1073 968 1268 1056">40 (high limit)</td> <td data-bbox="1268 968 1469 1056">40</td> </tr> </tbody> </table>	Servers	Maximum concurrent	Formula value	Jobs in progress	2 servers	3	10 (low limit)	3	2 servers	15	10 (low limit)	10	4 servers	5	12 (4*3)	5	4 servers	15	12 (4*3)	12	20 servers	5	40 (high limit)	5	20 servers	50	40 (high limit)	40
Servers	Maximum concurrent	Formula value	Jobs in progress																											
2 servers	3	10 (low limit)	3																											
2 servers	15	10 (low limit)	10																											
4 servers	5	12 (4*3)	5																											
4 servers	15	12 (4*3)	12																											
20 servers	5	40 (high limit)	5																											
20 servers	50	40 (high limit)	40																											
4767; [00056042, 00048240, 00050634, 00055970, 00058496]	4.0.0.96	Rendering Microsoft Word and Excel documents containing objects that reference external sources is not supported by the Rendering platform. To prevent such job requests from failing, this update suppresses errors associated with such objects and allows rendering of documents containing such content to complete successfully, although rendition fidelity is not assured.																												
4639; [00041423]	4.4 CHF 2	Large jobs sometimes failed and showed the error message, "Not enough storage is available to complete this operation." Tickets are now optimized to reduce their size.																												
4592	4.4.0.51	Publishes with many small distribute requests (as in NeeS or leaf-only publish submissions) failed intermittently with the error: "Unable to distribute folder". This issue is resolved.																												

Clarification of Behavior: Calyx RIM 7.0

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	<p>After migrating to Calyx RIM 7.0, the following user settings are reset to default for the migrated users.</p> <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	<p>After migrating to Calyx RIM 7.0, Public or Private queries saved in the Liquent InSight 6.2 query list will not be available in the Calyx RIM 7.0 query list for the migrated and newly added users.</p>
N/A	Assembly	<p>Performing any actions from Calyx RIM 7.0 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.</p>
N/A	N/A	<p>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.</p>

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 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 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 .

Issue	Affected Area	Description
22716; [00028730]	N/A	A hyphen "-" in the service account name prevents the ability to use that service account when adding a SharePoint repository.

Calyx RIM Publisher

Issue	Affected Area	Description
N/A	Assembly	For opening and viewing published XML files, Calyx RIM recommends using the Microsoft Internet Explorer Web browser. Although Calyx supports other Web browsers (Google Chrome and Microsoft Edge), opening published XML files is best accomplished using Internet Explorer.
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.
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.

Known Issues: Calyx RIM

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	Description
26814 (Added on Sep 28, 2021)	Using Prepare for Publishing with the Prepare Cross Reference Leafs option selected results in the <code>Unable to extract checksum error</code> if there is a reference leaf to leaf published to Documentum.
26799 (Added on Dec 23, 2022)	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> .
26807 (Added on Dec 23, 2022)	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.
26642	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.
26637 (Added on Dec 23, 2022)	In Data Administration, the Check for Date-based Notifications menu is not available on the Notification Specifications grid.
26728	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	Calyx RIM can incorrectly send a Native .PDF file to Calyx RIM Rendering for extraction. Also, while a large file can fail extraction, it might not prevent successful publishing.

Calyx RIM Publisher

Issue	Description
26784; [INC0061598]	When nodes are updated in a Working view via Mass Update Properties , the changes are not applied to the Sequence and Publishing views. The issue occurs for both common and extended attributes of the node. Workaround: Use the same values for the Mass Update Properties attributes for both Working and Publishing views.
25259; [00052856]	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]	Deleting large applications or removing multiple sequences from a lifecycle can take much longer than expected to produce results.
24019	eCTD import of a US v2.3 (DTD v3.3) application containing sequences submitted as part of a grouped submission is not supported.
20270; [136797FW]	Links for External Bookmarks are incorrect for split documents in paper published output.

Calyx RIM Outlook add-in

Issue	Description
26757	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)
26730	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>
26729	In the Add Notification Recipients field, it is not possible to delete any spaces.
26706	If more than 50 users try to submit a form, the system fails and an error is displayed.

Issue	Description
26704	When an API request with invalid product id is sent for CreateSubmissionAndReference, an incorrect error message is displayed.
26639	If Calyx RIM Outlook add-in fails to submit the forms, an incorrect error message is displayed.
26632	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.
26603	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.
26598	Trying to change the Calyx RIM Outlook add-in icon takes longer time than expected.
26587	Empty text files cannot be attached using the Browse File button.
26586	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.
26585	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	Description
26718	When eCTD assembly is published, the validation messages from the backbone generator are not displayed in Job Requests Details.

Data Administration Tables

Data Administration Tables Added: Calyx RIM 7.0

The following Data Administration tables, sections, or fields were modified with Calyx RIM 7.0.

Data Administration Section: Submission Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Submission Maintenance > Drug Registration File Documents Section	<ul style="list-style-type: none"> — EAEU Leaf — Drug Registration File Documents Section 	<ul style="list-style-type: none"> — Section Code — Section Name 	To maintain the drug registration file documents section of the EAEU region, the <i>Drug Registration File Documents Section Values</i> table is introduced. The values for Section Code and Section Name can be entered in their respective fields.
Submission Maintenance > Drug Registration File Document Values	<ul style="list-style-type: none"> — EAEU Leaf — Drug Registration File Document Values 	<ul style="list-style-type: none"> — Section — Document Code — Name 	To maintain the drug registration file documents of the EAEU region, the <i>Drug Registration File Document Values</i> table is introduced. The values for Section , Document Code and Name can be entered or selected in their respective fields.
Submission Maintenance > Submission Product Type Values	<ul style="list-style-type: none"> — CN 1.0 Folder — Submission Product Type Values 	<ul style="list-style-type: none"> — Region — eCTD Code — Product Type — Applicable DTD/Schema 	The <i>Submission Product Type Values</i> table is added to maintain the submission product types of the China region. The values for Region , eCTD Code , Product Type , and Applicable DTD/Schema can be entered or selected in their respective fields.

Data Administration Fields Updated: Calyx RIM 7.0

This table describes fields that were updated with Calyx RIM 7.0.

Pick List Name	Field Name	Field Type 7.0	Field Size Calyx RIM 7.0
Applicant Contact Values	Applicant Contact Name	Text box	
Applicant Contact Type Values	Applicant Contact Type	Text box	
Applicant ID Values	Applicant Name	Text box	
Application Form Type Values	Application Form Type	Text box	
Assembly Repository Variables	Variable Value	Text box	
ATC Values	ATC Description	Text box	
Concentration Measure Type Values	Concentration Measure Type Name	Text box	
Custom List Names	List Name	Text box	
Custom List Values	List Value	Text box	
Device Allergenicity Values	Code Name	Text box	
Device Nomenclature Values	Code Name	Text box	
Device Sterility Indicator Values	Code Name	Text box	
Device Type Values	Code Name	Text box	
Device Usage Values	Code Name	Text box	
Dosage/Pharmaceutical Form Values	Dosage Form (Long Name)	Text box	
	Dosage Form (Short Name)	Text box	
	Description	Text box	
Drug Registration File Documents Values	Name	Text box	500
Drug Registration File Documents Section Values	Name	Text box	500
Homepage Display Properties	Comments	Text box	
Indications/Intended Use Values	Indications/Intended Use	Text box	
Language Values	Language Name	Text box	
Legal Basis Values	Legal Basis Name	Text box	

Pick List Name	Field Name	Field Type 7.0	Field Size Calyx RIM 7.0
MAH/Development Sponsor/ Organisation Values	<ul style="list-style-type: none"> – MAH/Development Sponsor/ Organisation Name – Organisation Identifier – Address – Comments 	Text box	
Manufacturer Values	<ul style="list-style-type: none"> – Manufacturer Name – Organisation Identifier – Address Line 1 – Comments – Keywords – Description 	Text box	
Medical Device Values	Medical Device Name	Text box	
Medicinal Product Type Values	Medicinal Product Type Name	Text box	
Packaging Type Values	Name	Text box	
Procedure Type Values	Procedure Type Abbreviation		100
	Procedure Type Name	Text box	500
Product Characteristics Values	Code Name	Text box	
Product Family Values	Family Name	Text box	
Product Material Values	Code Name	Text box	
Promotional Material Doc Type Values	Promotional Material Doc Type	Text box	
Promotional Material Type Values	Promotional Material Type	Text box	
Promotional Material Audience Type Values	Promotional Material Audience Type	Text box	
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	QPPV Name	Text box	
Quantity Unit Of Measure Values	Code Name	Text box	
Reasons for Termination/Withdrawal List Values	Reasons for Termination/ Withdrawal	Text box	
Region Values	Region Abbreviation		– 100
	Region Name	Text box	– 200

Pick List Name	Field Name	Field Type 7.0	Field Size Calyx RIM 7.0
Region Type Values	Region Type Name	Text box	
Regulatory Activity Lead Values	Regulatory Activity Lead	Text box	
Route of Administration Values	Route of Administration (Long Name)	Text box	
RMS Values, for SPOR Maintenance section	Term Name	Text box	
	Short Name	Text box	
Secondary Event Type Values	Name	Text box	
Sequence Description Values	Sequence Description	Text box	
Shelf Life Type Values	Code Name	Text box	
Special Measure Values	Code Name	Text box	
Sterilization Requirement Values	Code Name	Text box	
Storage Condition Values	Storage Condition	Text box	
Sub Filing Type Values	Sub Filing Type	Text box	
Submission Product Type Values	Product Type	Text box	
Substances Values	<ul style="list-style-type: none"> – Substance Name – Molecular Formula – CBD – Description – Comments 	Text box	
Substance Attachment Values	<ul style="list-style-type: none"> – Attachment Name – File Name – Internal Name 	Text box	
Substance Class Values	Substance Class Name	Text box	
Supplement Effective Date Type Values	Supplement Effective Date Type Name	Text box	
Trade Name Values	Trade Name Values	Text box	
Unit Of Presentation Values	Code Name	Text box	
Volume Unit Of Measure Values	Code Name	Text box	

Data Administration Tables Updated: Calyx RIM 7.0

The following Data Administration tables, sections, or fields are updated in Calyx RIM 7.0 release.

Data Administration Section: Application Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Chief Investigator Values	N/A	N/A	The Chief Investigator Values table is hidden by default in the Data Administration > Application Maintenance section.
Sponsor Type Values	N/A	N/A	The Sponsor Type Values Sponsor Type Values table is hidden by default in the Data Administration > Application Maintenance section.
Application Status Values	Application	System Process Default Flag	When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Age Span Population Values – Application Category Values – Application Status Values – Application Type Values – Country Values – CTA Product Role Values – Legal Status Values – MedDRA Term Values – Medical Condition Investigated Values – Procedure Type Values – Reason for Premature Ending Values – Region Values – Region Type Values – Trial Design Values – Trial Phase Values – Trial Scope Values – Trial Subject Group Values 	Application	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.</p>

Data Administration Section: Assembly Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Assembly Category	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.
Assembly DTD/Schema Type			
Assembly Status			
Assembly Subcategory			

Data Administration Section: Change Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Change Type Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.
Event-Change-Detail Status Values	Event		
Event-Change-Detail Status Values	Event	System Process Default Flag	When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.

Data Administration Section: Custom Lists Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Custom List Names Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.
Custom List Values			

Data Administration Section: DMS Integration

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Bind to Label Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.
Bind to Status Values			
Rendition Identifier Values			

Data Administration Section: Event Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Action Type Values – EU Grouping or Worksharing Values – Event Status Values – Event Type Values – PSUR Report Code Values – Secondary Event Type Values – Timeline/Event Plan Type Values – Timeline/Event Plan Values 	Event	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Notifications

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Notification Specifications Values – Notifications Values 	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Other

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Concentration Measure Type Values – Denominator Unit Values – Entity XML/UI Mappings Values – Home Page Display Properties Values – Indications/ Intended Use Values – Language Values – Legal Basis Values – Length Unit Of Measure Values – MAH/Development Sponsor/ Organisation Values – Master File Location (MFL) Values – Message Sender Values – Numerator Unit Values – Previous EV Code Values – Quantity Unit Of Measure Values – Reason for E-Signature Values – Reason for Termination/ Withdrawal Values – SME Status Values – Sub-Indication Values – System Alert Type Values – Unit of Measure Prefix Values – Unit of Presentation Values – Weight Unit of Measure Values 	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.</p>
© Calyx 2022. Calyx.ai		51	<p style="text-align: right;">Calyx RIM Release Notes Data Administration Tables Updated: Calyx RIM 7.0</p>

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Numerator Unit Values	N/A	N/A	The RMS Term Name field in the initial table view now appears as a column in the grid view.

Data Administration Section: Product Detail Set Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Genetically Modified Cell Origin Species Values	N/A	N/A	The Genetically Modified Cell Origin Species Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Product Bio Type Values	N/A	N/A	The Product Bio Type Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Somatic Cell Therapy Cell Types Values	N/A	N/A	The Somatic Cell Therapy Cell Types Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Somatic Cell Therapy Origin Species Values	N/A	N/A	The Somatic Cell Therapy Origin Species Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Somatic Cell Therapy Origins Values	N/A	N/A	The Somatic Cell Therapy Origins Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Source of Scientific Advice Values	N/A	N/A	The Source of Scientific Advice Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Type of Dossier Submitted Values	N/A	N/A	The Type of Dossier Submitted Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Type of Gene Therapy Transfer Product Values	N/A	N/A	The Type of Gene Therapy Transfer Product Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Type of Gene Therapy Values	N/A	N/A	The Type of Gene Therapy Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Type of Genetically Modified Cell Origin Values	N/A	N/A	The Type of Genetically Modified Cell Origin Values table is hidden by default in the Data Administration > Product Detail Set Maintenance section.
Product Detail Set Maintenance	Product	System Process Default Flag	When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Color Values – Compendial Designation/Source Values – Dose Frequency Values – Human Consumption Product Values – Label Type Values – Manufacturer Values – Manufacturing Functions Values – Material Type Values – Material Values – Medical Device Part Code Values – Packaging Category Values – Product Detail Set Status Values – Product Material Values – Production Type Values – QC Status Values – Shape Values – Shelf Life Category Values – Shelf Life Type Values – Species Values – Storage Condition Values – Substance Role Values – Substance Type Values – Time Unit Values – Volume Unit of Measure Values 	Product	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.</p>

Data Administration Section: Product Family Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – ATC Values – Division Values – Product Family Status Values – Product Family Values – Substance Class Values – Substance Values – Therapeutic Area Values – Therapeutic Class Values – Trade Name Values 	N/A	N/A	The RMS Term Name field in the initial table view now appears as a column in the grid view.
	Product Family	<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date – Development Sponsor 	The Product Family Status , Product Family Status Date , Development Sponsor fields are hidden by default in Data Administration > Product Family Values section.
	Product Family	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Product Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Dosage/Pharmaceutical Form Values	N/A	N/A	The RMS Term Name field in the initial table view now appears as a column in the grid view.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Product Status Values	Product	System Process Default Flag	When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Applicable Standards Values – Conformity Assessment Body Values – Conformity Assessment Path Values – Country Specific Detail Type Values – Country Specific Detail Values – Device Allergenicity Values – Device Nomenclature Values – Device Sterility Indicator Values – Device Type Values – Device Usage Values – Dosage/ Pharmaceutical Form Values – EC Cert Values – Global Harmonization Task Force (GHTF) Class Values – Global Medical Device Nomenclature (GMDN) Code Values – Manufacturing Location Values – Medical Device Values – Product Characteristics Values – Product Status Values – Product Strength Unit Values – Route of Administration Values – Special Measure 	Product	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.</p>

Data Administration Section: Project Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Project Status Values – Project Type Values 	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Publishing Requirements Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Electronic Format Requirement Attributes	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Reference Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Reference Content Value – Reference Participant Values – Reference Status Values – Reference Type Values 	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Registration Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
EMA Authorisation Status Values	N/A	N/A	The RMS Term Name field in the initial table view now appears as a column in the grid view.
<ul style="list-style-type: none"> – EMA Authorization Status Values – Medicinal Product Type Values – Qualified Person Responsible for Pharmacovigilance (QPPV) Values – Registration Status Values 	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Sequence Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Sequence Status Values	Sequence	System Process Default Flag	When the status of an Application, Product, Product Detail Set, Event-Change Detail, and Sequence is updated as a result of running a status wizard or manually closing an event, the status set as the System Process Default Flag is used. Prior to this update, the system would randomly pick a display status to show as the status when multiple display statuses were set to the same internal system status.
<ul style="list-style-type: none"> – Filing Type Values – Sequence Status Values 	Sequence	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: SPOR Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Compendial Designation/Source RMS Values	N/A	N/A	The RMS Term Name field in the initial table view now appears as a column in the grid view.
Concentration Measure Type RMS Values			
Country RMS Values			
Denominator Unit RMS Values			
Language RMS Values			
Legal Basis RMS Values			
Medical Device RMS Values			
Medicinal Product Type RMS Values			
Procedure Type RMS Values			
Route of Administration RMS Values			
Unit of Measure Prefix RMS Values			

Data Administration Table Name	Entity Affected	Field Name	Value List Description
ATC RMS Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.</p>
Compendial Designation/Source RMS Values			
Concentration Measure Type RMS Values			
Country RMS Values			
Denominator/ Numerator Unit RMS Values			
Dosage/Pharmaceutical Form RMS Values			
EMA Authorisation Status RMS Values			
Language RMS Values			
Legal Basis RMS Values			
Medical Device RMS Values			
Medicinal Product Type RMS Values			
Procedure Type RMS Values			
Route of Administration RMS Values			
Unit of Measure Prefix RMS Values		<ul style="list-style-type: none"> – Created By – Created Date 	<p>The ability to identify by whom and when a SPOR Maintenance value was created, either via automated updates from the EMA or manually by Data Administration users. By default, this option is read-only . It is populated automatically when updates are made to the table.</p>

Data Administration Section: Submission Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Applicant Contact Type Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	<p>The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration, including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.</p>
Applicant Contact Values			
Applicant ID Values			
Application Form Type Values			
Drug Registration File Documents Section Values			
Drug Registration File Document Values			
Font Definition Values			
Leaf Status Values			
PDF Properties Values			
Promotional Material Audience Type Values			
Promotional Material Doc Type Values			
Promotional Material Type Values			
Regulatory Activity Lead Values			
Submission Product Type Values			
Sequence Description Values			
Sub Filing Type Values			
Supplement Effective Date Type Values			
Telephone Number Type Values			

Data Administration Section: Submission Plan Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Submission Plan Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Section: Task Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Secondary Task/Sub-Task Type Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.
Task/Sub-Task Priority Values			
Task/Sub-Task Status Progression Values			
Task/Sub-Task Status Values			
Task/Sub-Task Type Values			

Data Administration Section: Workflow Management

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Workflow Management Values	N/A	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date 	The ability to identify – and then export the results to .xls - historical audit trail data for any value in Data Administration , including when and by whom values were added. For SPOR Maintenance values, the audit trail will reflect in addition whether the values were updated from the EMA or manually by a Data Administration user.

Data Administration Tables Removed: Calyx RIM 7.0

The following Data Administration tables, sections, or fields are removed from Calyx RIM 7.0.

Data Administration Section: Contact Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Contact Maintenance > Contact Address/Phone/Email Type Values – Contact Maintenance > Contact Role Values – Contact Maintenance > Contact Type Values – Contact Maintenance > Recipient For Values 	N/A	N/A	The Contact Maintenance section is removed.

Data Administration Section: Dossier Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
<ul style="list-style-type: none"> – Dossier Maintenance > Component Source Type Values – Dossier Maintenance > Discipline Values – Dossier Maintenance > Dossier Metadata Values 	N/A	N/A	The Dossier Maintenance section is removed.

Data Administration Section: Product Family Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Product Family Maintenance > Substance Attachment Values	N/A	N/A	The Substance Attachment Values under the Product Family Maintenance section is removed.
Substance Values > Attachments	N/A	N/A	The Attachments tab of the Substance Values page under the Product Family Maintenance section is removed.

Data Administration Section: Regulatory Intelligence Maintenance

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Regulatory Intelligence Maintenance > Regulatory Intelligence Product Type Values	N/A	N/A	The Regulatory Intelligence Maintenance section is removed.

Entity Fields

Entity Fields and Columns Added: Calyx RIM 7.0

These tables describe fields and columns that were added in this release.

Home Page

Table 1: Tabs

Tab name	Column Name	Column Type	Description	Business Rules
Product Families	Family Code	Read-only text (populated automatically)	When you open the Select Entity List > Product Families from the left hand navigation pane, the Family Code field now displays as a column in the table view.	N/A

Table 2: Search Menu

Menu	Column Name	Column Type	Description	Business Rules
Search > Applications	Procedure Type	Read-only text (populated automatically)	The <i>Search Results</i> page now includes the Procedure Type column.	N/A
Search > Events	Application Code	Read-only text (populated automatically)	The <i>Search Results</i> page now includes the Application Code column.	N/A
	Application Name	Read-only text (populated automatically)	The <i>Search Results</i> page now includes the Application Name column.	N/A
Search > Registrations	Application Code	Read-only text (populated automatically)	The <i>Search Results</i> page now includes the Application Code column.	N/A
	Application Name	Read-only text (populated automatically)	The <i>Search Results</i> page now includes the Application Name column.	N/A

Entities

Entity Name	Field/Option Name	Field Type	Description	Business Rules
Product Family	Show in Tree	Drop-down list	The option Show in Tree is added to hide product families from being displayed when using the Tree Filter functionality in the <i>Product Family Attributes</i> and <i>Modify Product Family</i> pages.	You can use the Show in Tree option to show or hide the product families on the <i>Modify Product Family</i> page. By default, this option is set to Yes .
	Package Sets	Text (populated automatically, non-modifiable)	The Registrations tab of the <i>Product Family Attributes</i> page now includes the Package Sets column.	This column displays the value only when the Registration Type is Package Set . The column will be blank on Product Registration Type .

Entity Name	Field/Option Name	Field Type	Description	Business Rules
Event	Family Type	Text (populated automatically, non-modifiable)	The Products tab of the <i>Event Attributes</i> page now includes the Family Type column.	The Family Type field value display the Product family Type associated with an product.
	Family Name	Text (populated automatically, non-modifiable)	The Products tab of the <i>Event Attributes</i> page now includes the Family Name column.	The Family Name field value display the standard product family name recognized internally and across countries. The Family Name field value is hyperlinked. When selected navigates you to the appropriate Product Family Attributes page.
	Family Code	Text (populated automatically, non-modifiable)	The Products tab of the <i>Event Attributes</i> page now includes the Family Code column.	The Family Code field value display the company-specific code for the product family.

Entity Name	Field/Option Name	Field Type	Description	Business Rules
Registrations	Family Type	Text (populated automatically, non-modifiable)	The Products tab of the <i>Registration Attributes</i> page now includes the Family Type column.	N/A
	Family Name	Text (populated automatically, non-modifiable)	The Products tab of the <i>Registration Attributes</i> page now includes the Family Name column.	The Family Name field value is hyperlinked. When selected navigates you to the appropriate Product Family Attributes page.
	Family Code	Text (populated automatically, non-modifiable)	The Products tab of the <i>Registration Attributes</i> page now includes the Family Code column.	N/A

Entity Name	Field/Option Name	Field Type	Description	Business Rules
Applications	Family Type	Text (populated automatically, non-modifiable)	The Products tab of the <i>Application Attributes</i> page now includes the Family Type column.	N/A
	Family Name	Text (populated automatically, non-modifiable)	The Products tab of the <i>Application Attributes</i> page now includes the Family Name column.	The Family Name field value is hyperlinked. When selected navigates you to the appropriate Product Family Attributes page.
	Family Code	Text (populated automatically, non-modifiable)	The Products tab of the <i>Application Attributes</i> page now includes the Family Code column.	N/A
	Associate/Disassociate Products	Button	The Products tab of the <i>Application Attributes</i> page now includes the Associate/Disassociate Products icon.	You can associate/dissociate more than one product regardless of the Product Families to an Application.
	Application Code	Read-only text (populated automatically)	The Applications grid now includes the Application Code column.	N/A

Entity Name	Field/Option Name	Field Type	Description	Business Rules
Indications/ Intended Use	Mass Update	Action button	Mass Update enables you to update a MedDRA version for multiple indications/intended entities simultaneously.	You can use Mass Update to enter a MedDRA version. You can then use the option Update and Overwrite to update the new version for all selected Indications or use Update and Preserve to update the new version for only those selected Indications which have no values.
Publishing Settings Library	Optimize Font in Paper Output	Drop-down list	Optimize Font in Paper Output has been added to Publishing Settings Library .	Minimize font compatibility issues and provide stability to the process of printing the paper output. By default, the value is No. All assemblies migrated from a previous Calyx RIM version will have Optimize Fonts in Paper Output set to No.
Full Product Presentations	XEVMPD Submission Required?	Drop-down list	XEVMPD Submission Required? enables you to categorize the Full Product Presentations that are ready to submit for XEVMPD.	When you try to create or copy Full Product Presentations, the value of this field is automatically set to Yes. This indicates that the XEVMPD data is ready for submission.

Wizards

Entity Name	Field Name	Field Type	Description	Business Rules
Create Application	Associated Products	Multi-select Modifiable	The Family Name, Family Code and Family Type columns are added in the <i>Product selection</i> page of the Create Application Wizard.	N/A
	Procedure Type	Drop-down list	The Procedure Start Date, Procedure End Date and Procedure Identifier are added to the Create Application Wizard and display if the Procedure Type is indicated as MRP, CP, DCP, or National for all the Application Types except CTA or an IND.	The fields are included into Create Application > > Enter values for new application > Create Application.
Copy Task	Application Name	Read-only text (populated automatically)	The Copy Task > Select Event > Select a destination event page now includes the Application Name and Application Code columns.	This provides the Application uniqueness confirmation.
	Application Code	Read-only text (populated automatically)		
Move Task	Application Code	Read-only text (populated automatically)	The Move Task > Select Event > Select a destination event page now includes the Application Code column.	
Global Project Plan (all types)	Application Code	Read-only text (populated automatically)	The Select Applications > Select an Application grid now includes the Application Code column.	N/A

Entity Name	Field Name	Field Type	Description	Business Rules
XEVMPD Submission	Application Code	Read-only text (populated automatically)	The XEVMPD Submission > Authorised Product Search Results page now includes the Application Code column.	N/A
Update Project Event Country Status	Application Code	Read-only text (populated automatically)	The Select Event Countries > Select the event countries you would like to update page now includes the Application Code column.	N/A
	Application Name	Read-only text (populated automatically)	The Confirmation > Clicking Next will perform the following actions: page now includes Application Name.	N/A
	Application Name	Read-only text (populated automatically)	The Summary > Summary page now includes Application Name.	N/A
Calculate Project Dates	Application Code	Read-only text (populated automatically)	The Select Event Countries > Select the event countries you would like to update page now includes the Application Code column.	N/A
Bulk Update Events	Application Code	Read-only text (populated automatically)	The Select Events > Select Events to update page now includes the Application Code column.	N/A

Entity Name	Field Name	Field Type	Description	Business Rules
Bulk Update Sequences	Application Code	Read-only text (populated automatically)	The Enter Sequences Search Criteria > Select values to refine search page now includes the Application Code column.	N/A
Associate Workflow to Events or Sequences	Application Code	Read-only text (populated automatically)	The Associate Workflow > Select Events grid now includes the Application Code column.	N/A
			The Associate Workflow > Select Sequences grid now includes the Application Code column.	

Entity Name	Field Name	Field Type	Description	Business Rules
Create Sequence Create References for the Project Events or Sequences Associate Change Detail(s) to Events Leaf Updates for Assemblies	Application Code	Read-only text (populated automatically)	The following grids now include the Application Code column: <ul style="list-style-type: none"> – Project Attributes > Create Sequence > Select Events grid – Project Attributes > Create References for Events > Select Events grid – Project Attributes > Create References for Sequences > Select Events grid – Project Attributes > Associate Change Detail(s) to Events > Select Events grid – Project Attributes > Leaf Updates for Assemblies > Select Sequences grid 	N/A
Create Study Report	Update the sub-folder structure for 5.3.5 Reports of Efficacy and Safety Studies	Multi-select check box	The Update the sub-folder structure for 5.3.5 Reports of Efficacy and Safety Studies option is added to the <i>Create Study Reports > Enter Properties</i> page.	Study reports can be added to specific Indication folders to improve the data setup.

Entity Name	Field Name	Field Type	Description	Business Rules
Copy Full Product Presentation	Application Code	Read-only text (populated automatically)	The Copy Full Product Presentation > Select wizard flow > Select the flow for the Full Product Presentation copy you would like to perform > Full Product Presentation under different Registration(s) page now includes the Application Code column.	N/A
Copy Registration Attachment	Application Code	Read-only text (populated automatically)	The Copy Registration Attachment Attributes > Select Full Product Presentation(s) where newly copied Registration attachment should be created page now includes the Application Code column.	N/A

Entity Name	Field Name	Field Type	Description	Business Rules
Import eCTD to Application	EAEU XML with embedded PDFs	Read-only text (populated automatically)	The Enter the eCTD Folder > Choose the eCTD Folder to import page now includes the EAEU XML with embedded PDFs option in the Import Type drop-down list.	EAEU XML with embedded PDFs has been added to provide the functionality related to EAEU regulatory updates. You can use EAEU XML with embedded PDFs while importing EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
	EAEU XML Location	Browse button	The Enter the eCTD Folder > Choose the eCTD Folder to import page now includes the EAEU XML Location field.	You can use EAEU XML Location while importing EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>
	DMS Versioning Scheme	Radio button	The Enter the eCTD Folder > Choose the eCTD Folder to import page now includes the DMS Versioning Scheme field.	You can use DMS Versioning Scheme while importing EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions.</i>

Entity Name	Field Name	Field Type	Description	Business Rules
Export Published Output	Embed PDFs into EAEU XML?	Check box	The Export Published Output page now includes the Embed PDFs into EAEU XML? option.	Embed PDFs into EAEU XML? has been added to provide functionality related to EAEU regulatory updates. You can use Embed PDFs into EAEU XML? to export EAEU submissions. See: <i>Calyx RIM Best Practice: EAEU Submissions</i> .
Publishing Settings Library	Optimize Fonts in Paper Output	Drop-down list	<i>Publishing Settings Library</i> now includes the Optimize Fonts in Paper Output option.	Minimize font compatibility issues and provide stability to the process of printing the paper output. By default, the value is No. All assemblies migrated from a previous Calyx RIM version will have Optimize Fonts in Paper Output set to No.

Entity Fields and Columns Updated: Calyx RIM 7.0

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

Home Page

Table 3: Tabs

Tab name	Column Name	Column Type	Description	Business Rules
Product Families	Product Family Type	Read-only text (populated automatically)	This column is renamed to Family Type on the <i>Product Families</i> grid opened from the Product Families tab on the left pane.	N/A
	Product Family Name	Hyperlink	This column is renamed to Family Name grid from the Product Families tab on the left pane.	

Table 4: Search Menu

Menu	Column Name	Column Type	Description	Business Rules
Search > Product Families	Product Family Name	Hyperlink	This column is renamed to Family Name on the <i>Search Results</i> page.	N/A
Search > Full Product Presentations	Pack Set License Code	Hyperlink	This column is renamed to License Code on the <i>Search Results</i> page.	N/A
Search > Products	Product Family Name	Read-only text (populated automatically)	This column is renamed to Family Name on the <i>Search Results</i> page.	N/A
Search > Components	Product Family Name	Read-only text (populated automatically)	This column is renamed to Family Name on the <i>Search Results</i> page.	N/A

Table 5: Find Menu

Menu	Field Name	Field Type	Description	Business Rules
Find > Activities > Entity Type > Product Family	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>View Activities List</i> page.	N/A
	Product Family Name		This field is renamed to Family Name on the <i>View Activities List</i> page.	N/A
Find > Activities > Entity Type > XEVMPD	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>View Activities List</i> page.	N/A
	Product Family Name		This field is renamed to Family Name on the <i>View Activities List</i> page.	N/A
Find > Product Families > List of Product Families	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Product Families</i> page.	N/A
	Product Family Name	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Product Families</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	N/A

Menu	Field Name	Field Type	Description	Business Rules
Find > Applications > List of Applications with Product Query	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Applications with Product Query</i> page.	N/A
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Applications with Product Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	
Find > Package Set Registrations > List of Package Set Registrations with Application and Product Detail Properties Query	Product Family Type	Multi-select editable, Read-only text (populated automatically)	These fields are renamed to Family Type and Family Name on the: <ul style="list-style-type: none"> – <i>List of Package Set Registrations with Application and Product Detail Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	N/A
	Product Family Name			
Find > Product Registrations > List of Product Registrations with Application and Product Detail Properties Query	Product Family Type	Multi-select editable, Read-only text (populated automatically)	These fields are renamed to Family Type and Family Name on the: <ul style="list-style-type: none"> – <i>List of Product Registrations with Application and Product Detail Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	N/A
	Product Family Name			

Menu	Field Name	Field Type	Description	Business Rules
Find > Events > List of Events with Application Properties Query	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Events with Application Properties Query</i> page.	N/A
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Events with Application Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	
Find > Sequences > List of Sequences with Application and Event Properties Query	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Sequences with Application and Event Properties Query</i> page.	N/A
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Sequences with Application and Event Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page 	

Entities

Entity Name	Field Name	Field Type	Description	Business Rules
Product Family (MD, PMD)	Division	Drop-down list	This field is hidden by default in the <i>Product Family Attributes</i> page.	This field is not available when you modify (Medical Device and Pharmaceutical -Medical Device) Product Family.
Product Family (FV, P, PMD, V)	ATC Last Updated	Date	The date that the ATC was most recently updated.	N/A (attribute is removed)
Product Family (All)	International Birth Date	Date	This field is hidden by default in the <i>Product Family Attributes</i> page. This field is renamed from IBD to International Birth Date.	This field is not available when you modify (Medical Device, Pharmaceutical -Medical Device, Flu Vaccine, Pharmaceutical or Veterinary) Product Family.

Entity Name	Field Name	Field Type	Description	Business Rules
Product Family (All)	Product Family Status	Drop-down list	This field is hidden by default in the <i>Product Family Attributes</i> page. This field is not available when creating a (Medical Device, Pharmaceutical-Medical Device, Flu Vaccine, Pharmaceutical or Veterinary) Product Family.	You can create a Product Family (Medical Device, Pharmaceutical-Medical Device, Flu Vaccine, Pharmaceutical or Veterinary) with the following available attributes: <ul style="list-style-type: none"> Product Family Type Family Code Family Name
	Product Family Status Date	Date	This field is hidden by default in the <i>Product Family Attributes</i> page.	This field is not available when you create any type of (Medical Device, Pharmaceutical-Medical Device, Flu Vaccine, Pharmaceutical or Veterinary) Product Family.
	Product Family Type	Drop-down list	The field is renamed to Family Type .	Only the field display name is changed.
	Product Family	Text	The field is renamed to Family Name .	Only the field display name is changed.

Entity Name	Field Name	Field Type	Description	Business Rules
Product Family (FV, P, V, PMD)	Development Sponsor	Drop-down list	These fields are hidden by default in the <i>Product Family Attributes</i> page.	These fields are not available when you modify (Medical Device, Pharmaceutical -Medical Device, Flu Vaccine, Pharmaceutical or a Veterinary) Product Family.
	Approved Trade Names	View: Display only		
	PSUR Data Lock Date	Date		
	PSUR Due Date	Date		
	Therapeutic Area	Drop-down list		
	Therapeutic Classes (Available/ Selected)	Multi-select		
	Generic Name	Text		
Product (All Types) Component Component Active Ingredients Component Reference Active Ingredients Pharmaceutical Products Modify Event-Product CT Shared Date	Product Family Type	Label	The field is renamed to Family Type.	Only the field display name is changed.

Entity Name	Field Name	Field Type	Description	Business Rules	
N/A	Application Prefix	View: Display only	These fields are hidden for the Standalone Assemblies in the <i>Publish Request</i> window.	Now only the fields related to the selected Publishing Output Channel are displayed in the <i>Publish Request</i> window.	
	Application Number				
	Sequence Number				
	Filling Type	View: Display only	These fields are displayed only for the Sequence Assemblies in the <i>Publish Request</i> window.	N/A	
	Country				
	Submittor Name	View: Display only	This field is renamed to Country .	N/a	
	Application Prefix	View: Display only	These values now can be overridden.	N/A	
	Application Number				
	Sequence Number				
	Publish eCTD/ Electronic				
	Include Leaf with Status				
	Update Volume Page Counts				
	Publishing Output Channel	Drop-down list	Options selected in the <i>Publish Request</i> window for these fields are saved as per the assembly and not as per the logged in user.	N/A	
	Electronic Output Location	Browse			
	Paper Output Location	Browse			
	Output Document Type	Drop-down list			
	Append Application and Sequence Number	Checkbox			
	© Calyx™ 2022. Calyx.ai	Publish eCTD/ Electronic	Radiobutton 85		Calyx RIM Release Notes Entity Fields and Columns Updated: Calyx RIM 7.0
		Single File	Textbox		

Wizards

Wizard Name	Field Name	Field Type	Description	Business Rules
Global Project Plan (all types)	Product Family Type	Drop-down list	This field is renamed to Family Type .	N/A
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name .	N/A
Create Notification	When Status Changes to a Specific Value	Radio button	This option is hidden by default for all the Product Family types in the Create Notification > Choose Notification Type step.	This option is not available when you select Product Family as Entity Type .
	Product Family Type	Drop-down list	This field is renamed to Family Type .	N/A
XEVMPD Submission	Product Family Name	Multi-select editable	This field is renamed to Family Name in the XEVMPD Submission > Authorised Product Selection page.	N/A

Wizard Name	Field Name	Field Type	Description	Business Rules
Create Submission	Application Name	Read-only text (populated automatically)	The Application field now shows the value as a concatenation of [Application Code + Application Name] on the pages: <ul style="list-style-type: none"> – Create Submission Type > Major Update > Complete Submission Properties – Create Submission Type > Amendment > Product Family and Application Properties 	N/A
	Application Code	Drop-down list		
	Product Family Type	Drop-down list	This field is renamed to Family Type on the Create Submission Type > Amendment > Product Family and Application Properties page.	N/A
	Product Family	Drop-down list	This field is renamed to Family Name on the Create Submission Type > Amendment > Product Family and Application Properties page.	N/A
Copy Event	Applications	Multi-select editable	The Applications field on the Copy Event > Choose Applications page now shows field value as a concatenation of [Application Code + Application Name]. >	N/A
	Products	Multi-select editable	This field is renamed from Associated Products to Products on the Copy Event > Choose Products page.	N/A
	Product Family Type	Read-only text (populated automatically)	This field is renamed to Family Type on the Copy Event > Choose Products page.	

Entity Fields and Columns Removed: Calyx RIM 7.0

The following table describes fields and columns that are removed with Calyx RIM 7.0.

Home Page

Table 6: Tabs

Tab name	Column Name	Column Type	Description
Product Families	Therapeutic Area	Read-only text (populated automatically)	These columns are removed from the <i>Product Families</i> grid opened from the Product Families tab on the left pane.
	Therapeutic Class		
Registrations	Product Family Type	Read-only text (populated automatically)	This column is removed from the <i>Registrations</i> grid opened from the Registrations tab on the left pane.
Applications	Product Family	Hyperlink	This column is removed from the <i>Applications</i> grid opened from the Applications tab on the left pane.
Events	Family Name	Hyperlink	This column is removed from the <i>Events</i> grid opened from the Events tab on the left pane.
Full Product Presentations	Product Family Name	Read-only text (populated automatically)	This column is removed from the <i>Full Product Presentations</i> grid opened from the Full Product Presentations tab on the left pane.
Sequences	Family Name	Hyperlink	This column is removed from the <i>Sequences</i> grid opened from the Sequences tab on the left pane.
Submitted Views	Product Family	Hyperlink	This column is removed from the <i>Submitted Views</i> grid opened from the Submitted Views tab on the left pane.
Approved Views	Product Family	Hyperlink	This column is removed from the <i>Approved Views</i> grid opened from the Approved Views tab on the left pane.
My Tasks	Family Name	Read-only text (populated automatically)	This column is removed from the <i>My Tasks</i> grid opened from the My Tasks tab on the left pane.

Table 7: Search Menu

Menu	Column Name	Column Type	Description
Search > Applications	Family Type	Read-only text (populated automatically)	This column is removed from the <i>Search Results</i> page.
Search > Events	Family Type	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page.
	Product Family Name		
Search > Sequences	Family Type	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page.
	Product Family Name		
Search > Registrations	Family Type	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page.
	Product Family Name		
Search > Full Product Presentations	Product Family Name	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page.

Entities

Entity Name	Field Name	Field Type	Description	Business Rules
Product Families	Therapeutic Area	Read-only text (populated automatically)	The Therapeutic Area column and value are removed from: <ul style="list-style-type: none"> Product Families grid Columns menu on the Product Families grid Exported Excel file for the Product Families grid 	N/A (column is removed)
	Therapeutic Classes	Read-only text (populated automatically)	The Therapeutic Classes column and value are removed from: <ul style="list-style-type: none"> Product Families grid Columns menu on the Product Families grid Exported Excel file for the Product Families grid 	N/A (column is removed)
	Create Application	Button	The Create Application button is removed from the Applications tab of all the types of Product Families (Flue Vaccine, Pharmaceutical, Medical Device, Pharmaceutical-Medical Device, Veterinary).	N/A (button is removed)
	Choose a field	Drop-down list	The values are removed from the Choose a field drop-down menu on the Set Filter window for the Product Families grid: <ul style="list-style-type: none"> Product Family Status Product Family Status Date PSUR Data Lock Date PSUR Due Date Therapeutic Area 	Available options: <ul style="list-style-type: none"> IBD Product Family Product Family Type

Entity Name	Field Name	Field Type	Description	Business Rules
Registrations	Family Code	Hyperlink	This field is removed from the: <ul style="list-style-type: none"> – Registrations, Create, Modify, and View pages – <i>Registration-Package Set Attributes</i> page – <i>Package Set Country Attributes</i> page. 	N/A (attribute is removed)
	Family Name	Hyperlink	This field is removed from the: <ul style="list-style-type: none"> – Registrations, Create, Modify, and View pages – <i>Registration-Package Set Attributes</i> page – <i>Package Set Country Attributes</i> page. 	N/A (attribute is removed)
	Product Family Type	Read-only text (populated automatically)	<p>The Product Family Type column and value are removed from:</p> <ul style="list-style-type: none"> – Registrations grid – Columns menu on the Registrations grid – Exported Excel file for the Registrations grid <p>The Product Family Type field is removed from the Registrations, Create, Modify, and View pages.</p>	N/A (column and attribute are removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Applications	Family Code	Hyperlink	<p>This field is removed from the pages:</p> <ul style="list-style-type: none"> – Create Application – Modify Application – View Application – Applications > Countries > Application Country Attributes – Applications > Countries > Add Application Countries – Applications > Countries > Modify Application Country – Product Families > Applications > Application Attributes > Copy Application 	N/A (attribute is removed)
	Family Name	Hyperlink	<p>This field is removed from the pages:</p> <ul style="list-style-type: none"> – Create Application – Modify Application – View Application – Applications > Countries > Application Country Attributes – Applications > Countries > Add Application Countries – Applications > Countries > Modify Application Country – Product Families > Applications > Application Attributes > Copy Application <p>The Family Name value is removed from the Choose a field drop-down menu on the Set Filter window for the Applications grid.</p>	N/A (attribute is removed)
	Associated Products	Multi-select editable	<p>The Associated Products field is removed from the Applications > Application Attributes > Modify Application page and is now included in the Products tab of the Application Attributes page.</p>	N/A (attribute is removed)
	Product Family Type	Read-only text (populated automatically)	<p>The Product Family Type field is removed from the pages:</p> <ul style="list-style-type: none"> – Applications > Countries > Application Country Attributes – Applications > Countries > Add Application Countries – Applications > Countries > Modify Application Country – Product Families > Applications > Application Attributes > Copy Application 	N/A (column and attribute are removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Events	Product Family Type	Label	<p>This field is removed from the following Events pages:</p> <ul style="list-style-type: none"> – View – Create – Modify – Change Details > Associate Change Detail – Comparators > Associate/ Disassociate Comparator to/ from Event – Associate/Disassociate CT Shared Data to/from Event <p>This field is removed from the Associate/Disassociate CT Shared Data to/from Event page for EU CTA and US IND Application types.</p>	N/A (attributes are removed)
	Family Code	Hyperlink	<p>This field is removed from the following Events pages:</p> <ul style="list-style-type: none"> – View – Create – Modify – Change Details > Associate Change Detail – Comparators > Associate/ Disassociate Comparator to/ from Event – Associate/Disassociate CT Shared Data to/from Event <p>This field is removed from the Associate/Disassociate CT Shared Data to/from Event page for EU CTA and US IND Application types.</p>	N/A (attributes are removed)
	Family Name	Text (populated automatically, Hyperlink)	<p>The Family Name column and value are removed from:</p> <ul style="list-style-type: none"> – Events grid – Columns menu on the Events grid – Exported Excel file for the Events grid 	N/A (column attribute are removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Full Product Presentations	Family Code	Hyperlink	This field is removed from the Full Product Presentations View, Create, and Modify pages.	N/A (attribute is removed)
	Family Name	Hyperlink	<p>The Product Family Name column and value are removed from:</p> <ul style="list-style-type: none"> – Full Product Presentations grid – Columns menu on the Full Product Presentations grid – Exported Excel file for the Full Product Presentations grid <p>The Family Name field is removed from the Full Product Presentations View, Create, and Modify pages.</p>	N/A (column and attribute are removed)
FPP Previous EV Code	Family Code	Hyperlink	These fields are removed from the FPP Previous EV Code View, Create and Modify pages.	N/A (attributes are removed)
	Family Name	Hyperlink		
Registration FPP Attachment	Family Code	Hyperlink	These fields are removed from the Registration FPP Attachment View, Create and Modify pages.	N/A (attributes are removed)
	Family Name	Hyperlink		

Entity Name	Field Name	Field Type	Description	Business Rules
Sequences	Family Name	Hyperlink	<p>The Family Name column and value are removed from:</p> <ul style="list-style-type: none"> Sequences grid Columns menu on the Sequences grid Exported Excel file for the Sequences grid <p>The Family Name field is removed from the following Sequences pages:</p> <ul style="list-style-type: none"> Create Modify View Status Dates > Add Status Status Dates > Modify Status 	N/A (column and attribute are removed)
	Choose a field	Drop-down list	The Product Family value no longer appears in the Choose a field drop-down menu on the Set Filter window for the Sequences grid.	N/A
	Family Code	Hyperlink	<p>The Family Code field is removed from the following Sequences pages:</p> <ul style="list-style-type: none"> Create Modify View Status Dates > Add Status Status Dates > Modify Status <p>This field is removed from the Sequences Attributes > Tasks, Create, Edit, and View pages.</p>	N/A (attributes are removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Submitted Views	Product Family	Hyperlink	<p>The Product Family column is removed from:</p> <ul style="list-style-type: none"> – Submitted Views grid – Columns drop-down menu on the Submitted Views grid – Exported Excel file for the Submitted Views grid – Submitted Views tab of the Application Attributes page – Exported Excel file for the Submitted Views tab of the Applications Attributes page – Columns drop-down menu on the Submitted Views tab of the Application Attributes page 	N/A (column is removed)
Approved Views	Product Family	Hyperlink	<p>The Product Family column is removed from:</p> <ul style="list-style-type: none"> – Approved Views grid – Columns drop-down menu on the Approved Views grid – Exported Excel file for the Approved Views grid – Approved Views tab of the Application Attributes page – Exported Excel file for the Approved Views tab of the Applications Attributes page – Columns drop-down menu on the Approved Views tab of the Application Attributes page 	N/A (column is removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Tasks and Sub-tasks	Family Code	Hyperlink	These fields are removed from the Create, Edit, and View pages of the following entities: <ul style="list-style-type: none"> – Tasks > References > Tasks – Registration Attributes > Tasks – Application Attributes > Tasks – Event Attributes > Tasks – Sequences > Tasks 	N/A (attributes is removed)
	Family Name			
Projects	Product Family	Read-only text (populated automatically)	On the Project Attributes page, the Product Family column and value are removed from: <ul style="list-style-type: none"> – Event Change Details tab – Columns menu on the Event Change Details grid – Exported Excel file for the Event Change Details grid 	N/A (column is removed)
	Family Type	Text (populated automatically, Hyperlink)	The Products tab of the Project page now includes the Family Type column	N/A
	Family Name	Text (populated automatically, Hyperlink)	The Products tab of the Project page now includes the Family Name column	
	Family Code	Text (populated automatically, Hyperlink)	The Products tab of the Project page now includes the Family Code column	
Changes	Product Family	Read-only text (populated automatically)	On the View Change and View Change Detail pages, the Product Family column and value are removed from: <ul style="list-style-type: none"> – Related Events tab – Columns menu on the Related Events grid – Exported Excel file for the Related Events grid 	N/A (column is removed)

Entity Name	Field Name	Field Type	Description	Business Rules
Product Detail Sets	Family Name	Hyperlink	These fields are removed from the Events > Product Detail Sets > Create Product Detail Set page.	N/A (attributes are removed)
	Family Code			
N/A	Region	View: Display only	These fields are removed from the <i>Publish Request</i> window.	N/A (attributes are removed)
	Family Code			
	Submittor Name			

Wizards

Wizard Name	Field Name	Field Type	Description	Business Rules
Create Application	Product Family Type	Read-only text (populated automatically)	These fields are removed from the Create Application > Create Event page.	N/A (attributes are removed)
	Family Name			
	Family Code			
Global Project Plan (all types)	Product Family	Read-only text (populated automatically)	The Product Family Name column is removed from the Select applications > Select an Application grid.	N/A

Wizard Name	Field Name	Field Type	Description	Business Rules
Update Status	Family Name	<ul style="list-style-type: none"> – Drop-down list – Read-only text (populated automatically) 	This field is removed from: <ul style="list-style-type: none"> – Event Search Criteria > Select values to refine search page – Select Event(s) > Select Event(s) to update grid – Enter values to update entities page – Update Event Country Status page 	N/A (attributes are removed)
	Update PSUR Dates on the Product Family?	Drop-down list	This field is removed from the Enter values to update entities page.	
	Product Family Type	Read-only text (populated automatically)	This field is removed from the Update Event Country Status page.	
	Family Code	Read-only text (populated automatically)	This field is removed from the Update Event Country Status page.	
Create Submission Plan	Product Family	Read-only text (populated automatically)	This column is removed from the: <ul style="list-style-type: none"> – Create Submission Plan > Select Applications page – Create Submission Plan > Create Event > Select Applications page – Create Submission Plan > Associate Event > Select Events page – Create Submission Plan > Create Sequence > Select Events page – Create Submission Plan > Associate Sequence > Select Sequence page 	N/A (column is removed)

Wizard Name	Field Name	Field Type	Description	Business Rules
Create Notification	Available Options	Drop-down list	<p>The values are removed from the Available Options drop-down menu on the Create Notification > Select Rule Settings and Delivery Destinations step for the following Product Family types:</p> <ul style="list-style-type: none"> — Flu Vaccine: <ul style="list-style-type: none"> • Product Family Status • Product Family Status Date • PSUR Due Date • PSUR Data Lock Date • Generic Name • Therapeutic Area • Development Sponsor — Medical Device: <ul style="list-style-type: none"> • Product Family Status • Product Family Status Date • International Birth Date • Division — Pharmaceutical: <ul style="list-style-type: none"> • Product Family Status • Product Family Status Date • PSUR Due Date • PSUR Data Lock Date • Generic Name • Therapeutic Area • Development Sponsor — Pharmaceutical-Medical Device: <ul style="list-style-type: none"> • Product Family Status • Product Family Status Date • PSUR Due Date • PSUR Data Lock Date • Generic Name • Therapeutic Area • Division • Development Sponsor — Veterinary: <ul style="list-style-type: none"> • Product Family Status • Product Family Status Date • PSUR Due Date 	N/A (values are removed)

Wizard Name	Field Name	Field Type	Description	Business Rules
Import Assembly Wizard	Family Name	Text	<p>This field is removed from the <i>Search Criteria</i> page of the Import Assembly Wizard for the Sequence Assembly, Assembly Approved View, and Assembly Submitted View.</p> <p>This column is removed from the <i>Matching Assemblies</i> page of the Import Assembly Wizard for the Sequence Assembly, Assembly Approved View, and Assembly Submitted View.</p>	N/A (attributes are removed)
	Display Columns	Multi-select editable	The Family Name option is removed from the Display Columns multi-select field of the <i>Search Criteria</i> page in the Import Assembly Wizard for the Sequence Assembly, Assembly Approved View, and Assembly Submitted View.	
	Sort Order		The Family Name option is removed from the Sort Order multi-select field of the <i>Search Criteria</i> page in the Import Assembly Wizard for the Sequence Assembly, Assembly Approved View, and Assembly Submitted View.	

Wizard Name	Field Name	Field Type	Description	Business Rules
Update Applications	Product Family Status	<ul style="list-style-type: none"> – Multi-select editable – Read-only text (populated automatically) 	<p>These fields are removed from the Update Applications > Enter Applications Search Criteria > Select values to refine search page.</p> <p>These columns are removed from the Update Applications > Select Applications page.</p>	N/A (column and attribute are removed)
	ATC Code			
	Therapeutic Area			
	Therapeutic Class			
	PSUR Due Date			
	PSUR Data Lock Date			
	Family Name	Read-only text (populated automatically)	This column is removed from the Update Applications > Select Applications page.	N/A (column is removed)
Update Project Event Country Status	Product Family Name	Read-only text (populated automatically)	<p>The Product Family Name is removed from the:</p> <ul style="list-style-type: none"> – Select Event Countries > Select the event countries you would like to update grid – Confirmation > Clicking Next will perform the following actions: page – Summary > Summary page 	N/A (attributes are removed)
Calculate Project Dates	Product Family Name	Read-only text (populated automatically)	The Product Family Name column is removed from the Select Event Countries > Select the event countries you would like to update grid.	N/A (column is removed)

Wizard Name	Field Name	Field Type	Description	Business Rules
Bulk Update Events	Product Family	<ul style="list-style-type: none"> – Multi-select editable – Read-only text (populated automatically) 	<p>The Product Family is removed from the:</p> <ul style="list-style-type: none"> – Enter Events Search Criteria > Select values to refine search page – Select Events > Select Events to update grid 	N/A (attributes are removed)
	Sort Order		The Product Family value is removed from the <i>Sort Order</i> multi-select field of the Enter Events Search Criteria > Select values to refine search page.	
Bulk Update Sequences	Product Family	<ul style="list-style-type: none"> – Multi-select editable – Read-only text (populated automatically) 	<p>The Product Family field is removed from:</p> <ul style="list-style-type: none"> – Enter Sequences Search Criteria > Select values to refine search page – Select Sequences > Select Sequences to update grid 	N/A (attributes are removed)
	Sort Order		The Product Family value is removed from the <i>Sort Order</i> multi-select field of the Enter Sequences Search Criteria > Select values to refine search page.	
Create eCTD	Family Name	Read-only text (populated automatically)	These fields are removed from the Create eCTD > Choose Region page.	N/A (attributes are removed)
	Family Code			
XEVMPD Submission	Family Name	Read-only text (populated automatically)	The Family Name column is removed from the XEVMPD Submission > Authorised Product Search Results page.	N/A (column is removed)

Wizard Name	Field Name	Field Type	Description	Business Rules
Create Submission	Family Name	Drop-down list	The Family Name field is removed from the Create Submission > Complete Submission Properties (application) > Complete the submission status properties (application) page.	N/A (attribute is removed)
	Application Code	Drop-down list	This field is removed. Now the Application Code value is displayed in the Application field as a concatenation of [Application Code + Application Name].	N/A (attribute is removed)
	Product Family	Read-only text (populated automatically)	This column is removed from the Create Submission > Select Events page.	N/A (column is removed)
Copy Event	Product Family Type	Read-only text (populated automatically)	These fields are removed from the Copy Event > Choose Products page.	N/A (attributes are removed)
	Family Code			
	Family Name			

Wizard Name	Field Name	Field Type	Description	Business Rules
Associate Workflow to Events or Sequences	Product Family	Read-only text (populated automatically)	This column is removed from the Project Attributes > Associate Workflow > Select Events grid.	N/A (columns are removed)
			This column is removed from the Project Attributes > Associate Workflow > Select Sequences grid.	
Create Sequence	Product Family	Read-only text (populated automatically)	This column is removed from the Project Attributes > Create Sequence > Select Events grid.	
Create References for the Project Events or Sequences			This column is removed from the Project Attributes > Create References for Events > Select Events grid.	
			This column is removed from the Project Attributes > Create References for Sequences > Select Events grid.	
Copy Registration Attachment	Product Family Name	Read-only text (populated automatically)	This column is removed from The Copy Registration Attachment Attributes > Select Full Product Presentation(s) where newly copied Registration attachment should be created page.	

Query Fields

Query Fields and Columns Added: Calyx RIM 7.0

The following table describes fields that were added with Calyx RIM 7.0.

Registration Planning and Tracking

Query Name	Field Name	Field Type	Description
List of Events with Change Details	N/A	N/A	The Registration Planning and Tracking tab includes the List of Events with Change Details query.
XEVMPD Submissions - QC Verification and Audit	N/A	N/A	The Registration Planning and Tracking tab includes the XEVMPD Submissions - QC Verification and Audit query.
XEVMPD Submissions and Acknowledgments	N/A	N/A	The Registration Planning and Tracking tab includes the XEVMPD Submissions and Acknowledgments query.

Query Fields and Columns Updated: Calyx RIM 7.0

The following table describes fields that were updated with Calyx RIM 7.0.

Registration Planning and Tracking Queries

Query Name	Field Name	Field Type	Description
List of Medical Device Products and Components	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Medical Device Products and Components</i> page – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Applications with Products	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of Applications with Products Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Applications with Products Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Events with Application Properties	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of Events with Application Properties Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Events with Application Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
Event Change Detail Report	N/A	N/A	This report is renamed to <i>List of Events with Change Details</i> .
List of Events with Change Details	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Events with Change Details</i> page.
	Product Family Name	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Events with Change Details</i> page. – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Sequences with Application and Event Properties	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of Sequences with Application and Event Properties Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Sequences with Application and Event Properties</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Registrations with Application Properties	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Registrations with Application Properties Query</i> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family Name		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Registrations with Application Properties Query</i> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
PSUR World Wide Marketing Authorization Status Query	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>PSUR World Wide Marketing Authorization Status Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the <i>PSUR World Wide Marketing Authorization Status Query</i> page.

Query Name	Field Name	Field Type	Description
List of References - Rollup by Application	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of References - Rollup by Application Query</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of References - Rollup by Application Query</i> page.
List of References - Rollup by Product Family	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of References - Rollup by Product Family Query</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of References - Rollup by Product Family Query</i> page.
List of Tasks - Rollup by Product Family	Product Family Type	Drop-down list	This field is renamed to Family Type on the on the <i>List of Tasks - Rollup by Product Family</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of Tasks - Rollup by Product Family</i> page.
List of Tasks - Rollup by Application	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of Tasks - Rollup by Application</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of Tasks - Rollup by Application</i> page.
List of CTA Applications	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of CTA Applications</i> page. – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of CTA Applications</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of IND Applications	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of IND Applications</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of IND Applications</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Products with Event and Product Registration Details	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Products with Event and Product Registration Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family	Multi-select editable	This field is renamed to Family Type on the <i>List of Products with Event and Product Registration Details</i> page.
Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient	Product Family Name	Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
Applications Submitted and/or Approved and/or Terminated within a Date Range	Product Family Name	Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Product Detail Management Queries

Query Name	Field Name	Field Type	Description
List of Application Countries with PDS Country and Registration Details	Product Family Type	Drop-down list, Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Application Countries with PDS Country and Registration Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family Name		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Application Countries with PDS Country and Registration Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of CTA Applications with PDS Details	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of CTA Applications with PDS Details</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of CTA Applications with PDS Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Product Detail Sets	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the <i>List of Product Detail Sets Query</i> page.
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Product Detail Sets Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Registration Package Sets Withdrawn	Product Family Type	Drop-down list	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Registration Package Sets Withdrawn</i> page – <i>Search Results</i> page
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Registration Package Sets Withdrawn</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
Application History Query	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>Application History Query</i> page.
	Product Family		This field is renamed to Family Name on the <i>Application History Query</i> page.
Application QC Status History Report	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>Application QC Status History Report</i> page.
	Product Family		This field is renamed to Family Name on the <i>Application QC Status History Report</i> page.

Query Name	Field Name	Field Type	Description
Sunset Clause Marketing Status Query	Product Family Type	Drop-down list	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>Sunset Clause Marketing Status Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family	Drop-down list	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>Sunset Clause Marketing Status Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Active Ingredient Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Active Ingredient Function Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Function Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Function Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Active Ingredient Material Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Material Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Active Ingredient Material Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Excipient Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Excipient Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Excipient Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of PDS Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of PDS Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of PDS Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Component Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Component Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Component Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Package Set Manufacturers	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Package Set Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Package Set Manufacturers</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Species and Indications	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Species and Indications</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Dose Schedules	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Dose Schedules</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Withdrawal Times	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Withdrawal Times</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
Labeled Indications Query	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>Labeled Indications Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>Labeled Indications Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of IND Applications with PDS Details	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of IND Applications with PDS Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of IND Applications with PDS Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
<ul style="list-style-type: none"> – List of Product Registrations with Application and Product Detail Properties – List of Registrations with Indications/ Intended Use – List of Registrations with Excipients – List of Registrations with Active Ingredients – List of Registrations with Material – List of Registrations with Labeling – List of Registrations with Packaging – List of Registrations with Local Country Details 	Product Family Type	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – Queries – Display Columns multi-select field options of the queries. – Sort Order multi-select field options of the queries – <i>Search Results</i> page of the queries
	Product Family Name		This field is renamed to Family Name on the: <ul style="list-style-type: none"> – Queries – Display Columns multi-select field options of the queries – Sort Order multi-select field options of the queries – <i>Search Results</i> page of the queries.

Query Name	Field Name	Field Type	Description
List of Application Countries with PDS Country and Registration Details	Product Family Type	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Type on the: <ul style="list-style-type: none"> – <i>List of Application Countries with PDS Country and Registration Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family Name	Drop-down list, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>List of Application Countries with PDS Country and Registration Details</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
	Product Family Code	Read-only text (populated automatically)	This field is renamed to Family Code on the: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Submission Planning and Tracking Queries

Query Name	Field Name	Field Type	Description
List of Events with Application Properties	Product Family Type	Drop-down	This field is renamed to Family Type on the <i>List of Events with Application Properties Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on: <ul style="list-style-type: none"> – <i>List of Events with Application Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Sequences with Application and Event Properties	Product Family Type	Drop-down	This field is renamed to Family Type on the <i>List of Sequences with Application and Event Properties Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on: <ul style="list-style-type: none"> – <i>List of Sequences with Application and Event Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
List of Applications	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on: <ul style="list-style-type: none"> – <i>List of Applications Query</i> page – Display Columns multi-select field options – <i>Search Results</i> page
List of References - Rollup by Application	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of References - Rollup by Application Query</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of References - Rollup by Application Query</i> page.
List of References - Rollup by Product Family	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of References - Rollup by Product Family Query</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of References - Rollup by Product Family Query</i> page.

Registered Document Analysis Queries

Query Name	Field Name	Field Type	Description
Registered Document Query	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on the: <ul style="list-style-type: none"> – <i>Registered Document Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Query Name	Field Name	Field Type	Description
List of Events with Application Properties	Product Family Type	Drop-down	This field is renamed to Family Type on the <i>List of Events with Application Properties Query</i> page.
	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on: <ul style="list-style-type: none"> – <i>List of Events with Application Properties Query</i> page – Display Columns multi-select field options – Sort Order multi-select field options. – <i>Search Results</i> page
List of Applications	Product Family	Multi-select editable, Read-only text (populated automatically)	This field is renamed to Family Name on: <ul style="list-style-type: none"> – <i>List of Applications Query</i> page. – Display Columns multi-select field options – <i>Search Results</i> page.
List of Tasks - Rollup by Application	Product Family Type	Drop-down list	This field is renamed to Family Type on the <i>List of Tasks - Rollup by Application</i> page.
	Product Family		This field is renamed to Family Name on the <i>List of Tasks - Rollup by Application</i> page.

Query Fields and Columns Removed: Calyx RIM 7.0

The following table describes fields that were removed with Calyx RIM 7.0.

Registration Planning and Tracking Queries

Query Name	Field Name	Column Name	Field Type	Description
List of Application Countries with Registration Details	Product Family Status	N/A	Multi-select editable	This field is removed from the <i>List of Application Countries with Registration Details Query</i> .
	Display Columns	N/A	Multi-select editable	The following options are removed from the Display Columns multi-select field of the <i>List of Application Countries with Registration Details Query</i> : <ul style="list-style-type: none"> — Product Family Status — Product Family Status Date — Therapeutic Area — Therapeutic Class
	Sort Order	N/A	Multi-select editable	The following options are removed from the Sort Order multi-select field of the <i>List of Application Countries with Registration Details Query</i> : <ul style="list-style-type: none"> — Product Family Status (ASC, DESC) — Product Family Status Date (ASC, DESC) — Therapeutic Area (ASC, DESC) — Therapeutic Class (ASC, DESC)

Query Name	Field Name	Column Name	Field Type	Description
List of Application with Products	<ul style="list-style-type: none"> – Therapeutic Area – Therapeutic Class – Product Family Status – PSUR Due Date – PSUR Data Lock Date 	N/A	Multi-select editable	These fields are removed from the <i>List of Application with Products Query</i> .
		<ul style="list-style-type: none"> – Therapeutic Area – Therapeutic Class – Product Family Status – PSUR Due Date – PSUR Data Lock Date 		These columns are removed from the <i>Search Results</i> page.

Query Name	Field Name	Column Name	Field Type	Description
List of Product Families	Product Family Status	N/A	Multi-select editable	These fields are removed from the <i>List of Product Families</i> query.
	Therapeutic Area			
	Therapeutic Class			
	Development Sponsor			
	Product Family Status Date		Date	
	Next PSUR Date			
	PSUR Data Lock Date			
	Generic Name		Text	
N/A	<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date – Next PSUR Date – PSUR Data Lock Date – Generic Name – Area – Class – Development Sponsor 	Read-only text (populated automatically)		These columns are removed from the <i>Search Results</i> page of the List of Product Families query.
List of Pharmaceutical Products	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the <i>List of Pharmaceutical Products</i> query.
	N/A	<ul style="list-style-type: none"> – Family Status – Family Status Date – Classes 	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page of the List of Pharmaceutical Products query.

Query Name	Field Name	Column Name	Field Type	Description
List of Veterinary Products	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the <i>List of Veterinary Products</i> .
	N/A	<ul style="list-style-type: none"> – Family Status – Family Status Date – Classes 	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page of the List of Veterinary Products query.
List of Medical Device Products	N/A	<ul style="list-style-type: none"> – Family Status – Family Status Date 	Read-only text (populated automatically)	These columns are removed from the <i>List of Medical Device Products</i> .
List of Pharmaceutical and Medical Device Products	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the <i>List of Pharmaceutical and Medical Device Products</i> .
	N/A	<ul style="list-style-type: none"> – Family Status – Family Status Date – Classes 	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page of the List of Pharmaceutical and Medical Device Products query.

Query Name	Field Name	Column Name	Field Type	Description
List of Pharmaceutical Products and Components	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the List of Pharmaceutical Products and Components.
	N/A	<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date – Therapeutic Classes 	Read-only text (populated automatically)	These columns are removed from the Search Results page of the List of Pharmaceutical Products and Components query.
List of Medical Device Products and Components	N/A	<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date 	Read-only text (populated automatically)	These columns are removed from the List of Medical Device Products and Components query page.
List of Veterinary Products and Components	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the List of Veterinary Products and Components query page.
		<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date – Therapeutic Classes 	Read-only text (populated automatically)	These columns are removed from the Search Results page of the List of Veterinary Products and Components query.

Query Name	Field Name	Column Name	Field Type	Description
List of Pharmaceutical and Medical Device Products and Components	Therapeutic Classes	N/A	Multi-select editable	This field is removed from the List of Pharmaceutical and Medical Device Products and Components page.
	N/A	<ul style="list-style-type: none"> – Product Family Status – Product Family Status Date – Therapeutic Classes 	Read-only text (populated automatically)	These columns are removed from the Search Results page of the List of Pharmaceutical and Medical Device Products and Components query.

Query Name	Field Name	Column Name	Field Type	Description
List of Registrations with Application Properties	PSUR Data Lock Date	N/A	Date	This field is removed from the <i>List of Registrations with Application Properties Query</i> .
	PSUR Due Date			This field/value is removed from: <ul style="list-style-type: none"> — <i>List of Registrations with Application Properties Query</i> — Display Columns multi-select field options — Sort Order multi-select field options
	N/A	PSUR Due Date		This column is removed from the <i>Search Results</i> page.

Query Name	Field Name	Column Name	Field Type	Description
<ul style="list-style-type: none"> – List of Registrations for a Product Family – List of References - Rollup by Product Family – List of Tasks - Rollup by Product Family 	Division	N/A	Multi-select editable	This field/value is removed from: <ul style="list-style-type: none"> – Queries – Display Columns multi-select field options of the queries – Sort Order multi-select field options of the queries
	N/A	Division	Read-only text (populated automatically)	This column is removed from the Search Results page of these queries.

Product Detail Management Queries

Query Name	Field Name	Column Name	Field Type	Description
<ul style="list-style-type: none"> – <i>List of Registrations with Application Properties Query</i> 	PSUR Data Lock Date	N/A	Date	This field is removed.
	PSUR Due Date			<ul style="list-style-type: none"> – This field/value is removed from: – Queries – Display Columns multi-select field options of the queries – Sort Order multi-select field options of the queries
<ul style="list-style-type: none"> – List of Product Registrations with Application and Product Detail Properties – List of Registrations with Indications/ Intended Use – List of Registrations with Excipients – List of Registrations with Active Ingredients – List of Registrations with Material – List of Registrations with Labeling – List of Registrations with Packaging – List of Registrations with Local Country Details 	N/A	PSUR Due Date		<p>This column is removed from the Search Results page of these queries.</p>

Query Name	Field Name	Column Name	Field Type	Description
List of Application Countries with PDS Country and Registration Details	N/A	Product Family Status	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page.
	N/A	Product Family Status Date		
	Sort Order			The following values are removed from the Sort Order multi-select field: <ul style="list-style-type: none"> — Product Family Status — Product Family Status Date

Submission Planning and Tracking

Query Name	Field Name	Column Name	Field Type	Description
List of Applications	Product Family Status	N/A	Multi-select editable, Read-only text (populated automatically)	These fields are removed from: <ul style="list-style-type: none"> – <i>List of Applications Query</i> – Display Columns multi-select field options
	PSUR Due Date		Date	
	PSUR Data Lock Date			
	N/A	Product Family Status	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page of the List of Applications query.
		PSUR Due Date		
		PSUR Data Lock Date		
	Sort Order			Multi-select editable

Registered Document Analysis

Query Name	Field Name	Column Name	Field Type	Description
List of Applications	Product Family Status	N/A	Multi-select editable, Read-only text (populated automatically)	These fields are removed from: <ul style="list-style-type: none"> – <i>List of Applications Query</i> – Display Columns multi-select field options
	PSUR Due Date		Date	
	PSUR Data Lock Date			
		Product Family Status	Read-only text (populated automatically)	These columns are removed from the <i>Search Results</i> page of the List of Applications query.
		PSUR Due Date		
		PSUR Data Lock Date		
		Sort Order	N/A	Multi-select editable

Database Columns Changed: Calyx RIM 7.0

The following Database Columns were added, modified, or removed in this release.

Field Name	Field Size	Database Column Name	Db Column Size	Db Table Name
Application Name	N/A	NAME	VARCHAR2(500) is changed to VARCHAR2(2000).	APPLICATION

Access the Customer Service Portal

If you have issues when working in the system that you cannot resolve with the Help documentation, you can access the Service Portal to view knowledge articles or log a support ticket.

To access the Service Portal:

1. Navigate to mytrials.com.
The Perceptive MyTrials log in page appears.
2. Enter your Perceptive MyTrials user name and password, and click **Log On**.
If you do not have a Perceptive MyTrials account, click **Join Perceptive MyTrials** and register. Perceptive MyTrials confirms your account with an email.
The home page appears.
3. Do one of the following:
 - Click **Customer Care** at the bottom of the page.
 - In the *My Weblinks* portlet, click **Customer Service Portal**.

The home page for the [Service Portal](#) appears. You can browse and search for the information you need.

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