
Calyx RIM 7.2.2 Data Migration Documentation

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Data Migration Documents

Document Name
Calyx RIM 7.2.2 Data Migration Document
Calyx RIM 7.2 Data Migration Document
Calyx RIM 7.1.3 Data Migration Document
Calyx RIM 7.1 Data Migration Document
Calyx RIM 7.0 Data Migration Document
Data Migration Document - Previous Versions

***Note:** To migrate to Calyx RIM 7.2.2 from Calyx RIM 7.2.1, please contact your Business Development Representative for assistance.*

Calyx RIM Database Migration Release Notes

The Calyx RIM Database Migration Release Notes and the Calyx RIM Data Migration Documents provide information about the SQL database scripts and other procedures required to perform Calyx RIM database migrations. The installation and migration script package provides a convenient means for distributing the Calyx RIM database scripts and guidance for upgrading the Calyx RIM database.

Calyx RIM data migration documentation provides essential information to support new installations and upgrades, and to assist your migration planning and execution. It should be read with the Calyx RIM Release Notes, which describe the updates that have been implemented in each release.

Before executing any database scripts, verify that you have the most current version of the Calyx RIM Database Migration package. See the FTP site or contact Technical Support to confirm.

Prerequisites

Users and groups who use the Calyx RIM 7.2 system should have their accounts created in Azure AD and provide the User Object IDs for the user migration phase. For Data Migration requirements, see [Calyx RIM 7.2 Data Migration Requirements](#).

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

Calyx RIM Database Migration Details

The migration package includes SQL database scripts that are run on an Oracle database to establish the database instance for Calyx RIM.

You can use the database scripts as a guide for migrating your earlier version of Calyx RIM to a current release.

Note: The migration scripts delete all saved queries.

The scripts are supplied in ZIP files:

- DB Upgrade 70 to 71.zip(DB_update7_1_0_0000_0112.zip) (To migrate to Calyx RIM 7.1 from Calyx RIM 7.0, see: *Data Migration Documents*)
- DB Upgrade 71 to 711.zip(DB_update7_1_1_0000_0001.zip) (To migrate to Calyx RIM 7.1.1 from Calyx RIM 7.1, see: *Data Migration Documents*)
- DB Upgrade 711 to 712.zip(DB_update7_1_2_0000_0001.zip) (To migrate to Calyx RIM 7.1.2 from Calyx RIM 7.1.1, see: *Data Migration Documents*)
- DB Upgrade 712 to 713.zip(DB_update7_1_3_0000_0020.zip) (To migrate to Calyx RIM 7.1.3 from Calyx RIM 7.1.2, see: *Data Migration Documents*)

- DB Upgrade 713 to 715.zip(DB_update7_1_5_0000_0003.zip) (To migrate to Calyx RIM 7.1.5 from Calyx RIM 7.1.3, see: *Data Migration Documents*)
 - DB Upgrade 715 to 72.zip(DB_update7_2_0_0000_0096.zip) (To migrate to Calyx RIM 7.2 from Calyx RIM 7.1.5, see: *Data Migration Documents*)
 - DB Upgrade 72 to 721.zip(DB_update7_2_1_0000_0002.zip)
 - DB Upgrade 721 to 722.zip(DB_update7_2_2_0000_0011.zip)
-

Note: To migrate to Calyx RIM 7.2.2 from Calyx RIM 7.2.1, contact your Business Development Representative for assistance.

Calyx RIM 7.2.2 Updates

Calyx RIM 7.2.2 Security Administration Updates

This update will be available in Security Administration through data migration.

Application Country Rights

If no value is selected for the **Product Family** box and the **Select** option is chosen, the **NOT DEFINED** value is displayed. It means that the application is not connected to any of the products or product families. To set up a connection, a proper product family name must be selected.

Calyx RIM 7.2.2 Home Page Updates

Updates to the Home Page through data migration.

Product Family Tree

The applications in the system with no association to the product or product family are displayed in the **NOT DEFINED** folder in the **Product Family** tree.

Countries Tree

The applications in the system with no association to the product or product family are displayed in the **NOT DEFINED** folder under a country the application is created for in the **Countries** tree.

Entities

Calyx RIM 7.2.2 Application Updates

The following updates are available for the Application through data migration.

Application

When there is an application entity change in the database, a column is added to the `app_prod_fam` table. The following values appear after migration:

- If the application was created under a product family, the record will have `DEFAULT_FLAG = "Y"`
- If the application has products from the multiple product families, the record for a parent product family will be created with the `DEFAULT_FLAG = "Y"`, the other product families will have the `DEFAULT_FLAG = "N"`.

***Note:** If there is a request to change how this new column is populated by the out-of-the-box migration process described in the current document, please contact your Business Development Representative for assistance.*

Calyx RIM 7.2.2 Event Updates

Updates to Events through data migration.

Event

There is a change to the *Create Event* page, when creating it manually, the **CT Shared Data** field is now available for Clinical Trial Authorization (CTA), Investigational New Drug (IND) or European Union Clinical Trials Regulations (EU CTR) applications. Rules for the field are the same as on the *Create Application* wizard.

- For the CTA application type, the **CT Shared Data** field is not a required box.
- For the IND application type, the **CT Shared Data** field is not a required multi-select.
- For the EU CTR application type, the **CT Shared Data** field is not a required multi-select.

Data availability for **CT Shared Data**:

- If an application is created under the product family with no product association, the values for **CT Shared Data** are taken from this product family.
- If an application is created under the product family with a product association from another product family, the values for **CT Shared Data** are taken from the both product families.
- If an application is created via the *Create Application* wizard with no product association, the **CT Shared Data** field is empty.
- If an application is created via the *Create Application* wizard and there is at least one associated product, the values for **CT Shared Data** are taken from that product/product family association.

Optional Post Migration Scripts

Optional Post Migration Scripts

The post migration scripts identify the pseudo (placeholder) products and delete them if required.

It was not possible to migrate Calyx RIM 7.0 applications without products. Therefore, pseudo (placeholder) products were created.

You can use the optional post migration scripts below to identify the pseudo (placeholder) products and delete them if necessary:

- `post_mig_all_rpt_placeholder_appl_products.sql` script
- `post_mig_rpt_placeholder_appl_products.sql`
- `post_mig_delete_placeholder_appl_products.sql`

In Calyx RIM 7.2.2 it is possible to create an application without a product.

`post_mig_all_rpt_placeholder_appl_products.sql` script

The migration script identifies the pseudo (placeholder) products created via Calyx RIM 7.0 migration process.

The final output is in TXT format.

Table 1: Report Column Definition

post_mig_all_rpt_placeholder_appl_products.sql script	
Report Column	Value
FamilyName	Displays the Product Family Name.
FamilyType	Displays the Product Family Type.
ApplicationName/Study	Displays the Application Name with a Study Number for CTA Application Type.
ApplicationCode	Displays Internal System Status for Application Status value.
ApplicationType	Displays the Application Type.
ProcedureType	Displays the Application Procedure Type.
ReviewingCountry	Displays the Application Reviewing Country.
ProductName	Displays the Product Name created by the migration.
CreationDate	Displays the date that the product was created.
Creator	Displays the user who created the product.

post_mig_rpt_placeholder_appl_products.sql

The migration script identifies the pseudo (placeholder) products created via Calyx RIM 7.0 migration process which can be deleted by the next optional script.

This script generates a list of the pseudo (placeholder) products which can be deleted by the next script. Those products meet the following requirements:

- The absence of the PDS templates, or events as association for the non-CTA/IND application types.
- The absence of the event and the CT Shared Data selected for CTA/IND applications.

Script columns are the same as for **post_mig_all_rpt_placeholder_appl_products.sql script**. See *post_mig_all_rpt_placeholder_appl_products.sql script*.

For any requests of product deletion rules changes for out-of-the-box migration process, please contact your Business Development Representative for assistance.

post_mig_delete_placeholder_appl_products.sql

The migration script deletes the pseudo (placeholder) products created via Calyx RIM 7.0 migration process.

This script deletes all the products based on the name of the template (the same that was used for Calyx RIM 6.2 -> 7.0 migration). You can specify the PREFIX or use the default one.

The script will not affect any products that you have used or those which have PDS templates or events as association.

For the CTA/IND applications, when there is an event with the CT Shared Data association, and no PDS, the product will be deleted from both the application and the event.

Calyx RIM 7.2 Updates

Security Administration

Calyx RIM 7.2 Security Administration Updates

The following updates will be available in Security Administration through data migration.

XEVMPD License Module

To support IDMP, the XEVMPD (eXtended EudraVigilance Medicinal Product Dictionary) field in Calyx RIM 7.2 is renamed to IDMP and xEVMPD.

Entity Security and Home Page Access

Two new entities: Medicinal Products and Medicinal Product Actions are added to the Entity Security and Home Page Access sections.

Home Page

Calyx RIM 7.2 Home Page Updates

The following updates will be available on the Home Page through data migration.

My Home

For better navigation to the IDMP entities, the Medicinal Products and the Medicinal Product Actions tabs are added to the *My Home* page.

Data Administration Updates

Data Administration Updates for Calyx RIM 7.2

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated, if necessary.

Application Maintenance

For the Country Values, Legal Status Values, Orphan Status Values, Procedure Type Values, Product Information Document Type Values, Regulatory Entitlement Type Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Medical Device Maintenance

To capture the data of Class III High Risk Medical Device products for UDI FDA and UDI MDR submissions, the new **Medical Device Maintenance** section is added to the *Data Administration* and includes the following sub sections:

- EU Device Nomenclature Category Values .
- EU Device Nomenclature Values .
- FDA GMDN In-Vitro Term Type Values
- Global Medical Device Nomenclature (GMDN) Code Values is moved from the Product Maintenance section.

Other

To support IDMP specification, the **Certificate Master File Values** and **File Identifier Type Values** sections are added to the **Other** section.

For the **Application Submission Type Values**, **Concentration Measure Type Values**, **Indications/Intended Use Values**, **Language Values**, **Legal Basis Values**, **Units of Measurement Values**, **Unit of Presentation Values**, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Product Detail Set Maintenance

To support IDMP specification, the **Origin of Substance Values** list is added to the **Product Detail Set Maintenance** section.

The **Packaging Category Values** list now includes the **IDMP Package Level** field.

To define more than one material for a package component, the following changes are implemented for **Package Component Values**:

- the **Product Material** field type is changed to multiple selection.
- the **Product Material** field is not required.

The following changes are implemented for **Manufacturer Values**:

- The **Confidentiality Indicator** is available on the **Manufacturer Values > Global Product Details** when you select the **Packaging** or **Substance** option for the **Detail Type** field.
- The **Manufacturing Authorization Reference Number** tab now includes the **Country** that approved the manufacturing site and the **Regulatory Agency** in the country that approved the manufacturer.
- The **Regulatory Agency** is populated from the **Country Values > Health Authority** tab.
- The **Labeler DUNS Number/Legal Manufacturer Single Registration Number(SRN)** and **Authorised Representative Name** are added to the *Manufacturer* page

For the Data Classification Type Values, Manufacturing Functions Values, Medical Device Values, Packaging Type Values, Product Material Values, Shelf Life Type Values, Storage Condition Values, Substance Role Values, Time Unit Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Product Family Maintenance

The EURD Procedure Identifier) field and column are renamed to Family Identifier / Active Substances on the *EURD ID Values* page.

For the ATC Values and Domain Type Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Product Maintenance

For the Dosage/Pharmaceutical Form Values, Medical Device Values, Product Category Values, Product Cross Reference Type Values, Routes of Administration Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Registration Maintenance

The Registration Status Values list is now mapped to the Regulatory Entitlement Status from the SPOR Master Lists section. The RMS tab is added and mapping is done using the RMS search widget to associate RMS term to RIM value.

The Marketing Status Reason Values is renamed to Risk of Shortage of Supply Reason Values

For the Marketing Status Values, Master File Type Values, Medicinal Product Name Part Type Values, Medicinal Product Type Values, Provenance Reason Values, Qualified Person Responsible for Pharmacovigilance (QPPV) Values, Registration Status Values, Risk of Shortage of Supply Reason Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

SPOR Master Lists

The Reason of Marketing Unavailability list is added to the the SPOR Master Lists section and mapped to the Risk of Shortage of Supply Reason Values list from the Registration Maintenance section.

For the Data Classification Type Values, Manufacturing Functions Values, Medical Device UID Values, Packaging Type Values, Product Material Values , Shelf Life Type Values, Storage Condition Values, Substance Role Values , Time Unit Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

- RMS Term ID - the term ID from the SPOR Master List.
- RMS Modified On - the modified data from the operational attributes of the SPOR Master List.
- RMS Status - the status of the term from the SPOR Master List.

Entities

Entities Updates: Calyx RIM 7.2

Calyx RIM 7.2 Product Family Updates

New changes and implementations are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Product Family

Calyx RIM 7.2 includes the following changes:

- The **Product Family Indication** is renamed to **Product Family Indication(s)** for all the Product Family Types, except for Veterinary.
- The **Product Family Comorbidity** is renamed to **Product Family Comorbidity(s)** for all the Product Family Types, except for Veterinary.
- It is now possible to modify active Ingredient(s) association with product Family, when there is a product created with no components.
- The **EU CT Number** is added to *CT Shared Data Attributes* page.

Calyx RIM 7.2 Active Ingredient and Reference Active Ingredient Updates

Active Ingredients and Reference Active Ingredients are updated through data migration.

Active Ingredient Updates

To support IDMP, Calyx RIM 7.2 includes:

Field Name	Description
Alternate IDMP Active Ingredient	<ul style="list-style-type: none"> For Manufactured Item Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients. For Pharmaceutical Product Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients of Components associated with a Pharmaceutical Product. To search for a Component Active Ingredient, you need to assign Components to Pharmaceutical Product <p>For both: this field can also be configured as the substance selection widget with all the active values from Data Administration > Substance Values.</p>
Concentration Measure Type	This field field is added to the IDMP Concentration Strength set of fields for Component Active Ingredient, Manufactured Item Active Ingredient, Pharmaceutical Product Active Ingredient, Substance and Reference Substance.

Reference Active Ingredient Updates

To support IDMP, Calyx RIM 7.2 includes:

Field Name	Description
Concentration Measure Type	This field is added to the IDMP Concentration Strength set of fields for Component Reference Active Ingredient, Manufactured Item Reference Active Ingredient, Pharmaceutical Product Reference Active Ingredient, Substance and Reference Substance.
Use for xEVMPD	This field is added for Reference Active Ingredient Attributes for Pharmaceutical Product.

Manufactured Item Reference Active Ingredient can now be a multiple value for Manufactured Item Active Ingredient, Pharmaceutical Product, Component Active Ingredients.

Calyx RIM 7.2 Application Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Application

The **Legal Status** attribute is renamed to **Legal Status of Supply**.

Calyx RIM 7.2 includes the ability to track Pending Changes for the entities at the **Event** level and select attributes for Pending Changes in a wizard. The new **Pending Changes** tab on the Event Attributes page displays the Pending Changes attributes. The **Legal Status of Supply** and **Procedure Type** fields are tracked for application.

Calyx RIM 7.2 PhPIDs Updates

New changes and implementations are included in Calyx RIM 7.2 to conform to the regulatory requirements.

PhPIDs

To support IDMP, the following new fields and columns are added to the PhPID entity:

- Version
- Version Date

Calyx RIM 7.2 PDS and PDS Template Updates

PDS and PDS Templates are updated through data migration.

To support IDMP, Calyx RIM 7.2 includes these changes for PDS and PDS Templates:

- The **Origin of Substance** field is added to the *Active Ingredient Detail Attributes* and *Substance Detail Attributes* pages.
- The **Composition Grouping Description** field is added to the *Active Ingredient Detail Attributes* and *Substance Detail Attributes* pages.
- The **Concentration Measure Type** field is added the IDMP Concentration Strength set of fields to the *Substance Detail Attributes*, *Flu Strain Attributes*
- The **Packaging MI Quantity** field is updated to include both integer and non-integer values on the *Package Detail Attributes* page.
- The **Device Quantity Unit** is added to the *Package Detail Attributes* pages and mapped to the **Data Administration > Other > Unit of Presentation Values**

Calyx RIM 7.2 Registration Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Registration

Calyx RIM 7.2 includes the ability to track Pending Changes for the entities at the **Event** level and select attributes for Pending Changes in a wizard. The new **Pending Changes** tab on the Event Attributes page displays the Pending Changes attributes. The following fields are tracked for registration:

- Subject to Additional Monitoring
- MAH
- QPPV
- MFL
- Enquiry Email
- Enquiry Phone Number
- Next Renewal Date
- Last Renewal Date
- License Status
- License Date

Calyx RIM 7.2 Registration Package Set Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Registration Package Set

To support IDMP, Calyx RIM 7.2 includes the following changes for registration package set:

- The **Status** field is renamed to **PDS Package Set Status**.
- The **Status Date** field is renamed to **PDS Package Status Date**.
- The **PCID** field is removed from the *Registration- Package Sets Attributes* page.
- The **PCID** tab is added to the *Registration- Package Sets Attributes* page.
- The **MAH** field is added to the *Registration- Package Sets Attributes* page.
- The **Package Description Description** field is renamed to **Package Description** on the *Registration- Package Set Attributes > Package Set- Package Description Attributes* page.

Calyx RIM 7.2 includes the ability to track Pending Changes for the entities at the **Event** level and select attributes for Pending Changes in a wizard. The new **Pending Changes** tab on the Event Attributes page displays the Pending Changes attributes. The following fields are tracked for registration package set:

- **MAH**
- **License Status**
- **License Date**
- **Withdrawn Date**

Calyx RIM 7.2 Registration Package Set Country Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Registration Package Set Country

To support IDMP, Calyx RIM 7.2 includes the following changes for registration package set country:

- The **Currently Marketed in this country?** field is updated from a check box to a drop-down list and mapped to the **Data Administration > Registration Maintenance > Marketing Status Values**.
- Migration for existing data for this field is as follows:
 - If the check box value is **Y**, then **Marketed** value is displayed.
 - If the check box value is **N**, then **Not Marketed** value is displayed.

Changes related to **Data Carrier Identifier**:

- The **Data Carrier Type**, **Data Carrier Identifier**, **Data Carrier Language** fields are removed from the *Registrations Package Set-Country Attributes* and *Modify Package Set Country Association* pages.
- The **Data Carrier Identifiers** tab is added to the *Registrations Package Set-Country Attributes* page

Calyx RIM 7.2 includes the ability to track Pending Changes for the entities at the **Event** level and select attributes for Pending Changes in a wizard. The new **Pending Changes** tab on the Event Attributes page displays the Pending Changes attributes. The **Legal Status of Supply** field is tracked for registration package set country.

Calyx RIM 7.2 Medicinal Product Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Medicinal Product

To support IDMP, Calyx RIM 7.2 includes the following changes for the medicinal product:

- The Medicinal Product entity and all the associated child entities are moved from the Registration to the Application level.
- The **Medicinal Product** tab is added to the *Application Attributes* page.
- The **PMSID** field is removed from the *Medicinal Product Attributes* page.
- The **PMSIDs** tab is added to the *Medicinal Product Attributes* page.
- The following fields are added to the *Medicinal Product Attributes* page:
 - Full Indication Text
 - Full Indication Language
 - Country
 - Registrations
 - License Root Number
- The following columns are now displayed for the *Medicinal Product* tab:
 - Registration Country
 - Product
 - PMSID
 - MPID
 - License Root Number
 - Related Registration(s)

Calyx RIM 7.2 includes the ability to track Pending Changes for the entities at the **Event** level and select attributes for Pending Changes in a wizard. The new **Pending Changes** tab on the *Event Attributes* page displays the Pending Changes attributes. The following fields are tracked for medicinal product:

- Pediatric Use Indicator
- Full Indication Text

The **Full Indication Language** attribute was added to medicinal product to correspond with **Full Indication Text**. However, this new attribute will not be tracked with the Pending Changes functionality.

MPIDs

To support IDMP, Calyx RIM 7.2 includes the following changes for the **MPIDs**:

- The **MPIDs** tab is editable now.
- The **Country** field is added to the *MPID Attributes*. This field is available if the application procedure type is CP and includes the values: **European Union** , **Iceland** , **Liechtenstein** , **Norway** .
- The **MPIDs** tab now includes the **Country** column.

Calyx RIM 7.2 Medicinal Product Name Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Medicinal Product Name

To support IDMP, Calyx RIM 7.2 includes the following changes for the medicinal product name:

- The **Country** field is now hidden on the *Medicinal Product Name Attributes* page for applications with non-centralized procedure.
- The **Country** field is updated to include **European Union** for applications with Centralized Procedure (CP).
- The following fields are added to the *Medicinal Product Name Attributes* page:
 - **Date of First Approval**. This field is available only for the applications with Centralized Procedure (CP), and for Iceland, Liechtenstein, and Norway countries.
 - **Full Indication Text**

Calyx RIM 7.2 Medicinal Product Action Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

Medicinal Product Action

To support IDMP, Calyx RIM 7.2 includes the following changes for the medicinal product actions:

- The Medicinal Product Action entity and all the associated child entities are moved from the Registration to the Application level.
- The **Sequence** field is updated to display a concatenation of the **Sequence Name** and **Sequence Code** values on the *Medicinal Product Actions Attributes* page.
- The **Tasks**, **References** and **Notifications** tabs are added to the *Medicinal Product Actions Attributes* page.

Calyx RIM 7.2 IDMP Updates

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

IDMP

To support IDMP, Calyx RIM 7.2 includes the following changes for the **IDMP** tab:

- The **IDMP** entity tab is moved from the Registration to the Application level.
- The **IDMP** tab is added to the *Application Attributes* page.
- The following columns are now displayed for the **IDMP** tab:
 - **Medicinal Product Name**
 - **PMSID**
 - **Registration Country**
 - **Product**
 - **MPID**
 - **License Root Number**
 - **Related Registration(s)**
 - **Related MAH(s)**
 - **Medicinal Product Action(s)**

- Related Sequence

Queries

Calyx RIM 7.2 Queries

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

The following table lists the changes for Calyx RIM 7.2 Queries.

Change	Field or Column Name/Entity Name	Query Name
New Added Fields and Columns	Concentration Measure Type	<ul style="list-style-type: none"> – List of Pharmaceutical Products – List of Veterinary Products – List of Pharmaceutical and Medical Device Products – List of Pharmaceutical Products and Components – List of Veterinary Products and Components – List of Pharmaceutical and Medical Device Products and Components
	Version	<ul style="list-style-type: none"> – Entity History Query – Entity Audit Trail

Change	Field or Column Name/Entity Name	Query Name
New Added Queries	<ul style="list-style-type: none"> – RMS List Name – RMS Term Name – RMS Term ID – RMS Status – Associated DA List Name – Display Columns – Sort Order 	List of RMS Fields
	<ul style="list-style-type: none"> – OMS Organisation Name – OMS Organisation ID – OMS Location ID – OMS Address – OMS City – OMS Country – OMS Status – Associated DA List Name – Display Columns – Sort Order 	List of OMS Fields
New Added Entities	Medicinal Product Action entity	<ul style="list-style-type: none"> – List of References – List of References - Rollup by Application – List of Tasks – List of Tasks - Rollup by Application
	Data Carrier Identifier entity	<ul style="list-style-type: none"> – List of Application Countries with PDS Country and Registration Details Query – Sunset Clause Marketing Status Query

Wizards

Calyx RIM 7.2 Wizards

New features and fields are included in Calyx RIM 7.2 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Calyx RIM 7.2

Change	Field Name	Wizard Name
The wizard is updated to select only European Union when an Event is created for EU CP application. European Union is selected in the Selected. All other countries are in the Available box.	Countries	Create Application
The Application Type field is updated with the EU Clinical Trial Regulation in the Available box on the Global Project Plan > Select Filter Criteria page.	Application Type	Global Project Plan
The Use for xEVMPD field is now added to the wizard logic to take into consideration only that Pharmaceutical Product Reference Active Ingredient which has a field value as a Yes.	Use for xEVMPD	XEVMPD Submission Wizard

Database Script Error messages

Description of database script errors that you may encounter when running the scripts.

Upgrade path	Error	Description/Resolution
5.0 or 5.0 CHF 6 to 5.1	ORA-01920: user name 'MIGRATION' conflicts with another user or role name	The migration user already exists.
5.0 or 5.0 CHF 6 to 5.1	ora-01543: tablespace 'IDX_MIG' already exists	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	ora-01543: tablespace 'DAT_MIG' already exists	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	ORA-02296: cannot enable (ODS.) - null values found	The data will be updated later in the migration, and the constraint on SETTINGS_PROFILE.LINK_STYLE_TYPE_ID will be added at that point.
5.0 or 5.0 CHF 6 to 5.1	ORA-02273: this unique/primary key is referenced by some foreign keys	Ignore any index and constraint errors on asm_pub_settings/asm_pub_settings_profile tables.
5.0 or 5.0 CHF 6 to 5.1	ORA-02429: cannot drop index used for enforcement of unique/primary key	Ignore any drop index errors on “enforcement of unique/primary key”.
5.0 or 5.0 CHF 6 to 5.1	ORA-00936: missing expression	Ignore
5.0 or 5.0 CHF 6 to 5.1	ORA-04098: trigger 'ODS.UCNTNT' is invalid and failed re-validation	Ignore
5.0 or 5.0 CHF 6 to 5.1	Any errors for the PACKAGE BODY ISM.PRODUCT_FAMILY_COPY:	Ignore

Upgrade path	Error	Description/Resolution
5.1 to 6.0	<p>Any indexing or constraint errors regarding the following tables can be ignored:</p> <ul style="list-style-type: none"> – Excipient – Active_ingredient – Prod_acting – Prodfam_acting – Pds_excip – Pds_excip_change – Concentration_unit_type – Fda_device_class_type – Eu_class_type <p>Also ignore the following error messages:</p> <ul style="list-style-type: none"> – Warning: Package Body created with compilation errors. Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY: 285/26 PL/SQL: ORA-00942: table or view does not exist – Revoke inherit privileges on system from dbo ERROR at line 1: ORA-00990: missing or invalid privilege revoke select any table privilege from aud ERROR at line 1: ORA-00990: missing or invalid privilege 	<p>Ignore</p> <p>Example:</p> <p>Error dropping constraint ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT</p> <p>ORA-02273: this unique/primary key is referenced by some foreign keys</p> <p>Dropping index: ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT Columns: ID--></p> <p>Error dropping index ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT</p> <p>ORA-02429: cannot drop index used for enforcement of unique/primary key</p>
5.1 to 6.0	ORA-01543: tablespace 'IDX_IDMP' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'DAT_IDMP' already exists	Ignore

Upgrade path	Error	Description/Resolution
5.1 to 6.0	ORA-01543: tablespace 'IDX_DM' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'DAT_DM' already exists	Ignore
5.1 to 6.0	ORA-01918: all ORA-01918 messages	Ignore
5.1 to 6.0	ORA-01919: all ORA-01919 messages	Ignore
5.1 CHF 3 to 6.0 to 6.0 CHF 1	<p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.REGULATORY_ACT_LEAD(</pre> <p>ERROR at line 1:</p> <p>ORA-00955: name is already used by an existing object</p> <pre>CREATE TABLE MGR.SEQ_DESCR_TYPE(*</pre> <p>ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated</p> <p>ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated</p>	Ignore
6.0 to 6.0 CHF 1	ORA-01952: system privileges not granted.	Ignore. This error can appear when running the master-pre.sql script. It means that the system privileges are not granted to MGR, ODS, or SEC.

Upgrade path	Error	Description/Resolution
6.0 CHF 1 to 6.0 CHF 2 to 6.0 CHF 3	<pre>drop table view_column_metadata * ERROR at line 1: ORA-00942: table or view does not exist comment on column vd_conten.logical_parent _id is 'Reserved for Internal Use; Do not Use' * ERROR at line 1: ORA-00942: table or view does not exist</pre>	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 2 to 6.0 CHF 3	<pre> ***** ***** build dimension views ***** ***** ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST6 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST1 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST3 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST2 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST4 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS _LAB_HIST5 PL/SQL procedure successfully completed. </pre>	Ignore
6.0 CHF 2 to 6.0 CHF 3 to 6.0 CHF 4 to 6.0 CHF 5	<pre> from dba_views v * ERROR at line 36: </pre>	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 3 to 6.1	<pre>drop table tmp_ind_expressions * ERROR at line 1: ORA-00942: table or view does not exist</pre>	Ignore
6.0 CHF 3 to 6.1	<p>When executing the data migration from 6.0 CHF 3 to Calyx RIM 6.1 (script DB Upgrade 60 CHF3 to 61), the following error messages appeared:</p> <ul style="list-style-type: none"> — Line 146: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME": — Line 363: ORA-00942: table or view does not exist — Line 4344: ORA-02437: cannot validate (AUD.PKAPPLICANT_CONTACT) - primary key violated — Line 4345: ORA-06512: at line 58 — Line 9644: ORA-00942: table or view does not exist — Line 15517: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME": 	Resolved with the Calyx RIM 6.1 CHF 1 database migration script.
6.0 CHF 7 to 6.1	<ul style="list-style-type: none"> — ORA-24344: success with compilation error — ORA-06512: at line 115 	Ignore

Upgrade path	Error	Description/Resolution
6.1 to 6.1 CHF 1	<ul style="list-style-type: none"> — ***** fix EU-3-0 EMA-eAF ***** declare * ERROR at line 1: ORA-01403: no data found ORA-06512: at line 9 — drop table tmp_ind_expressions * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.1 to 6.1 CHF 1	<ul style="list-style-type: none"> — ORA-00955: name is already used by an existing object — ORA-02260: table can have only one primary key — ORA-24344: success with compilation error — ORA-06512: at line 115 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.1 CHF 1 to 6.1 CHF 2	<p>ERROR at line 1: ORA-04043: object WRITE_STORAGE_REQUIREMEN TS does not exist</p>	Ignore
6.1 CHF 1 to 6.1 CHF 2	<ul style="list-style-type: none"> — ORA-24344: success with compilation error — ORA-06512: at line 115 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.

Upgrade path	Error	Description/Resolution
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> — ORA-01918: user 'DBCOMMON' does not exist — ORA-04043: object GET_DIRLIST does not exist — ORA-00904: "SUB_TO_ADD_MONITOR_CODE": invalid identifier — ORA-00904: "ORPHAN_DRUG_FLAG": invalid identifier 	Ignore
6.1 CHF 2 to 6.1 CHF 3	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3 to 6.1 CHF 4	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3	<ul style="list-style-type: none"> — ORA-00001: unique constraint (MGR.AK0BROAD_INDC_COUNTRY) violated — ORA-00955: name is already used by an existing object 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 CHF 3 to 6.1 CHF 4	<ul style="list-style-type: none"> — ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated — ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated 	Ignore. These errors can be ignored if the migration path contained Calyx RIM 6.0 CHF 6 or Calyx RIM 6.0 CHF 7.
6.1 to 6.2	ORA-01418: specified index does not exist	Ignore

Upgrade path	Error	Description/Resolution
6.1 CHF 4 to 6.2 CHF 1	<ul style="list-style-type: none"> – ORA-24344: success with compilation error – Any errors for the PACKAGE BODY ISM.PRODUCT_FAMILY_COPY: – ORA-02298: cannot validate (MGR.T_1671) <ul style="list-style-type: none"> - parent keys not found 	Ignore
6.2 (new installation only)	<pre>drop table d_date * ERROR at line 1: ORA-00942: table or view does not exist</pre>	<p>Ignore</p> <p>This error does not appear during the migration from the previous Calyx RIM versions to Calyx RIM 6.2. It may be seen only if you install a new Calyx RIM 6.2 database. If you see this error, you can ignore it.</p>
6.2 CHF 1 to 6.2 CHF 2	<ul style="list-style-type: none"> – drop table dbcommon.role *ERROR at line 1:ORA-00942: table or view does not exist – drop table dbcommon.entity_type *ERROR at line 1:ORA-00942: table or view does not exist 	Ignore.

Upgrade path	Error	Description/Resolution
6.2 CHF 2 to 6.2 CHF 3	<ul style="list-style-type: none"> - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.2 CHF 3 to 6.2 CHF 4	<ul style="list-style-type: none"> - drop table assembly_totals * ORA-00942: table or view does not exist - drop index XAK1CONTENT * ERROR at line 1: ORA-01418: specified index does not exist - drop view vw_assembly_totals * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist - drop table view_column_name_overrides * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore

Upgrade path	Error	Description/Resolution
6.2 CHF 4 to 6.2 CHF 5	<ul style="list-style-type: none"> - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.2 CHF 5 to 6.2 CHF 6	<ul style="list-style-type: none"> - drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist - drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist 	Ignore
6.2 CHF 6 to 7.0	<ul style="list-style-type: none"> - ORA-02443: Cannot drop constraint - nonexistent constraint - ORA-01418: specified index does not exist 	Ignore

Upgrade path	Error	Description/Resolution
7.1.2 to 7.1.3	<ul style="list-style-type: none"> – ORA-30674: identity column cannot have a default value – ORA-20000: extension does not exist/ ORA-20007: extension already exists in the table – Error changing data type for column AUD.SOURCE_SYSTEM_TYPE BEG_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_MEMBER_TYPE BEG_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_TYPE CREATION_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_MEMBER_TYPE CREATION_DATE: ORA-00942: table or view does not exist 	Ignore
7.1.3 to 7.2	ORA-30674: identity column cannot have a default value	Ignore
7.2 to 7.2.2	ORA-30674: identity column cannot have a default value	Ignore

The following are the common errors you may encounter when migrating to a subsequent version.

Table 2: Common Errors

Error	Description
SP2-0310: unable to open file "define.passwords"	Ignore
SP2-0310: unable to open file "define.application"	Ignore
ORA-02264: name already used by an existing constraint	DO NOT IGNORE. Contact Technical Support

Errors Message - Example

Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY

LINE/COL ERROR

```

971/11 PL/SQL: SQL Statement ignored
973/21 PL/SQL: ORA-00942: table or view does not exist
977/9 PLS-00364: loop index variable 'IREC' use is invalid
977/9 PL/SQL: Statement ignored
978/9 PLS-00364: loop index variable 'IREC' use is invalid
978/9 PL/SQL: Statement ignored
979/9 PLS-00364: loop index variable 'IREC' use is invalid
979/9 PL/SQL: Statement ignored
980/9 PLS-00364: loop index variable 'IREC' use is invalid
980/9 PL/SQL: Statement ignored
982/9 PL/SQL: SQL Statement ignored

```

LINE/COL ERROR

```

991/35 PL/SQL: ORA-00904: "IREC"."PRODUCT_ID": invalid identifier

```

993/9 PL/SQL: SQL Statement ignored

993/25 PL/SQL: ORA-00942: table or view does not exist

1004/11 PL/SQL: SQL Statement ignored

1006/21 PL/SQL: ORA-00942: table or view does not exist

1010/9 PLS-00364: loop index variable 'IREC' use is invalid

1010/9 PL/SQL: Statement ignored

1011/9 PLS-00364: loop index variable 'IREC' use is invalid

991/35 PLS-00364: loop index variable 'IREC' use is invalid

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