

---

# Calyx RIM 7.0 Data Migration Documentation

CALYX™

# Contents

|  |          |
|--|----------|
| <b>Data Migration Documents.....</b>                           | <b>1</b> |
| <b>Calyx RIM Database Migration Release Notes.....</b>         | <b>2</b> |
| Calyx RIM Database Migration Details.....                      | 2        |
| Calyx RIM 7.0 Data Migration: Product Family Decoupling.....   | 2        |
| Calyx RIM 7.0 Data Migration: Data Administration Updates..... | 3        |
| Calyx RIM 7.0 Data Migration: Home Page Updates.....           | 4        |
| Calyx RIM 7.0 Data Migration: Entities Updates.....            | 6        |
| Data Administration Tables.....                                | 16       |
| Calyx RIM 7.0: Data Administration Tables.....                 | 16       |
| Brexite: Pre-Migration Manual Tasks for Calyx RIM 7.0.....     | 16       |
| Create Country Values.....                                     | 16       |
| Associate Region Values.....                                   | 18       |
| Create Region Values.....                                      | 18       |
| Modify Application Type Values.....                            | 19       |
| Create Procedure Type Values.....                              | 19       |
| Modify Country Values.....                                     | 20       |
| Modify Procedure Type Values.....                              | 20       |
| Event Type and Secondary Event Types.....                      | 21       |
| Timeline/Event Plan Values (TEP).....                          | 22       |
| Modify Existing Timeline/Event Plan Values.....                | 22       |
| Change Type.....   | 22       |
| Modify Assembly DTD/Schema Values.....                         | 22       |
| Create Filing Type Values.....                                 | 23       |
| Modify Filing Type Values.....                                 | 24       |
| Entities.....  | 27       |
| Calyx RIM 7.0 Entities Updates .....                           | 27       |
| Technical Administration.....                                  | 28       |
| Calyx RIM 7.0: Technical Administration .....                  | 28       |
| Calyx RIM 7.0 Prerequisite: Oracle Configuration Update.....   | 28       |

|  |           |
|--|-----------|
| Increase Maximum Size of VARCHAR2, NVARCHAR2, and RAW Columns in a Non-CDB ..... | 29        |
| Post-Migration Script Updates for Calyx RIM 7.0.....                             | 29        |
| Database Script Error Messages.....  | 29        |
| Errors Message - Example.....  | 40        |
| <b>Index.....</b>  | <b>42</b> |



## Data Migration Documents

Document Name

Calyx RIM 7.0 Data Migration Document

Data Migration Document - Previous Versions

## 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 migrations for the Calyx RIM database. The installation and migration script package provides a convenient means for distributing the Calyx RIM database scripts and clarifies the approach 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. The data migration documentation should be read in conjunction with the Calyx RIM Release Notes, which describe the updates that have been implemented in each release.

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

### 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.*

---

## Calyx RIM Database Migration Details

The migration package consists of 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 the saved queries.*

---

The scripts are supplied in ZIP files:

- DB Upgrade 62 CHF6 to 70.zip (DB\_update7\_0\_0\_0000\_0095.zip) (To migrate to Calyx RIM 7.0 from either Calyx RIM 6.2 CHF 1 or later Calyx RIM. See: *Data Migration Documents*.)

## Calyx RIM 7.0 Data Migration: Product Family Decoupling

The Calyx RIM 7.0 database migration provides the changes related to **Product Family Decoupling**.

Calyx RIM 7.0 restructures the product hierarchy to separate the product data from the process data. These changes provide the flexibility to include products from different product families (PF) in a single submission.

From a regulatory perspective, it is possible to have a product included in a submission that falls under a different product family. Removing the relationship where a PF "owns" applications provides the flexibility to associate any product to the application, and to capture the process and submission data for those products under the same application.

Product Family Decoupling includes updates to the following:

— **Data Administration**

- Value Lists
- Product Family Values

— **Home Page**

- Tabs
- Navigation Trees
- Search
- Find

— **Entities**

- Product Family Attributes
- Application
- Create Application Wizard
- Product
- Entities Attributes and Tabs Updates for Product Family Changes
- Wizards
- Queries

## Calyx RIM 7.0 Data Migration: Data Administration Updates

The Calyx RIM 7.0 database migration provides the changes related to **Product Family Decoupling Data Administration Updates**.

### Data Administration Updates

In preparation for Data Module changes in Calyx RIM 7.0, the Data Administration sections are revised and the actions described below are provided:

| Data Administration Section Name | Value List Name           | Action |
|----------------------------------|---------------------------|--------|
| Application Maintenance          | Chief Investigator Values | Hidden |
|                                  | Sponsor Type Values       | Hidden |

| Data Administration Section Name | Value List Name                                    | Action  |
|----------------------------------|--|---------|
| Product Detail Set Maintenance   | Genetically Modified Cell Origin Species Values    | Hidden  |
|                                  | Product Bio Type Values                            | Hidden  |
|                                  | Somatic Cell Therapy Cell Types Values             | Hidden  |
|                                  | Somatic Cell Therapy Origin Species Values         | Hidden  |
|                                  | Somatic Cell Therapy Origins Values                | Hidden  |
|                                  | Source of Scientific Advice Values                 | Hidden  |
|                                  | Type of Dossier Submitted Values                   | Hidden  |
|                                  | Type of Gene Therapy Transfer Product Values       | Hidden  |
|                                  | Type of Gene Therapy Values                        | Hidden  |
|                                  | Type of Genetically Modified Cell Origin Values    | Hidden  |
| Product Family Maintenance       | Substance Attachment Values                        | Deleted |
|                                  | Sub-Tab on Substance Values: Substance Attachments | Deleted |

### Product Family Values Changes

With the changes introduced with the Calyx RIM 7.0 release, the relationship between an Application and Product Family is changed. The following updates are made for the Product Family Values, under Product Family Maintenance:

- Product Family Name: the uniqueness is derived from this field
- Product Family Code: non-mandatory field, does not affect the entity uniqueness
- Product Family Status: non-mandatory field
- Product Family Status Date: non-mandatory field
- Development Sponsor: this field is hidden

### Product Status Values Changes

A new Internal System Status value for Product is introduced to isolate inactive Products. A migration script will create the Internal System Status as "INACTIVE" and it will be mapped to a new display status **Inactive** in the *Product Status Values* list in **Data Administration**. Products with a status mapped to the new Internal System Status of "INACTIVE" will not be available for selection in wizards, selection widgets, multi-selects, and drop-down lists. This rule does not apply to reports.

### Calyx RIM 7.0 Data Migration: Home Page Updates

The Calyx RIM 7.0 database migration provides the changes related to **Product Family Decoupling Home Page Updates**.

### Home Page

Changes related to the **Entity Tabs** based on the relationship updates between an Application and Product Family:

Product Families:

| Column Name         | Action                              |
|---------------------|-------------------------------------|
| Product Family Type | Renamed to Family Type              |
| Product Family      | Renamed to Family Name              |
| Family Code         | Added                               |
| IBD                 | Renamed to International Birth Date |
| Therapeutic Area    | Deleted                             |
| Therapeutic Class   | Deleted                             |

Changes applied to other tabs:

| Tab                        | Column Name         | Action  |
|----------------------------|---------------------|---------|
| Registrations              | Product Family Type | Deleted |
| Applications               | Product Family      | Deleted |
| Events                     | Family Name         | Deleted |
| Full Product Presentations | Product Family Name | Deleted |
| Sequences                  | Family Name         | Deleted |
| Submitted Views            | Product Family      | Deleted |
| Approved Views             | Product Family      | Deleted |
| My Tasks                   | Family Name         | Deleted |

### Navigation Trees Changes

For Country and Product Family trees, the same **Application Name** is shown for multiple product families if they assigned to it via the Product association.

### SEARCH Functionality Changes

| Change  | Column Name                           | Entity Name                            |
|---------|---------------------------------------|--|
| Renamed | Product Family to Family Name         | Product Families, Products, Components |
|         | Pack Set License Code to License Code | Full Product Presentation              |
| Deleted | Family Type                           | Applications                           |
|         | Product Family Name                   | Full Product Presentation              |
|         | Family Type                           | Events, Sequences, Registrations       |
|         | Product Family Name                   |  |

| Change | Column Name      | Entity Name           |
|--------|------------------|-----------------------|
| Added  | Procedure Type   | Applications          |
|        | Application Code | Events, Registrations |
|        | Application Name |                       |

### FIND Functionality Changes

| Change  | Column Name                        | Entity Type  |
|---------|------------------------------------|--|
| Renamed | Product Family Type to Family Type | Activities > Product Families  |
|         | Product Family Name to Family Name | List of Product Families   |
|         |                                    | List of Applications with Product Query  |
|         |                                    | List of Package Set Registrations with Application and Product Detail Properties Query |
|         |                                    | List of Events with Application Properties Query                                       |
|         |                                    | List of Sequences with Application and Event Properties Query                          |

### Calyx RIM 7.0 Data Migration: Entities Updates

The Calyx RIM 7.0 database migration provides the changes related to **Product Family Decoupling** Entities Updates.

### Product Family Attributes Changes

The changes in this table are provided for each of the *Product Family Type Attributes* windows based on the preparation for the future Data Module updates, and updates provided in the current release, for the relationship between an Application and a Product Family:

| Flu Vaccine, Pharmaceutical, Veterinary | Pharmaceutical-Medical Device | Medical Device             | Action                 |
|---|-------------------------------|----------------------------|------------------------|
| Product Family Type                     | Product Family Type           | Product Family Type        | Renamed to Family Type |
| Family Code                             | Family Code                   | Family Code                | Non-mandatory          |
| Product Family Status                   | Product Family Status         | Product Family Status      | Non-mandatory, Hidden  |
| Product Family Status Date              | Product Family Status Date    | Product Family Status Date | Non-mandatory, Hidden  |
| PSUR Due Date                           | PSUR Due Date                 | -                          | Hidden                 |
| PSUR Data Lock Date                     | PSUR Data Lock Date           | -                          | Hidden                 |

| Flu Vaccine, Pharmaceutical, Veterinary | Pharmaceutical-Medical Device | Medical Device           | Action  |
|---|-------------------------------|--------------------------|---------|
| Generic Name                            | Generic Name                  | -                        | Hidden  |
| ATC Last Updated                        | ATC Last Updated              | -                        | Deleted |
| Therapeutic Area                        | Therapeutic Area              | -                        | Hidden  |
| Therapeutic Classes                     | Therapeutic Classes           | -                        | Hidden  |
| Development Sponsor                     | Development Sponsor           | -                        | Hidden  |
| Approved Trade Names                    | Approved Trade Names          | Approved Trade Names     | Hidden  |
| -                                       | Division                      | Division                 | Hidden  |
| -                                       | -                             | International Birth Date | Hidden  |

*Note: To be able to see Hidden fields, the meta overrides file should be updated accordingly. By default, these values in Data Administration are not hidden: Division Values, Product Family Status Values, Therapeutic Area Values, Therapeutic Class Value, but they are invisible on the Product Family entity. When the meta override file is configured, you will be able to see and use these fields for the Product Family entity.*

The **Create Application** icon is no longer available on the **Application** tab on the **Product Family Attributes** screen. See Application section for more details regarding Application creation.

### Application Changes

In Calyx RIM 7.0 the decoupling of Product Family from Application changes the relationship between Product Family and Application. A Product Family connection with an Application is now through the Product association. This is necessary to implement the change in determining the Application unicity in the system.

The unicity of an Application is the combination of the Application Name and Application Code system-wide in Calyx RIM 7.0. For Clinical Trial Applications, the unicity is a combination of the **Study Number** and **Application Code**.

An available migration script will identify Applications in the system that do not comply with the new Application uniqueness rule. The script can be executed more than once.

For records that do not comply with the new Application uniqueness rule, there is a migration script that will resolve the duplicate names by appending the **Application Name** with either the **Product Family Name** or the **Product Family Code**. In support of the appended Application Names, the database field size for the Application Name is increased from VARCHAR2(500) to VARCHAR2(2000).

There is also a migration script that identifies Application Names that are updated as a result of running the script.

This table describes the migration script that identifies Applications that do not comply with the Application unicity for Calyx RIM 7.0 (output is in .xlsx format):

Table 1: Report Column Definition

| rpt_migration_application_duplicate_.sql |  |
|--|--|
| Report Column                            | Value  |
| PRODUCT FAMILY NAME                      | Displays the Product Family Name               |
| PRODUCT FAMILY CODE                      | Displays the Product Family Code               |
| APPLICATION NAME                         | Displays the Application Name                  |
| APPLICATION CODE                         | Displays the Application Code                  |
| APPLICATION STUDY NUMBER                 | Displays Study Number for CTA Application Type |
| APPLICATION TYPE                         | Displays Application Type                      |
| PROCEDURE                                | Displays Application Procedure Type            |
| REVIEWING COUNTRY                        | Displays the Application Reviewing Country     |

*Note: To update Applications that do not comply with the Application uniqueness rule, the script provides the option to append the Application Name with either the Product Family Name OR the Product Family Code. The choice of appending with Product Family Name or Product Family Code can be defined in the script.*

This table describes the migration script that identifies Applications that do not comply with the Application names that have been updated to comply with the Application unicity rule.

Table 2: Report Column Definition

| rpt_migration_application_uniqueness.sql |   |
|--|---|
| Report Column                            | Value   |
| PRODUCT FAMILY NAME                      | Displays the Product Family Name  |
| PRODUCT FAMILY CODE                      | Displays the Product Family Code  |
| APPLICATION NAME                         | Displays the Application Name that has been updated as a result of running the migration script |
| APPLICATION CODE                         | Displays the Application Code   |
| APPLICATION STUDY NUMBER                 | Displays Study Number for CTA Application Type  |
| APPLICATION TYPE                         | Displays Application Type   |
| PROCEDURE                                | Displays Application Procedure Type   |
| REVIEWING COUNTRY                        | Displays the Application Reviewing Country  |

### Create Application Wizard Changes

In Calyx RIM 7.0, you can create an Application from the **Wizards** menu, for example with the *Create Application* wizard.

These changes apply to the wizard:

- The **Product Family Type** field is deleted.
- The **Family Name** field is deleted.
- The **Associated Products** selection is mandatory:
  - Additional columns are added to the *Product Selection* widget:
    - **Family Type**
    - **Family Name**
    - **Family Code**

### Product Changes

The Product Family decoupling requires the association of at least one Product with an Application. This means Calyx RIM Publishers will need to have access to Products. For the users with SPT, ELP, and PRP licenses, the following permissions can be set up in *Security Administration* for Calyx RIM 7.0:

- **Read/Write/Admin** access to **Product**
- **Home page** access to **Product Family**

As part of the migration there is a migration script to identify Applications without a Product. This script can be executed more than once.

A migration script is provided that automatically creates a Product and associates it with Applications that do not have at least one Product. An additional migration script is available that identifies Products that have been created and associated with Product Families and Applications as a result of the migration to v.7.0.

The Migration script to identify Applications with no Product (output is in `.xlsx`):

Table 3: Report Column Definition

| rpt_migration_application_no_product.sql |  |
|--|--|
| Report Column                            | Value  |
| PRODUCT FAMILY NAME                      | Displays the Product Family Name.  |
| PRODUCT FAMILY TYPE                      | Displays the Product Family Type.  |
| PRODUCT FAMILY PRODUCT                   | If a Product is associated with the Product Family, the Product Name is displayed.<br>If no Product is associated with the Product Family, the value is blank. |
| APPLICATION NAME                         | Displays the Application Name.   |

| rpt_migration_application_no_product.sql |  |
|--|--|
| Report Column                            | Value  |
| APPLICATION STUDY NUMBER                 | Displays Study Number for CTA Application Type.  |
| APPLICATION CODE                         | Displays Application Code.   |
| APPLICATION TYPE                         | Displays Application Type.   |
| PROCEDURE                                | Displays the Application Procedure Type.   |
| REVIEWING COUNTRY                        | Displays the Application Reviewing Country.  |
| APPLICATION PRODUCT NAME                 | Should be blank as this report identifies applications that do not have a Product association. |

Migration Script to create a Product:

- The script provides a prefix that can be company-defined, to prefix a value to the new Product name. The default prefix will be "MIG PROD\_". A company defined prefix can be set in the script.
- The Product Name will be populated with the value of the Product Family Name as follows:
  - Default: "MIG PROD\_ <Product Family Name>"
  - Company Defined: <Pre-Fix>\_<Product Family Name>
  - The status of the new Product created as a result of the migration will be set to **Inactive** which is the new display status mapped to the new internal system status of INACTIVE.
  - The newly created Product will be associated will all Applications for the PF that do not have at least one product already associated with it.

The migration script that identifies the new Products created. (output is .xlsx):

Table 4: Report Column Definition

| rpt_migration_product.sql |  |
|---------------------------|--|
| Report Column             | Value  |
| PRODUCT FAMILY NAME       | Displays the Product Family Name                               |
| PRODUCT FAMILY TYPE       | Displays the Product Family Type                               |
| PRODUCT FAMILY PRODUCT    | Displays the Product Name created as a result of the migration |
| APPLICATION NAME          | Displays the Application Name                                  |
| APPLICATION STUDY NUMBER  | Displays Study Number for CTA Application Type                 |
| APPLICATION CODE          | Displays Internal System Status for Application Status value   |
| APPLICATION TYPE          | Displays the Application Type                                  |
| PROCEDURE                 | Displays the Application Procedure Type                        |
| REVIEWING COUNTRY         | Displays the Application Reviewing Country                     |
| APPLICATION PRODUCT NAME  | Displays the Product Name created as a result of the migration |

| rpt_migration_product.sql |  |
|---------------------------|--|
| Report Column             | Value                                      |
| PRODUCT CREATION DATE     | Displays the date the product was created  |
| PRODUCT CREATION TIME     | Displays the time the product was created  |
| PRODUCT CREATED BY        | Displays the user that created the product |

As part of capturing data within Calyx RIM 7.0 for Clinical Trials perspectives when you do not have Products associated with the Applications, and instead are using Comparators to track the clinical trial supplies, we recommend that you associate newly created Products with the CTA / IND Application Types for facilitating data integrity activities with the Investigational Medicinal Product(s) (IMP) included in the CTA process.

### Entities Attributes and Tabs Updates for Product Family Changes

These changes apply for the described Entities:

| Fields Changes   | Entity Name                            |
|--|--|
| Renamed: Product Family Type to Family Type            | Product (All Types)                    |
|  | Component                              |
|  | Component Active Ingredients           |
|  | Component Reference Active Ingredients |
|  | Pharmaceutical Products                |
|  | Modify Event-Product                   |
|  | CT Shared Date                         |
| Deleted: Product Family Type, Family Code, Family Name | Application (All Types)                |
|  | Application Country                    |
|  | Registration (both Types)              |
|  | Event                                  |
|  | Event Country                          |
|  | Event-Change Detail                    |

| Fields Changes                    | Entity Name                               |
|-----------------------------------|---|
| Deleted: Family Code, Family Name | Registration-Package Set                  |
|                                   | Registration-Package Set Country          |
|                                   | Registration Full Product Presentation    |
|                                   | Registration FPP Attachment               |
|                                   | Registration Previous EV Codes            |
|                                   | Sequence                                  |
|                                   | Sequence Status Schedule                  |
|                                   | Reference (when created not under PF)     |
|                                   | Task/Sub Task (when created not under PF) |

The **Products** tab available on *Application Attributes*, *Event Attributes*, *Registration Attributes* is updated with additional columns:

- Family Type.
- Family Name, hyperlinked to a Product Family Attributes screen.
- Family Code.

### Wizards Changes

The following changes apply for the **SEARCH** functionality:

| Changes  | Column Name                        | Wizard Name   |
|----------|------------------------------------|---|
| Renamed: | Product Family Type to Family Type | Global Project Plan (all flows), Notifications, XEVMPD Submission, Copy Event.  |
|          | Product Family to Family Name      |   |
| Deleted: | Product Family                     | Global Project Plan (all flows), Create Submission Plan, Bulk Update Events, Bulk Update Sequences, Create Sequence, Create References for the Project Events or Sequences. |
|          | Family Name                        | Update Status, Import Assembly, Update Project Event Country Status, Calculate Project Dates, XEVMPD Submission, Copy Event.  |
|          | Family Code                        | Update Status, Copy Event.  |
|          | Product Family Type                | Copy Event.   |
|          | Product Family Name                | Copy Registration Attachment.   |

| Changes | Column Name      | Wizard Name   |
|---------|------------------|---|
| Added:  | Application Name | Copy Task   |
|         | Application Code | Copy Task, Move Task, Global Project Plan (all types), XEVMPD Submission, Update Project Event Country Status, Calculate Project Dates, Bulk Update Events, Bulk Update Sequences, Associate Workflow to Events or Sequences, Create Sequence, Associate Change Detail(s) to Events, Leaf Updates for Assemblies, Copy Full Product Presentation, Copy Registration Attachment. |

**Queries Changes**

The following changes apply for the **SEARCH** functionality:

| Changes  | Column/Filters<br>Column Name  | Report Name  |
|----------|--|--|
| Renamed: | <p>Product Family Type to Family Type</p> <p>Product Family to Family Name</p> | <p>List of Applications with Products, List of Events with Application Properties, List of Sequences with Application and Event Properties, PSUR World Wide Marketing Authorization Status Query, List of References - Rollup by Application, List of References - Rollup by Product Family, List of Tasks - Rollup by Application, List of CTA Applications, List of IND Applications, List of Products with Event and Product Registration Details, Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient, Applications Submitted and/or Approved and/or Terminated within a Date Range, List of Registrations with Application Properties, List of Events with Change Details, List of Application Countries with PDS Country and Registration Details, List of CTA Applications with PDS Details, List of Product Detail Sets, List of Product Detail Sets, List of Registration Package Sets Withdrawn, Application History Query, Application QC Status History Report, Application QC Status History Report, Sunset Clause Marketing Status Query, List of Active Ingredient Manufacturers, List of Active Ingredient Function Manufacturers, List of Active Ingredient Material Manufacturers, List of Excipient Manufacturers, List of PDS Manufacturers, List of Component Manufacturers, List of Package Set Manufacturers, List of Species and Indications, List of Dose Schedules, List of Withdrawal Times, Labeled Indications Query, List of IND Applications with PDS Details, List of Registrations with Application Properties Query, 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, List of Application Countries with PDS Country and Registration Details, List of Events with Application Properties, List of Applications, List of References - Rollup by Application, List of References - Rollup by Product Family, Registered Document Query, List of Events with Application Properties, List of Applications.</p> |

| Changes  | Column/Filters<br>Column Name | Report Name   |
|----------|-------------------------------|---|
| Deleted: | Product Family Status         | List of Application Countries with Registration Details, List of Product Families, List of Veterinary Products, List of Pharmaceutical Products and Components, List of Medical Device Products and Components, List of Application with Products, List of Product Families, List of Medical Device Products, List of Pharmaceutical and Medical Device Products, List of Pharmaceutical and Medical Device Products and Components, List of Veterinary Products and Components, List of Pharmaceutical Products and Components, List of Application Countries with PDS Country and Registration Details, List of Applications, List of Applications. |
|          | Therapeutic Area              | List of Application with Products, List of Product Families, List of Applications.  |
|          | Therapeutic Class             | List of Applications with Products, List of Events with List of Application with Products, List of Product Families, List of Pharmaceutical Products, List of Veterinary Products, List of Veterinary Products, List of Pharmaceutical and Medical Device Products, List of Pharmaceutical Products and Components, List of Pharmaceutical Products and Components, List of Pharmaceutical and Medical Device Products and Components, List of Veterinary Products and Components, List of Pharmaceutical Products and Components.  |
|          | PSUR Data Lock Date           | List of Application with Products, List of Product Families, List of Registrations with Application Properties, List of Registrations with Application Properties Query, 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, List of Applications, List of Applications.                                       |
|          | Next PSUR Date                | List of Product Families  |
|          | PSUR Due Date                 | List of Product Families, List of Registrations with Application Properties, List of Registrations with Application Properties Query, 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, List of Applications, List of Applications.  |
|          | Generic Name                  | List of Product Families.   |
|          | Product Family Status Date    | List of Pharmaceutical Products, List of Veterinary Products, List of Medical Device Products, List of Pharmaceutical and Medical Device Products, List of Pharmaceutical Products and Components, List of Pharmaceutical and Medical Device Products and Components, List of Veterinary Products and Components, List of Medical Device Products and Components, List of Pharmaceutical Products and Components, List of Application Countries with PDS Country and Registration Details.  |
|          | © Calyx™ 2021.<br>Calyx.ai    |   |

## Data Administration Tables

### Calyx RIM 7.0: Data Administration Tables

Calyx RIM 7.0 includes Data Administration table updates for Audit fields and Status default flags.

#### Data Administration Updates: Audit Fields

Two new fields, **Last User Updated** and **Last Changed Date**, are added to the UI for every **Data Administration** value, including sub-tables. After migrating to Calyx RIM 7.0, you will see them in the grids with the data from the database, the same as on the other screens for the value.

Two new fields **Created By** and **Created Date**, are added for every **SPOR Maintenance** value. After migrating to Calyx RIM 7.0, you will see them in the grids with the data from the database, the same as on the other screens for the value.

#### Data Administration Updates: Default Flag for Statuses


A new flag with **Yes/No** values, named **System Process Default Flag** to indicate which status Name mapped to the same **Internal System Status** shows by default in the Calyx RIM UI after event functionality logic completion, both manually or via wizards. The field is added to the following **Data Administration Values**:

- Application Status Values
- Event-Change Detail Status Values
- Product Status Values
- Product Detail Set Status Values
- Sequence Status Values

## Brexit: Pre-Migration Manual Tasks for Calyx RIM 7.0

### Create Country Values

To support a country implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the country values must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. Click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Country Values**.
3. Click **Create** .  
The Country page appears.
4. Enter the following:

| Field Name   | Description |
|--------------|-------------|
| Country Code | XU          |

| Field Name   | Description   |
|--------------|---------------|
| Country Name | Great Britain |
| eCTD Code    | uk            |

5. Save.

6. Click **Create** .

7. Enter the following:

| Field Name   | Description      |
|--------------|------------------|
| Country Code | XI               |
| Country Name | Northern Ireland |
| eCTD Code    | uk               |

8. Save.

9. Find the Great Britain in the countries list and click the **XU** link.

10. From the **Heath Authority** tab, click **Create** .

11. Enter the following:

| Field Name            | Description   |
|-----------------------|---|
| Health Authority Name | Medicines and Healthcare Products Regulatory Agency |
| Default Flag          | Yes   |

12. Save.

13. Click **Back**.

14. Find the Northern Ireland country and click the **XI** link.

15. From the **Heath Authority** tab, click **Create** .

16. Enter the following:

| Field Name            | Description   |
|-----------------------|---|
| Health Authority Name | Medicines and Healthcare Products Regulatory Agency |
| Default Flag          | Yes   |

17. Save.

18. Click **Back** and **Return Menu**.


## Associate Region Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the region must be associated in your Calyx RIM Data Administration configuration section before executing the migration.

1. Click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Select the **EU** hyperlink.
4. In the **Selected Countries** list, **United Kingdom** and move it to the **Available Countries** list.
5. In the **Available Countries** list, select **Northern Ireland** and move it to the **Selected Countries** list.
6. **Save**, and then click **Return to menu**.

## Create Region Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the region must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Region Values**.
3. Click **Create** .  
The Region page appears.
4. Enter the following:

| Field Name          | Description       |
|---------------------|-------------------|
| Region Type         | Regulatory Region |
| Region Abbreviation | XU                |
| Region Name         | Great Britain     |
| Countries           | Great Britain     |

5. **Save**.
6. Click the **Create**  and enter the following:

| Field Name          | Description       |
|---------------------|-------------------|
| Region Type         | Regulatory Region |
| Region Abbreviation | UK                |
| Region Name         | United Kingdom    |
| Countries           | United Kingdom    |

7. **Save**, and then click **Return to menu**.


## Modify Application Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the application type values must be modified to your Calyx RIM Data Administration configuration section before executing the migration.


1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Application Type Values**.
3. Find the Marketing Authorisation Application in the list and click the **MAA** link.
4. Click the **Edit** icon.
5. In the **Available** Countries list, select Northern Ireland and Great Britain.
6. Move them to the **Selected** Countries list.
7. **Save**, and then click **Return** to menu.

## Create Procedure Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the procedure type values must be created in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Procedure Type Values**.
3. Click **Create** .
4. Enter the following:

| Field Name                  | Description            |
|-----------------------------|------------------------|
| Procedure Type Abbreviation | National GB            |
| Procedure Type Name         | National GB            |
| Display Name                | National Great Britain |
| Internal Procedure Code     | NATIONAL               |
| eCTD Code                   | national               |
| Countries                   | Great Britain          |

5. **Save**.
6. Click **Create** .
7. Enter the following:

| Field Name                  | Description |
|-----------------------------|-------------|
| Procedure Type Abbreviation | National UK |
| Procedure Type Name         | National UK |

| Field Name              | Description             |
|-------------------------|-------------------------|
| Display Name            | National United Kingdom |
| Internal Procedure Code | NATIONAL                |
| eCTD Code               | national                |
| Procedure Type Code     | 4                       |
| Countries               | United Kingdom          |

8. **Save**, and then click **Return to menu**.

### Modify Country Values

To support a country implementation by the database upgrade from Calyx RIM7.0 CHF 6 to Calyx RIM 7.0, the country values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Country Values**.
3. Find the United Kingdom and click the **GB** link.
4. From the **Procedure Type Details** tab, select **National United Kingdom**.
5. Click the **Set to Default** icon, and then **Back**.
6. Find Great Britain and click the **XU** link.
7. From the **Application Type Details** tab, select **Marketing Authorisation Application**.
8. Click the **Set to Default** icon.
9. From the **Procedure Type Details** tab select **National Great Britain**.
10. Click the **Set to Default** icon, and then **Back**.
11. Find Northern Ireland and click the **XI** link.
12. From the **Application Type Details** tab, select **Marketing Authorisation Application**.
13. Click the **Set to Default** icon, and then **Back**.
14. Click **Return to menu**.

### Modify Procedure Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the procedure type values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.



1. Click **Go To > Data Administration**.
2. Under **Application Maintenance**, click **Procedure Type Values**.
3. Search for EU CP procedure and click the **EU CP** link.

4. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
5. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
6. **Save**.
7. Search for the EU DCP procedure and click the **EU DCP** link.
8. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
9. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
10. **Save**.
11. Search for the EU MRP procedure and click the **EU MRP** link.
12. In the **Available Countries** list, select Northern Ireland and move it to the **Selected Countries** list.
13. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
14. **Save**.
15. Find the EU - National procedure and click the **EU - National** link.
16. In the **Selected Countries** list, select United Kingdom and move it to the **Available Countries** list.
17. **Save** and then click **Return to menu**.
18. Repeat steps 3-6 for any other EU procedure.

### Event Type and Secondary Event Types

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the event type values must be created in your Calyx RIM Data Administration configuration section before executing the migration.

To to create a new Event Type /Secondary Event Type:

1. Click **Go To > Data Administration**.
2. Under **Event Maintenance**, click **Event Type Values**.
3. Click **Create** .
4. In the **Name** field, enter `Data Administration Activities`.
5. **Save**.
6. Click **Return Menu**.
7. Under **Event Maintenance**, click **Secondary Event Type Values**.
8. Click **Create** .
9. Enter the following:

| Field Name    | Value                          |
|---------------|--------------------------------|
| Name          | Brexit Conversion              |
| Primary Event | Data Administration Activities |

10. **Save**.
11. Click **Return Menu**.

## Timeline/Event Plan Values (TEP)

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the event type values must be modified in your Calyx RIM Data Administration configuration section.

To enable region changes by database upgrade, you must:

- Modify existing Procedure Based Timeline/Event Plans to remove the United Kingdom and to add Northern Ireland
- Modify existing Event Based Timeline/Event Plans to add Great Britain
- Create new Timeline/Event Plans as applicable

### *Modify Existing Timeline/Event Plan Values*

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the event type values must be modified in your in your Calyx RIM Data Administration configuration section.

To modify existing Timeline/Event Plan Values:

1. Click **Go To > Data Administration**.
2. Under **Event Maintenance**, click **Timeline/Event Plan Values**.
3. Select the impacted timeline value from the list.
4. Click the **Delete Countries** icon.
5. In the Countries list select United Kingdom and move it to the **Disassociated from Plan** list.
6. **Save**.
7. Click the **Add Countries** icon.
8. In the Countries list select Northern Ireland and move it to the **Countries Selected** list.
9. Set **Copy Default Lead Times from the following Country** as required.
10. **Save**.
11. Click **Back**.
12. Click **Return to menu**.

## Change Type

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, new values must be created in Calyx RIM Data Administration configuration section.

Create new values to capture specific activities related with BREXIT, where no existing terms can be used.

### Modify Assembly DTD/Schema Values


To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the assembly values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Assembly**, click **Assembly DTD/Schema Types** .

3. Find the **EU-3-0-1** and click the **EU-3-0-1** link.
4. In the **Available** Regions list, select United Kingdom and Great Britain and move them to the **Selected** Regions list.
5. Verify that all EU Countries, Northern Ireland, Great Britain, and United Kingdom exist in the **Selected** Countries list.
6. **Save**, and then click **Return to menu**.

### Create Filing Type Values

To support a region implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the filing type values must be added to your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Sequence Maintenance**, click **Filing Type Values**.
3. Click **Create** .  
The *Filing Type Values* Values page appears.
4. Enter the following:

| Field Name   | Description                                 |
|--------------|---|
| Filing Type  | CAP Grandfathering Full Initiating Sequence |
| Display Name | CAP Grandfathering Full Initiating Sequence |
| Countries    | Great Britain                               |

5. **Save**.

To add the other filing types from the table, repeat steps 3 to 5.


*Note: Add a proper eCTD code to use any of the following Filing Type values for **Create eCTD** wizard and publishing functionality.*

| Filing Type   | Display Name  | Countries     |
|---|---|---------------|
| CAP Grandfathering Full Initiating Sequence   | CAP Grandfathering Full Initiating Sequence   | Great Britain |
| CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA) | CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA) | Great Britain |
| CAP Grandfathering Minimal Initiating Sequence                                      | CAP Grandfathering Minimal Initiating Sequence                                      | Great Britain |

| Filing Type  | Display Name   | Countries     |
|--|--|---------------|
| CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA) | CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA) | Great Britain |
| Variation 1A Filing - Establishing UK QPPV-PSMF  | Variation 1A Filing - Establishing UK QPPV-PSMF  | Great Britain |
| Ownership Application (COA) - EU to UK MAH   | Ownership Application (COA) - EU to UK MAH   | Great Britain |

### Modify Filing Type Values

To support a country implementation by the database upgrade from Calyx RIM 6.2 CHF 6 to Calyx RIM 7.0, the filing type values must be modified in your Calyx RIM Data Administration configuration section before executing the migration.

1. On the Calyx RIM *home* page, click **Go To > Data Administration**.
2. Under **Sequence Maintenance**, click **Filing Type Values**.
3. Find the ASMF Filing and click the **ASMF Filing** link.
4. On the **Filing Type eCTD Code** tab, click **Create** .
5. Enter the following:

| Field Name            | Description   |
|-----------------------|---------------|
| Applicable DTD/Schema | eu-3-0-1      |
| Countries             | Great Britain |

6. **Save**.
7. Repeat the steps above to get the following results.

---

*Note: Add a proper eCTD code to use any of the following Filing Type values for **Create eCTD** wizard and publishing functionality.*

---

For Great Britain:

| Filing Type              | Display Name             | Countries     |
|--------------------------|--------------------------|---------------|
| ASMF Filing              | ASMF Filing              | Great Britain |
| Follow-Up Measures       | Follow-Up Measures       | Great Britain |
| Notification 61-3 Filing | Notification 61-3 Filing | Great Britain |
| Original Filing          | Original Filing          | Great Britain |
| PAED Article 46          | PAED Article 46          | Great Britain |

| Filing Type         | Display Name        | Countries     |
|---------------------|---------------------|---------------|
| Plasma Master File  | Plasma Master File  | Great Britain |
| Renewal Filing      | Renewal Filing      | Great Britain |
| Transfer MA Filing  | Transfer MA Filing  | Great Britain |
| Variation 1A Filing | Variation 1A Filing | Great Britain |
| Variation 1B Filing | Variation 1B Filing | Great Britain |
| Variation 2 Filing  | Variation 2 Filing  | Great Britain |
| Withdrawal Filing   | Withdrawal Filing   | Great Britain |

For Northern Ireland:

| Filing Type                                       | Display Name                                      | Countries        |
|---|---|------------------|
| Additional PV Activity in the RMP Related to PAM  | Additional PV Activity in the RMP Related to PAM  | Northern Ireland |
| Annex II Condition Related to PAM                 | Annex II Condition Related to PAM                 | Northern Ireland |
| Annual Reassessment Filing                        | Annual Reassessment Filing                        | Northern Ireland |
| Arbitration Filing                                | Arbitration Filing                                | Northern Ireland |
| Article 107i Referral                             | Article 107i Referral                             | Northern Ireland |
| Article 16c (1c)i Referral                        | Article 16c (1c)i Referral                        | Northern Ireland |
| Article 16c(4) Referral                           | Article 16c(4) Referral                           | Northern Ireland |
| Article 20 Referral                               | Article 20 Referral                               | Northern Ireland |
| Article 29 Paediatric Referral                    | Article 29 Paediatric Referral                    | Northern Ireland |
| Article 29(4) Referral                            | Article 29(4) Referral                            | Northern Ireland |
| Article 30 Referral                               | Article 30 Referral                               | Northern Ireland |
| Article 31 Referral                               | Article 31 Referral                               | Northern Ireland |
| Article 35 Referral                               | Article 35 Referral                               | Northern Ireland |
| Article 5(3) Referral                             | Article 5(3) Referral                             | Northern Ireland |
| Article 58 Filing                                 | Article 58 Filing                                 | Northern Ireland |
| Clinical Data for Publication - Final Version     | Clinical Data for Publication - Final Version     | Northern Ireland |
| Clinical Data for Publication - Redacted Proposal | Clinical Data for Publication - Redacted Proposal | Northern Ireland |
| Conditional Specific Obligation Filing            | Conditional Specific Obligation Filing            | Northern Ireland |

| Filing Type                                       | Display Name                                      | Countries        |
|---|---|------------------|
| Corrective/Preventative Action Related to PAM     | Corrective/Preventative Action Related to PAM     | Northern Ireland |
| DMF Filing  | DMF Filing  | Northern Ireland |
| Extension Filing                                  | Extension Filing                                  | Northern Ireland |
| Follow-up Filing                                  | Follow-up Filing                                  | Northern Ireland |
| Follow-up Measures                                | Follow-up Measures                                | Northern Ireland |
| Legally Binding Measure Related to PAM            | Legally Binding Measure Related to PAM            | Northern Ireland |
| Lifting Suspension Filing                         | Lifting Suspension Filing                         | Northern Ireland |
| Marketing Authorisation Application               | Marketing Authorisation Application               | Northern Ireland |
| National Variation Filing                         | National Variation Filing                         | Northern Ireland |
| Notification 61-3 Filing                          | Notification 61-3 Filing                          | Northern Ireland |
| Original filing                                   | Original filing                                   | Northern Ireland |
| PAED Article 29 Filing                            | PAED Article 29 Filing                            | Northern Ireland |
| PAED Article 45                                   | PAED Article 45                                   | Northern Ireland |
| PAED Article 46                                   | PAED Article 46                                   | Northern Ireland |
| PAED Related to PIP (Article 7, 8, 30)            | PAED Related to PIP (Article 7, 8, 30)            | Northern Ireland |
| Paediatric Submission Related to PAM (Article 45) | Paediatric Submission Related to PAM (Article 45) | Northern Ireland |
| Paediatric Submission Related to PAM (Article 46) | Paediatric Submission Related to PAM (Article 46) | Northern Ireland |
| PAES Submission Related to PAM                    | PAES Submission Related to PAM                    | Northern Ireland |
| PASS Protocol Submission (Article 107n)           | PASS Protocol Submission (Article 107n)           | Northern Ireland |
| PASS Report Submission (Article 107q)             | PASS Report Submission (Article 107q)             | Northern Ireland |
| Plasma Master File                                | Plasma Master File                                | Northern Ireland |
| Periodic Safety Update Report                     | PSUR Filing                                       | Northern Ireland |
| PSUR single assessment procedure                  | PSUR single assessment procedure                  | Northern Ireland |
| Recommendation Related to PAM                     | Recommendation Related to PAM                     | Northern Ireland |
| Referral Filing                                   | Referral Filing                                   | Northern Ireland |
| Reformat Filing                                   | Reformat Filing                                   | Northern Ireland |

| Filing Type                        | Display Name                       | Countries        |
|------------------------------------|------------------------------------|------------------|
| Renewal Filing                     | Renewal Filing                     | Northern Ireland |
| Repeat Use Procedure               | Repeat Use Procedure               | Northern Ireland |
| Safety Filing                      | Safety Filing                      | Northern Ireland |
| SDA Submission Related Filing      | SDA Submission Related Filing      | Northern Ireland |
| Specific Obligation Filing         | Specific Obligation Filing         | Northern Ireland |
| Specific Obligation Related to PAM | Specific Obligation Related to PAM | Northern Ireland |
| Supplement Filing                  | Supplement Filing                  | Northern Ireland |
| Transfer MA Filing                 | Transfer MA Filing                 | Northern Ireland |
| USR Filing                         | USR Filing                         | Northern Ireland |
| Variation 1A Filing                | Variation 1A Filing                | Northern Ireland |
| Variation 1AIN Filing              | Variation 1AIN Filing              | Northern Ireland |
| Variation 1B Filing                | Variation 1B Filing                | Northern Ireland |
| Variation 2 Filing                 | Variation 2 Filing                 | Northern Ireland |
| Withdrawal Filing                  | Withdrawal Filing                  | Northern Ireland |

## Entities

### Calyx RIM 7.0 Entities Updates

The migration performs multiple changes to the Calyx RIM entities.

#### Product Family

A new field **Show in Tree** with **Yes/No** is added to the **Product Family** entity, applicable for all the **Product Family Types**.

All entities migrated from previous application versions will migrate with 'Yes' selected, and will be shown in the Product Family Tree.

#### Full Product Presentation

A new flag with **Yes/No** values, **XEVMPD Submission Required?**, is added to the **Full Product Presentation** entity before the **Use Reference Active Ingredient** field to indicate that XEVMPD Submission for current Full Product Presentation is ready to be submitted to EMA authority. By default, the flag value is **Yes**.

After migrating to Calyx RIM 7.0, the new flag value will be **Yes** if **Full Product Presentation** does not have an EV Code value. If there is an EV Code value for the entity, the flag value will be **No**.

In addition, this new field as a column should be available on the **Full Product Presentation** tabs on the **Registration Attributes** window and on the Home page navigation pane respectively, and in the **Notifications > When a Value Changes** flow as an option for selection.

**Queries**

Two new OOTB Queries are introduced in Calyx RIM 7.0 for XEVMPD functionality:

- XEVMPD Submissions - QC Verification and Audit
- XEVMPD Submissions and Acknowledgement

To view new reports, you must have at least Read permission for the XEVMPD component. Reports appear in the **Registration Planning and Tracking** tab.

**Leafs**

For every leaf that has **Actuate** populated, the **Actuate** value must be changed as follows:

| Actuate Value | Change to |
|---------------|-----------|
| onLoad        | L         |
| onRequest     | R         |
| other         | O         |
| none          | N         |

**Technical Administration**

**Calyx RIM 7.0: Technical Administration**

Be aware that migration performs the changes for some values in the Technical Administration section of Calyx RIM.

After migrating to Calyx RIM 7.0, Livelink and SharePoint values will be removed from the Server Type value on the **Add Server** page in **DMS Server Management**.

Any Livelink or SharePoint servers will be deactivated.

**Calyx RIM 7.0 Prerequisite: Oracle Configuration Update**

The following Oracle configuration modifications must be performed on your database server before migrating any data and before installing Calyx RIM 7.0.

Please note the following descriptions and settings when performing the Oracle configuration update:

- MAX\_STRING\_SIZE controls the maximum size of VARCHAR2, NVARCHAR2, and RAW data types in SQL.
- STANDARD means that the length limits for Oracle Database releases prior to Oracle Database 12c apply (for example, 4000 bytes for VARCHAR2 and NVARCHAR2, and 2000 bytes for RAW).
- EXTENDED means that the 32767 byte limit introduced in Oracle Database 12c applies.

- The COMPATIBLE initialization parameter must be set to 12.0.0.0 or higher to set MAX\_STRING\_SIZE = EXTENDED.
- You can change the value of MAX\_STRING\_SIZE from STANDARD to EXTENDED. However, you cannot change the value of MAX\_STRING\_SIZE from EXTENDED to STANDARD.

### Increase Maximum Size of VARCHAR2, NVARCHAR2, and RAW Columns in a Non-CDB

To increase the maximum size of VARCHAR2, NVARCHAR2, and RAW columns in a non-CDB:

1. Shut down the database.
2. Restart the database in UPGRADE mode.
3. Change the setting of MAX\_STRING\_SIZE to EXTENDED.
4. Run the rdbms/admin/utl32k.sql script.  
You must be connected as SYSDBA to run the script.
5. Restart the database in NORMAL mode.

---

*Note: The utl32k.sql script increases the maximum size of the VARCHAR2, NVARCHAR2, and RAW columns for the views where this is required. The script does not increase the maximum size of the VARCHAR2, NVARCHAR2, and RAW columns in some views because of the way the SQL for those views is written.*

---

6. Run the rdbms/admin/utl1rp.sql script to recompile invalid objects.

### Post-Migration Script Updates for Calyx RIM 7.0

Be aware of the multiple changes the migration script performs.

The following changes take place:

- Any leaf that had **Actuate** populated must have the same value after the migration.
- **Server Type** value on Add Server page in *DMS Server Management* should not have Livelink or SharePoint available.
- Any Livelink or SharePoint server in **Servers** list should have **Active Flag** set to N.

### Database Script Error Messages

The following table represents previously detected database script errors that you might 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. |

| Upgrade path            | Error   | Description/Resolution  |
|-------------------------|---|---|
| 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"> <li>– Excipient</li> <li>– Active_ingredient</li> <li>– Prod_acting</li> <li>– Prodfam_acting</li> <li>– Pds_excip</li> <li>– Pds_excip_change</li> <li>– Concentration_unit_type</li> <li>– Fda_device_class_type</li> <li>– Eu_class_type</li> </ul> <p>Also ignore the following error messages:</p> <ul style="list-style-type: none"> <li>– 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</li> <li>– 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</li> </ul> | <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--&gt;</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 style="text-align: center;">*</p> <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"> <li>— Line 146: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":</li> <li>— Line 363: ORA-00942: table or view does not exist</li> <li>— Line 4344: ORA-02437: cannot validate (AUD.PKAPPLICANT_CONTACT) - primary key violated</li> <li>— Line 4345: ORA-06512: at line 58</li> <li>— Line 9644: ORA-00942: table or view does not exist</li> <li>— Line 15517: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":</li> </ul> | 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"> <li>— ORA-24344: success with compilation error</li> <li>— ORA-06512: at line 115</li> </ul>  | Ignore   |

| Upgrade path                  | Error  | Description/Resolution  |
|-------------------------------|--|---|
| 6.1 to 6.1 CHF 1              | <pre> - ***** 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                     </pre> | Ignore  |
| 6.1 to 6.1 CHF 1              | <pre> - 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                     </pre>                         | 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              | <pre> ORA-02264: name already used by an existing constraint                     </pre>  | DO NOT IGNORE. Call Technical Support   |
| 6.1 to 6.1 CHF 1 to 6.1 CHF 2 | <pre> ERROR at line 1: ORA-04043: object WRITE_STORAGE_REQUIREMEN TS does not exist                     </pre>   | Ignore  |
| 6.1 CHF 1 to 6.1 CHF 2        | <pre> - ORA-24344: success with compilation error - ORA-06512: at line 115                     </pre>  | 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"> <li>— ORA-01918: user 'DBCOMMON' does not exist</li> <li>— ORA-04043: object GET_DIRLIST does not exist</li> <li>— ORA-00904: "SUB_TO_ADD_MONITOR_CODE": invalid identifier</li> <li>— ORA-00904: "ORPHAN_DRUG_FLAG": invalid identifier</li> </ul> | 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"> <li>— ORA-00001: unique constraint (MGR.AK0BROAD_INDC_COUNTRY) violated</li> <li>— ORA-00955: name is already used by an existing object</li> </ul>   | 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"> <li>— ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated</li> <li>— ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated</li> </ul>  | 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  |
| 6.1 CHF 4 to 6.2 CHF 1              | ORA-24344: success with compilation error  | Ignore  |

| Upgrade path                | Error  | Description/Resolution  |
|-----------------------------|--|---|
| 6.1 CHF 4 to 6.2 CHF 1      | Any errors for the PACKAGE BODY<br>ISM.PRODUCT_FAMILY_COPY:  | Ignore  |
| 6.1 CHF 4 to 6.2 CHF 1      | ORA-02298: cannot validate (MGR.T_1671) - parent keys not found  | Ignore  |
| 6.2 (new installation only) | drop table d_date * ERROR at line 1: ORA-00942: table or view does not exist   | Ignore<br>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. |
| 6.2 CHF 1 to 6.2 CHF 2      | <ul style="list-style-type: none"> <li>- drop table</li> <li>- dbcommon.role *ERROR at line 1:ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type *ERROR at line 1:ORA-00942: table or view does not exist</li> </ul> | Ignore.   |
| 6.2 CHF 2 to 6.2 CHF 3      | <ul style="list-style-type: none"> <li>- drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist</li> <li>- drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist</li> </ul>        | Ignore  |

| Upgrade path           | Error   | Description/Resolution |
|------------------------|---|------------------------|
| 6.2 CHF 3 to 6.2 CHF 4 | <pre> - 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_ove rides * ERROR at line 1: ORA-00942: table or view does not exist           </pre> | Ignore                 |
| 6.2 CHF 4 to 6.2 CHF 5 | <pre> 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           </pre>   | Ignore                 |

| Upgrade path           | Error   | Description/Resolution |
|------------------------|---|------------------------|
| 6.2 CHF 5 to 6.2 CHF 6 | <pre>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</pre> | Ignore                 |
| 6.2 CHF 6 to 7.0       | <ul style="list-style-type: none"> <li>— ORA-02443: Cannot drop constraint - nonexistent constraint</li> <li>— ORA-01418: specified index does not exist</li> </ul>                       | Ignore                 |

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

**Table 5: 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. Call 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

# Index

## D

Data Migration 1–4, 6, 16, 18–24, 27–29, 40