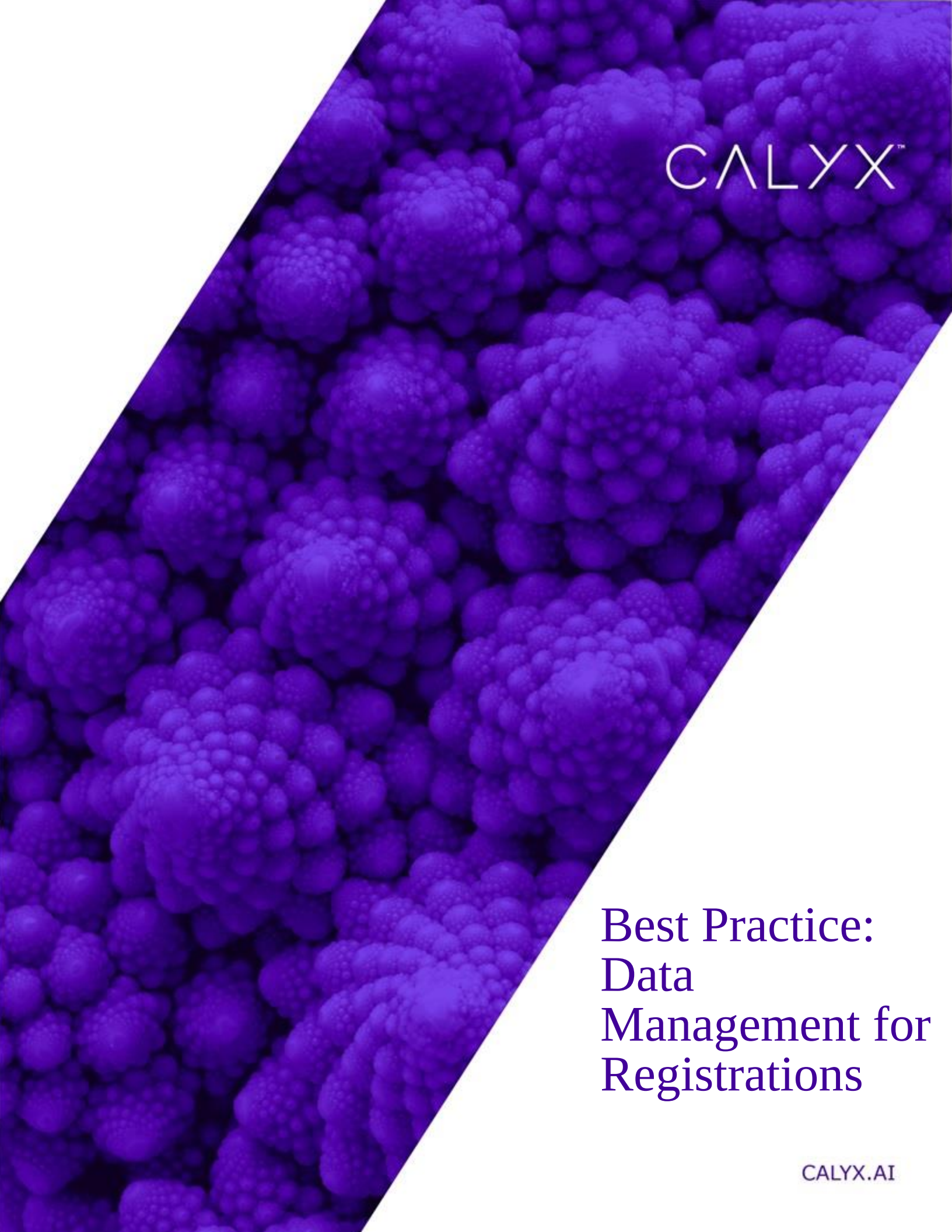


Best Practice: Data Management for Registrations

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s)
v7.0	30-Apr-2021	Update Best Practice for v7.0 - Impact
N/A	18-Mar-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

2 Contents

3 Document Purpose

The purpose of this document is to provide best practice guidance for tracking data in Calyx RIM Registrations component. It is the responsibility of each organization to decide what and how data are tracked. This document reflects Calyx's best practices based on why and how the system was designed and implemented, taking into consideration industry standards and experiences.

This best practice document focuses on the Registration Planning and Tracking (RPT) and Product Detail Management (PDM) modules of Calyx RIM for Registrations. Calyx RIM Publisher and Submission Planning and Tracking Data Management best practices are covered in a Calyx RIM Publisher specific best practice document and specific publishing best practice documents. If utilizing the full Calyx RIM suite within your organization, the Calyx RIM Publisher best practice documents should be used in conjunction with this document. Publishing should be taken into consideration when implementing these best practices.

4 General Considerations

This section describes basic rules and expectations.

1. Company Style Guides and Operation Guides should be in place (including naming conventions and abbreviations) and should be used consistently throughout the organization. Standard, agreed upon naming conventions are highly recommended. They are critical for consistency, searching, reporting and migration. Company Style Guides and Operation Guides will help enforce the use of the conventions.
2. The System Configuration Specification will identify the fields that are included in each client's configuration of Calyx RIM for Registrations and company user guides will define any specific fields as required. Not every field in the system is described in this document.
3. Fields should not be repurposed. Using fields for reasons other than what was intended could lead to future migration and upgrade problems.
4. Special characters should be avoided. Different characters are often "reserved" in most software, meaning they are used in performing specific functions. One example is that the "/" and "\" often implies a change in folder structure, which is the case for Application Name when clients are using the entire Calyx RIM Suite. It is considered best practice to not use any special characters.
5. The use of Descriptions, Comments, and Keywords fields should be clearly stated in the Company Style Guide or Operation guide. If it is determined that these fields do not add extra value on a particular entity, they should be hidden. This will ensure that erroneous information is not being entered.
6. Best practice is for each client to have a Business Process Workshop (BPW) and System Set-up Workshop (SSW). At the BPW, essential data and processes are determined. The SSW will streamline the client's specific needs and identify fields to be hidden (attributes that are not needed), renamed, or added into the client specific configuration. This will minimise user errors and maximise data and process efficiency. This will also help identify and limit any potential conflicts with future migrations and upgrades.
7. Best practice is to use the required fields for XEVMPD and those proposed for IDMP that are identified within the System Configuration Specification documentation. This will ensure alignment with harmonised regulatory requirements.

5 Design Overview

The Calyx RIM for Registrations data model is designed with a hierarchy and also with relationships.

The relationship of the entities is as follows:

Project can be for -

- 1 Family Type
- 1 or more Product Families within the Family Type
- 1 or more Events within each Product Family
- 1 or more Events within an Application
- 0 or more Sequences within an Application
- 0 or more Product Detail Sets (PDS) – these can be both within a Product Family and across Product Families

Product can -

- have 0 or more Components; however, as best practice at least one Component is required for each Product
- be associated to 0 or more Applications
- have 0 or more PDSs. One Product is likely to have more than 1 PDS when there are formulation changes to the product (e.g. flavors)

Application must -

- have 1 or more Products associated to it
- be for 1 or more Countries (e.g. GCC, EU DCP, MRP and CP Procedure Types)
- have 0 or more Event(s)
- have 0 or more Sequences
- have 0 or more PDS
- have 0 or more Registrations
- either have Package Set Registrations OR Product Registrations, but NOT both. (Once the Application entity is saved the Registration Type cannot be modified.)

Event can -

- have 0 or more Sequences
- have 0 or more Products associated to it (only those Products associated with the Application may be associated with an Event)
- have 0 or more PDS associated to it (this is how Calyx RIM for Registrations tracks the history of the detail changes – the Application owns the PDS, but the details are tracked through the Event)
- have 0 or more Change Details associated to it from 1 or more Change

Sequence can -

- have 0 or 1 Assembly

Change can -

- have 0 or 1 Change Detail

Change Detail can -

- be associated to 0 or 1 open Event within an Application

Package Set Registration can

- be for 0 or more Package Sets;, however, as best practice at least one Package Set is required.

- have 0 or more Full Product Presentations

Full Product Presentation can -

- have 0 or more Registration FPP Attachments

Product Registration can -

- be associated to 0 or 1 Event
- be associated to 0 or more Products for an Event

Product Detail Set -

- will have 0 or more Details – details may be broken out by component, specific to the entire PDS, or a combination of both

6 Product Family (PF)

Product Family (PF) is the highest level for logically grouping products and the information tied to products. Defining the Product Family (PF) will depend upon the Family Type being created. Best practice is to have a company Style Guide/Operation Guide with these agreed upon terms to be used throughout the organization

- When considering the naming convention for Family Names, keep in mind that the system will be used globally. Family Name should be a name that is common to all areas (avoid names specific to one region or a handful of countries).

6.1 Family Types

Family Types are used to control the type of data that is tracked at the various Product levels (PF, Product, PDS) regardless of how an Application for the Product may be made in various countries. There are Products that are considered as Pharmaceutical (Medicinal) products in some countries and Medical Devices in other countries. It is important to select the correct Family Type based on the **data** that needs to be tracked. The Application level in the system will identify how the product is actually classified in a country.

The following Family Types are included out-of-the-box:

- Pharmaceutical
- Medical Device
- Pharma-Med Device
- Veterinary
- Flu Vaccine

6.2 Pharmaceutical Families

In the case where the PF has only 1 or 2 Active Ingredients, it is considered best practice to use a concatenation of the Active Ingredient names as the Family Name. If there are more than 2 active ingredients, the name can get quite long. Therefore, it is appropriate to discuss alternate naming conventions to ensure that the Name will be easily recognized globally.

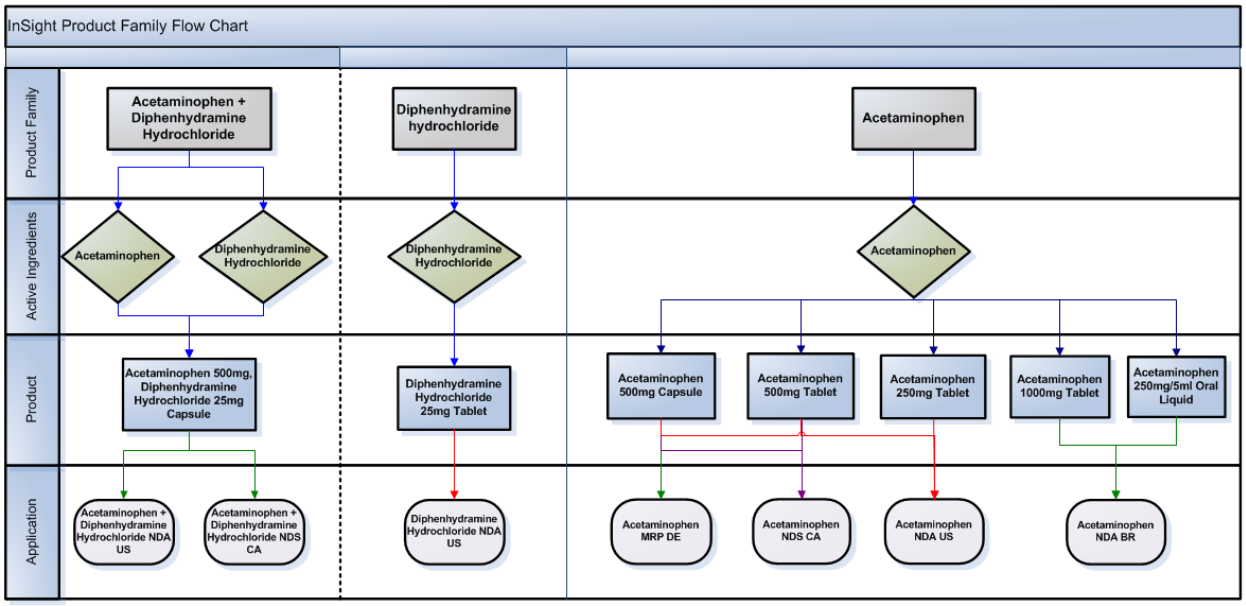
Scenarios to consider when defining a Product Family:

- A Pharmaceutical Product Family is a grouping based on the sum of its active ingredients.
- New active ingredients cannot be added to an established Product Family (one where a Product has already been created).

- A Pharmaceutical Product Family should not include active ingredients that are not used in all Products within that Product Family.

The following example demonstrates how different Products with the same active ingredients are handled in Calyx RIM Product Families. Care should be given to ensure that Products within the Product Family could realistically be included within the same MAA or NDA. In this example, the Acetaminophen + Diphenhydramine hydrochloride capsules would never be considered in the same application as the Diphenhydramine hydrochloride tablet and are therefore tracked in a separate Product Family.

Figure 1 Product Family example schematic



More Product Family examples are provided in Appendix 1: Product Family Scenarios.

6.2.1 Veterinary Families

When defining a Veterinary Product Family, the same rules apply as with Pharmaceutical Product Families. There are some fields that are different when comparing a Veterinary Product Family to a Pharmaceutical Product Family. Details on fields can be found in the Calyx RIM for Registrations System Configuration Specification documentation.

6.2.2 Medical Device Families

When defining a Medical Device Family, most of the same rules apply as with Pharmaceutical and Veterinary Product Families. The exceptions are that there are no active ingredients, substances, or species for a medical device. Even with these exceptions, best practices are similar. Products with the same mode of action are grouped together. Typical examples of Medical Devices Product Families are:

- Syringes
- Heart pacemakers
- X-ray machine
- Scalpels
- Insulin packs (even if that pack contains a Syringe captured in the Syringes Product Family)
- Medicated plasters
- Heart valves

- Bone cement

6.2.3 Pharma-Med Device Families

When defining a Pharma-Med Device Family, most of the same rules apply as with Pharmaceutical Product Families and Medical Device Product Families.

6.2.4 Flu Vaccine Families

When defining a Flu Vaccine Product Family, most of the same rules apply as with Pharmaceutical Product Families unless specifically described within this document. At the Product Family level, substitute active ingredients (of type AI Placeholder) are assigned rather than the specific Flu strain itself. This allows for the annual strain updates while still maintaining the restrictions of the active ingredient at the Product Family Level.

6.3 Further Best Practice for Product Families

1. Product Trade Names are defined in Data Administration, assigned at the Product Family Level, and associated in the Product Detail Set that falls below the Application in the Calyx RIM for Registrations hierarchy. Product Trade Name is the short trademark name known within a country without describing the strength and the form of the product; it is often assigned to a trademark. It is therefore not best practice to create separate Product Families for products that are marketed with different names, even if they are marketed in the same country under different names.

2. A Product that spans both Human and Animal health must be managed separately under two different Product Families to accommodate the way Calyx RIM for Registrations handles the two Family Types.

3. A Product that is registered as a Pharmaceutical in some countries and as a Medical Device in other countries may be tracked in a Pharma-Med Device Product Family or Pharmaceutical Product Family, depending on the type of data that needs to be tracked. The Pharma-Med Device Family Type is a Product Family that captures a combination of all the data tracked in a pharmaceutical product or a medical device product. During the SSW, the Calyx consultants will assess the Family Types required to support the Client's portfolio.

7 Products

The Product Name must be unique within a Product Family.

7.1 Products - Pharmaceutical

Products defined under a Pharmaceutical Product Family in Calyx RIM for Registrations are the various Dosage Forms and Strengths within a Product Family. A Product is defined as the unique combination of dosage form and active ingredient strength (differences in the formulation are tracked as different PDSs associated with the same Product). As best practice, a Product Name should contain the same name as the Product Family. There are several fields on the product that are automatically concatenated by the system when the full product name is displayed. These fields should be taken into consideration when defining the Product Name. Otherwise, the Product Name could have repeated information within it. The fields that concatenate are:

- Product Name – As best practice this should at least start with the name chosen for the Product Family. Samples shown below will provide more explanation
- Product Strength Measure 1

- Product Strength Unit 1
- Product Strength Measure 2 (used for liquid strength measurements)
- Product Strength Unit 2 (used for liquid strength measurements)
- Product Dosage Form

The full product name when displayed is concatenated as:

<Product Name> <Product Strength Measure 1> <Product Strength Unit 1>/< Product Strength Measure 2> <Product Strength Unit 2> <Product Dosage Form>

Example 1

- Product Name: paracetamol 500 mg / caffeine 50 mg
- Product Strength Measure 1 <blank>
- Product Strength Unit 1<blank>
- Product Strength Measure 2 <blank>
- Product Strength Unit 2 <blank>
- Product Dosage Form: tablet

When concatenated, the Product Name is displayed as:

paracetamol 500 mg / caffeine 50 mg tablet

Example 2

- Product Name: paracetamol, caffeine, aspirin / 500 mg, 50 mg, 25 mg
- Product Strength Measure 1 <blank>
- Product Strength Unit 1<blank>
- Product Strength Measure 2 <blank>
- Product Strength Unit 2 <blank>
- Product Dosage Form: capsule

When concatenated, the Product Name is displayed as:

paracetamol, caffeine, aspirin / 500 mg, 50 mg, 25 mg capsule

The following is an example of a liquid measurement that demonstrates the use of the Strength Measure 2 and Strength Unit 2 fields.

- Product Name – Ibuprofen
- Product Strength Measure 1 – 40
- Product Strength Unit 1 – mg
- Product Strength Measure 2 – 1
- Product Strength Unit 2 – ml
- Product Dosage form – Oral Suspension

When concatenated, the Product Name is displayed as:

Ibuprofen 40 mg/1ml Oral Suspension

As a best practice, the product Dosage form should refer to the combined pharmaceutical form of the product. (e.g.: Powder and Solvent for Solution for Injection)

The following is an example of a product that is reconstituted before administration:

- Product Name – Ibuprofen 200mg
- Product Strength Measure 1 <blank>

- Product Strength Unit 1<blank>
- Product Strength Measure 2 <blank>
- Product Strength Unit 2 <blank>
- Product Dosage form – Powder and Solvent for Solution for Injection

When concatenated, the Product Name is displayed as:

Ibuprofen 200mg Powder and Solvent for Solution for Injection

Another Best practice for Product level data is that all Routes of Administration should be entered at the Product level. Even in cases where there are multiple components having their own specific routes of administration, all of these Routes should be entered at the Product Level.

7.1.1 Sample Best Practice Product Names

Although the full Product Name is concatenated as explained above, it does not always make sense to use the Strength fields when defining the full Product Name. For consistency, most products (even those containing only 1 active ingredient) should include the strength information directly in the Product Name. From a best practice perspective. The most important aspects of naming the product are to include the Family Name in the Product Name field and to ensure the name is familiar to the entire organization. Some examples:

- Ibuprofen 250 mg
  - Single active ingredient
  - Dosage Form = Tablet*
- Ibuprofen 40 mg/ml
  - Translates to: for every 1ml of product, there is 40 mg of the active ingredient
  - Dosage Form = Injection*
- Ibuprofen 0.5 ml
  - One active ingredient with one strength defined
  - Dosage Form = Solution for Injection*
- Ibuprofen + Caffeine 0.5 mg/2.5 mg
  - One product with 2 active ingredients, the ibuprofen content is 0.5 milligrams, the caffeine content is 2.5 milligrams
  - Dosage Form = Inhalation Gas*
- Ibuprofen + Caffeine + Aspirin. 500 mg, 25 mg, 100 mg
  - One product with 3 active ingredients, the active ingredient strengths follow the same order as the active ingredients
  - Dosage Form = Tablet*

*The Dosage Form will be concatenated with the Product Name when the Product Name is displayed system wide.

7.2 Products - Veterinary

When defining a Product under a Veterinary Product Family, the same rules apply as with Product for Pharmaceutical Product Family. There are some fields that are different when comparing both Products. Details on fields can be found in the Calyx RIM for Registrations System Configuration Specification documentation.

7.2.1 Sample Best Practice Product Names

For Product Family Ivermectin:

- Ivermectin 55 mcg
  - Single active Ingredient
  - Dosage Form = Chewable Tablets*

For Product Family Ivermectin + Pyrantel Pamoate

- Ivermectin + Pyrantel Pamoate 272 mcg/227 mcg
  - Two active ingredients
  - Dosage Form = Chewable Tablets*

*The Dosage Form will be concatenated with the Product Name when the Product Name is displayed system wide.

7.3 Products - Medical Device

Medical Device Products in Calyx RIM for Registrations are the various Presentation and Dimensions within a Product Family. As best practice, a Product Name should contain the same name as the Product Family. There are other fields that are specific to Medical Device Products. Details on fields can be found in the Calyx RIM for Registrations System Configuration Specification documentation.

7.3.1 Sample Best Practice Product Names

- For Product Family Stainless V-Clamp
  - Product 1 = Stainless V-Clamp 15°
  - Product 2 = Stainless V-Clamp 20°
  - Product 3 = Stainless V-Clamp 25°
  - Product 4 = Stainless V-Clamp 30°
- For Product Family Titanium V-Clamp
  - Product 1 = Titanium V-Clamp 15°
  - Product 2 = Titanium V-Clamp 20°
- For Product Family Fabric Composite Stent
  - Product 1 = Fabric Composite Stent 16-32mm Carotid Surgical Stent
  - Product 2 = Fabric Composite Stent 16-32mm Thoracic Surgical Stent
  - Product 3 = Fabric Composite Stent 18-42mm Carotid Surgical Stent
  - Product 4 = Fabric Composite Stent 15-42mm Thoracic Surgical Stent

7.4 Products - Pharma-Med Device

When defining a Pharma-Med Device Product, the same rules apply as with Product for Pharmaceutical and Medical Devices Products.

7.5 Products - Flu Vaccine

When defining a Flu Vaccine Product, the same rules apply as with Product for Pharmaceutical.

7.5.1 Sample Best Practice Product Names

- Trivalent Influenza Vaccine
  - No strength is defined at the Product level
- Diphtheria + Tetanus + Pertussis Vaccine 30 IU, 40 IU, 20 mcg
  - One vaccine with 3 antigens, the strengths follow the same order as the antigens

7.6 Product - Country Specific Details

Country Specific Details is applicable for Medical Device and Pharma-Med Device Family Type only. The Country Specific Details entity captures information related to Medical Device classification defined in advance of the approval process. Classification can be Country or Region specific. The organization will define the list of classifications that need to be captured. Some best practice examples are:

- FDA Regulation Number
- FDA Device Class
- EU Class
- Australian Medical Device Class

8 Components

Components help to define complex products. To understand the concept of a simple product it is helpful to understand the concept of a complex product. Examples of complex products may be those that have either more than 1 simple product packaged together to treat a specific indication (e.g. bi-phasic tablets), or products that are packaged with items that need reconstitution to treat the indication. Simple products only have 1 component (e.g.: tablet, syrup, capsule, scalpel, etc.).

Best practice is to always create at least 1 Component. Even for products considered to be “simple”, a Component should be created. This enforces consistency across the system and ensures that the Product Detail Set is set up correctly.

8.1 Pharmaceutical Components

Best practice for the naming convention of the Pharmaceutical Component is to use the Dosage Form as the name. In the case where there are multiple components with the same Dosage Form, the Dosage Form should be used as part of the name. Each Component should be clearly identifiable. For example, a birth control with two tablets, placebo and the active tablets. The Components could be identified as:

Component 1 = Active Tablet

Component 2 = Placebo Tablet

Best practice is that Dosage Form should be entered for each Component.

Best practice for entering Route of Administration will depend on the type of Component. If the Component itself truly has its own Route of Administration, then that is the Route of Administration that should be entered. If a Component does not have a route of administration by itself, the Route of Administration entered should be the same as for the

entire Product. An example of this type of Component would be an injectable product where Components must be combined prior to administration.

8.1.1 Sample Best Practice Pharmaceutical Components

Following are some samples that can be followed when defining Components.

Single Component Product for Pharmaceutical

Single Component Product examples are:

- Product: Ibuprofen 250 mg Tablet
  - Component Name: Tablet
  - Component Route of Administration: Oral
- Product: Ibuprofen 10mg/1mL Gel
  - Component Name: Gel
  - Component Route of Administration: Topical Use

Multi-Component Product for Pharmaceutical

Multiple Component Product examples are:

- Product: Ibuprofen 200mg Powder and Solvent for Solution for Injection
  - Component 1 Name: Powder
  - Component 1 Route of Administration: Subcutaneous
  - Component 2 Name: Diluent
  - Component 2 Route of Administration: Subcutaneous
- Product: Ibuprofen Multi-phase Tablets
  - Component 1 Name: Phase-1 Tablet
  - Component 1 Route of Administration: Oral
  - Component 2 Name: Phase-2 Tablet
  - Component 2 Route of Administration: Oral
  - Component 3 Name: Phase-3 Tablet
  - Component 3 Route of Administration: Oral
  - Component 4 Name: Phase-4 Tablet
  - Component 4 Route of Administration: Oral

8.1.2 Active Ingredients Pharmaceutical Products

All the active ingredients that are included in the Product Family level are available to associate with each Component being created. The user should enter the quantitative composition for the active ingredients that are in the Component. It is possible that a Component will not have an active ingredient such as placebos and diluents.

Note: If the active ingredient values are not completed at the Component Level, they will not be available for use in the Product Detail Set. Additionally, active ingredients that are not defined at the Product Family level will not be available for the Components.

8.2 Veterinary Product Components

Veterinary product naming and component management should follow the same convention and best practice as Pharmaceutical Products.

8.3 Medical Device Components

Medical Device Component creation will depend on the type of Medical Device being entered. In most cases, it is best practice to create at least 1 component for a Medical Device Product, especially if data will be tracked at the Product Detail Set Level. Since the types of Medical Devices and their make-up are quite vast, defining the structure of a Medical Device is typically done in the System Setup Workshops to ensure it is created appropriately. Below is just 1 possible example of how Medical Device Components may be defined:

For Product Family Stainless V-Clamp

- Product 1 = Stainless V-Clamp 15°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp
- Product 2 = Stainless V-Clamp 20°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp
- Product 3 = Stainless V-Clamp 25°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp
- Product 4 = Stainless V-Clamp 30°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp

For Product Family Titanium V-Clamp

- Product 1 = Titanium V-Clamp 15°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp
- Product 2 = Titanium V-Clamp 20°
  - Component 1 = Rubber Tip
  - Component 2 = Clamp

8.4 Flu-Vaccines Components

Flu-Vaccine product naming and Component management should follow the same convention and best practice as Pharmaceutical Products.

8.4.1 Active Ingredients Flu Vaccine Products

Placeholders for each strain are selected at the Product Family level (one for each potential strain) and captured for each Component. In Data Administration the Substance Type is defined as Placeholder (see Figure 2) strains are also captured in the Substances Data Administration with the Substance Type of Strain (see Figure 3).The association of the

Strain (and the name of any derived strain) to the Placeholder and the capturing of its concentration is described in the active ingredient, Flu Strain Detail in the Product Detail Set (see Figure 4).

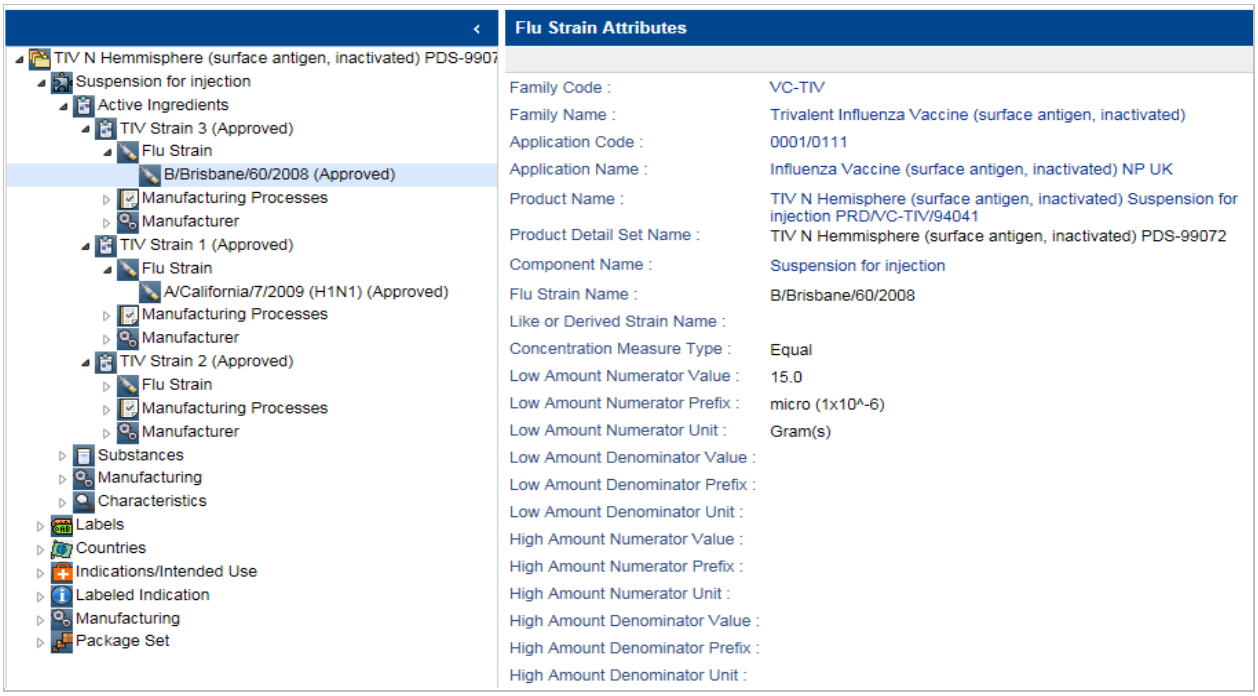
Figure 2 Flu Placeholders captured in Substance Data Administration table

Substance Name	Type	Active Flag
TIV Strain 1	Placeholder	Active
TIV Strain 2	Placeholder	Active
TIV Strain 3	Placeholder	Active

Figure 3 Flu Strains captured in Substance Data Administration table

Substance Name	Type	Active Flag
A/Brisbane/10/2007 (H3N2)	Strain	Active
A/Brisbane/59/2007 (H1N1)	Strain	Active
A/California/7/2009 (H1N1)	Strain	Active

Figure 4 Associating Flu Strains with Placeholders and concentration in PDS



9 Pharmaceutical Products (XEVMPD)

The Pharmaceutical Product entity is used to capture elements included in the XEVMPD schema required by the European Medicines Agency (EMA). The technical concept of a Pharmaceutical Product refers to an administrable dose form product. To understand the concept of a Pharmaceutical Product it is helpful to understand the concept of a "complex" product as for Component.

Best practice is to always create at least 1 Pharmaceutical product even for products considered to be "simple". If Calyx RIM is the source of information for XEVMPD generation, the Pharmaceutical Product must be used to capture XEVMPD relevant details. If Calyx RIM for Registrations is not being used for XEVMPD message generation or for capturing XEVMPD-relevant information, then consideration should be made to hide the entity.

As a best practice the Pharmaceutical Product Name should contain the Family Name, the strength and the administrable form of the product.

9.1 Sample Best Practice for Pharmaceutical Products

9.1.1 Single Pharmaceutical Product with single component

Single Pharmaceutical Product with single component examples:

- Product: Ibuprofen 250 mg Tablet
  - Pharmaceutical Product: Ibuprofen 250 mg Tablet
    - Associated with Component: Tablet
    - Administrable Dosage Form: Tablet
- Product: Ibuprofen 10mg/1mL Gel
  - Pharmaceutical Product: Ibuprofen 10mg/1mL Gel
    - Associated with Component: Gel
    - Administrable Dosage Form: Gel

9.1.2 Single Pharmaceutical Product with multiple components

This example will help you to understand a "complex" medicinal product and the difference between Product, Component, and Pharmaceutical Product entities.

Single Pharmaceutical Product with multiple component examples:

- Product: Ibuprofen 200mg Powder and Solvent for Solution for Injection
  - Pharmaceutical Product: Ibuprofen 200mg Solution for Injection
    - Associated with 2 Components:
      - Powder
      - Solvent
    - Administrable Dosage Form: Solution for Injection

9.1.3 Multiple Pharmaceutical Products

Multiple Pharmaceutical products will be created for a medicinal product that contains different administrable product.

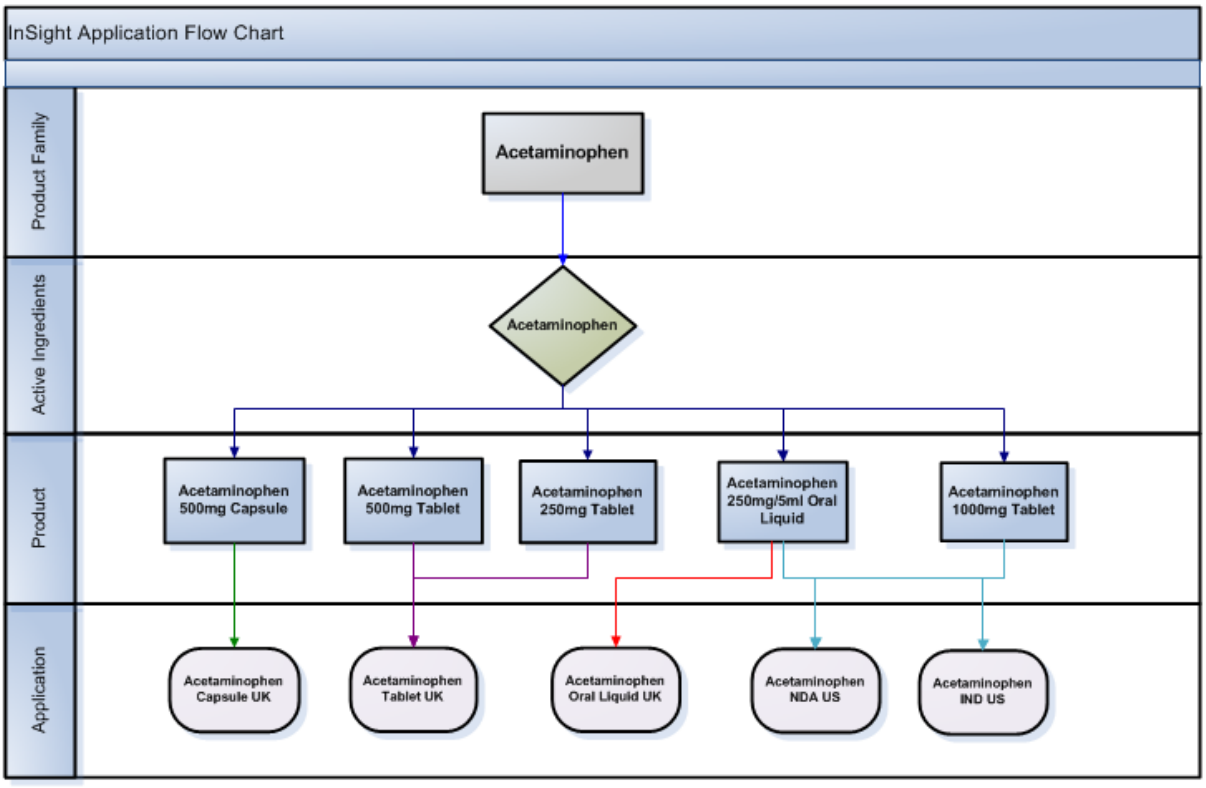
Multiple Pharmaceutical Product examples are:

- Product: Ibuprofen Multi-phase Tablets
  - Pharmaceutical Product: Ibuprofen 50mg Tablet
    - Associated with Component: Phase-1 Tablet
    - Administrable Dosage Form: Tablet
  - Pharmaceutical Product: Ibuprofen 100mg Tablet
    - Associated with Component: Phase-2 Tablet
    - Administrable Dosage Form: Tablet
  - Pharmaceutical Product: Ibuprofen 500mg Tablet
    - Associated with Component: Phase-3 Tablet
    - Administrable Dosage Form: Tablet
  - Pharmaceutical Product: Ibuprofen 1000mg Tablet
    - Associated with Component: Phase-4 Tablet
    - Administrable Dosage Form: Tablet
- Product: Ibuprofen Combi Tablet and Capsule
  - Pharmaceutical Product: Ibuprofen 100mg Tablet
    - Associated with Component: Tablet
    - Administrable Dosage Form: Tablet
  - Pharmaceutical Product: Ibuprofen 250mg Capsule
    - Associated with Component: Capsule
    - Administrable Dosage Form: Capsule

10 Application

Applications are captured at the country or region (EU, GCC etc.) level. This level facilitates tracking the lifecycle of a Product as it is approved by the regulatory authority. Products with different strengths and/or dosage forms can be associated with an Application if they share a **common** dossier that is maintained through the same lifecycle. The association of a Product (or Products) to an Application may differ depending on specific country regulations. Where possible the Application and its association with Products should match the regulatory process in each country.

Figure 5 Application example schematic. (In 7.0, it is possible to associate an Application with Products from multiple Product Families.)



10.1 Internal Code

The Internal Code should only be used if the organization has an established internal coding mechanism for identifying an Application. If this does not exist, best practice would be to hide the field from the user.

10.2 Application Code

10.2.1 Pharmaceutical, Flu Vaccine and Veterinary Applications

Best practice for the Application Code is to use the code provided by the regulatory body or organization being applied to for Marketing Authorization. If the Application Code is not known at the creation of the Application entity, best practice would be to use the Application Name until such time as the Application Code is known. The Application Code is used within Calyx RIM Publisher to create the parent folder for the output file of a submission. Therefore, it is not recommended to use the special character '/'.

Some best practice examples:

- FR-H-0450-001-003
- EMEA-H-C-002835

Beginning in v7.0, a new uniqueness rule requires that the Application Code/Application Name combination be unique for all Applications.

10.2.2 Medical Device Applications

Best practice for the Application Code for Medical Device Applications is to use the code provided by the regulatory body or the organization seeking marketing approval. If the Application Code is not known at the creation of the Application entity, best practice would be to use the Application Name until such time as the Application Code is known.

10.3 Application Name

Regardless of the Family Type, when determining the Name for an Application, apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

Beginning in v7.0, a new uniqueness rule requires that the Application Code/Application Name combination be unique for all Applications.

10.3.1 Pharmaceutical, Flu Vaccine, and Veterinary Applications

The Pharmaceutical and Veterinary Application Name should conform to a naming convention that can be applied across all Pharmaceutical or Veterinary Applications and should have some logical meaning to the users. It may also take into consideration the organizations registration strategy.

Pharmaceutical, Flu Vaccine, and Veterinary Application Name Examples

- <Family Name> <Type of Application> <Country or EU Procedure> <RMS/Rapp (if appropriate)
  - Ibuprofen + Caffeine MAA UK
  - Ibuprofen + Caffeine MAA CP DK
  - Ibuprofen + Caffeine MAA MRP BE
  - Ibuprofen + Caffeine MAA DCP DE
  - Ibuprofen + Caffeine NDA US
  - Ibuprofen + Caffeine ABNDS CA
  - Ibuprofen + Caffeine IND US
  - Ibuprofen + Caffeine CTA BE
  - Ivermectin + Pyrantel Pamoate ANADA US

10.3.2 Medical Device Applications

The Medical Device Application Name should conform to a naming convention that can be applied across all Medical Device Applications and should have some logical meaning to the users.

Medical Device Application Name Examples

- <Family Name> <Type of Application> <Country/Region>
  - Stainless V-Clamp PMA US
  - Pacemaker 510K US
  - Stainless V-Clamp CE-Cert EU

10.4 Procedure Identifier

Best practice for the Procedure Identifier is to use the code provided by the regulatory body that is common to all products that are part of the Application.

Note: For a European MRP / DCP, the Procedure Identifier should contain the country code of the Reference Member State + Human or Veterinary indicator + the medicinal product number. Whereas the speciality number characterizing the strength or pharmaceutical form will be tracked at the PDS level under the Speciality Number field.

Examples:

- FR/H/0450/
- EMEA/H/C/002835

10.5 Basic Considerations

When using the Copy Application or the Create New Application in Global Project Planning functionality, Calyx RIM for Registrations will append the 2-digit country code to the Internal Code, Application Code, and Application Name to add uniqueness to those fields. If using the Copy Application functionality, it is suggested that the Application being used to copy from NOT include a country identifier until after the copy is performed.

11 Management of Change

Management of Change functionality enables the description of individual changes to be included in a regulatory submission. Management of Change gives the capability to be linked with external change control tools. This functionality enables the organization to track individual Change Details statuses included in a regulatory Submission. This enables effective cross-reporting between Calyx RIM and external control changes and the ability to use Data Exchange functionality to automate some activities, e.g. creation, status updates, etc. within each tool. Where an external change control tool is used, it is anticipated that a Change will be initiated in Calyx RIM once the initial impact assessment has been undertaken in the external change control tool.

11.1 Changes

Changes enable you to plan and track global changes with Change numbers that can refer to external tools or software. Although it is up to individual organizations, it is considered best practice to use Changes to provide a connection

between external change control tools and Calyx RIM. The Calyx RIM Change is the overall change that the organization wishes to implement.

11.1.1 Change Type

Change Types are used to categorize the Change to support reporting needs, they can be modified to suit the needs of each organization. The appropriate Change Types should be captured for each Change and at least one Change Type must be selected for each Change.

11.1.2 External Change Number

If there is an intention to cross-report across an external change control tool and Calyx RIM, or if there is a need to capture an external change control number from an external tool, the External Change Number field should be used.

11.1.3 Change Short Description

Change Short Description is a mandatory field that is used to identify the overall Change. This field will be used in views of the Change from other entities and so a concise description should be provided.

Examples:

- Finished Product Acetominophen 250mg Tablet, Calyx London Site Change to Calyx Berlin
- modification to use FD&C blue in film coat

11.1.4 InSight Change Number

The InSight Change Number is an automatically created sequential number applied to each Change to provide a unique reference within the system. The number is immutable.

11.2 Change Details

Due to different regulatory requirements across countries, each Change may need to be split into 1 or more Change Details. This allows different combinations of Change Details to be associated with an Event (regulatory objective) to support these regulatory differences. It is the Change Detail that has the association with the Event. Each Change Detail has a status related to its associated Event named “Event-Change Detail Status”.

11.2.1 Change Detail Number

The Change Detail Number is a modifiable reference number to identify each Change Detail. It is recommended to ensure that this number is unique within Calyx RIM by modifying only the suffix and retaining the prefix as the InSight Change Number.

11.2.2 Change Detail Short Description

The Change Detail Short Description is a mandatory field that is used to identify each specific Change Detail. This field will be used in views of the Change Detail from other entities and so a concise description should be used.

Examples:

- pH modification
- address change

- label update

12 Event

Events are used to track the Regulatory Actions (Variations, Supplements, etc.) that occur against each Application. An Event represents a regulatory objective that can group multiple actions (Change Details) depending on country requirement. Note that this section applies to all Family Types.

12.1 Event Code

The Event Code may be used if the organization has an established internal coding mechanism for identifying an Event. If not, the best practice would be to hide the field from the user.

12.2 Event Name

The Event Name should conform to a naming convention that can be applied across all Events/Applications and should have some logical meaning to the users. It may also take into consideration the organization's registration strategy. The Event has additional fields to help in identifying the type of Event, so adding detail specific to the Event can be helpful when querying. Since adding this detail can also make it difficult to define the naming convention clearly, it is considered best practice to come up with an example of the Events that happen most often so users can follow the convention as closely as possible. Event Code and Event Name within an Application must be unique. When Event Code is hidden, Event Name must be unique.

Some best practice examples:

- <Basic Type> followed by one of the following
  - <Name of Manufacturer>
  - <Type Detail>
- Examples:
  - Initial Filing
  - Mar 2017 Safety Report – 6 months
  - New Manufacturer – Vandelay Industries
  - Labeling – Storage Condition to 18 months
  - New Packaging – 24 count blister
  - March 2017 Renewal
  - New Strength – 500 mg
  - 513(g) Request – Jun 2017
  - 30 Day Notice – Dec 2016
  - Class III Period Report – Sep

12.3 Event Type and Secondary Event Type

These fields allow for easier querying on "like" Events. Regional differences should be taken into consideration when defining these types, although wherever possible it is best practice to agree on a global definition of Event Types and Secondary Event Types. Some out of the box Types from a best practice perspective are:

- Primary: New Application
- Secondary: Full Filing
- Secondary: Abridged Filing

- Primary: Extension
- Secondary: Active Substance
- Secondary: Indication
- Secondary: Strength/Form/Route

- Primary: Type I Variation
- Secondary: Deletion of an indication
- Secondary: Type IA
- Secondary: Type IB
- Secondary: Change in content – manuf. Author
- Secondary: Change in shelf life after first opening
- Secondary: Change to markings on tablet

12.4 Basic Considerations

Event Codes and Event Names must be unique within an Application. Naming convention should be considered to ensure uniqueness constraint. For repeating Events (like Annual Reports, PSUR, or Renewals) it is considered best practice to add a date to provide more clarity to the Event. Just as with Applications, when determining the Name for an Event it is best practice to apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

12.5 Event Status Schedules

Event Status Schedules are used for tracking the milestones planned and achieved for each Event (Regulatory Action). It is considered best practice to use the Event Planning functionality to assist in the tracking of these milestones. Timeline/Event Plans are created in the Data Administration section of Calyx RIM for Registrations. Timeline/Event Plans are either Procedure Type or Event Type specific; this determination is made at the time of creation and will depend on the type of Timeline/ Event Plan being created.

Timeline/Event Plans are defined ahead of time for the various types of Events that occur. The statuses (milestones, e.g. Dispatch, Submission, Approval) are defined with the appropriate lead times. When Events are created, an Event Plan is used to automatically add the milestones and include the projected dates on which the milestones are expected to be reached. (See the Calyx RIM for Registrations User Guide for instructions on the use of this feature). A standard plan should be available for selection for Events that will often follow the same path and the same approval times for a country. Since Plans are created in Data Administration, it is Business Administrators who will need to apply a naming convention and users would be trained to understand which plans should be used when.

Timeline / Event Plan Names should conform to naming conventions and be easily understood by the user so that the desired Plan is selected. To help users conform to the naming conventions, define examples based on the Events that happen most often so users can follow the convention as closely as possible.

Examples:

- Initial Filing <country> or <region> or <”global”> or <procedure>
- New Manufacturer <country> or <region> or <”global”> or <procedure>
- Labeling Update <country> or <region> or <”global”> or <procedure>

- New Packaging <country> or <region> or <"global"> or <procedure>
- New Strength <country> or <region> or <"global"> or <procedure>

13 Sequences

Sequences are used to track the actual submissions (document set) sent to a regulatory authority for the purposes of gaining approval for the Event (Regulatory Action). There can be multiple Sequences that occur for each Event.

Although it is ultimately up to individual organizations, it is considered best practice to track the submissions at the Sequence level and as part of that best practice to attach the Sequence to only 1 Event, whereas each Event may have multiple Change Details. This provides the organization with the ability to know the status of submissions at any given time. Historically, it helps in the planning of new submissions because it shows exactly how long it took to obtain approvals of the various types of changes.

Note: If Calyx RIM is already being used for Assembly tracking and Publishing, the conventions for Sequences should follow the rules that have been established for the Publishing process.

Note: If one Sequence is linked to multiple Events, it will require careful handling of the Wizards used.

13.1 Sequence Code

Sequence Code must be unique within an Application. It is considered best practice to use the eCTD conventions for Sequence Code values for eCTD or NeeS. If an Application is not under eCTD publishing rules, care should be taken to not use eCTD numbering in case of future conflicts. When eCTD will be implemented the sequence numbering will continue.

13.2 Sequence Name

The Sequence Name should conform to a naming convention that can be applied across all Sequences, regardless of the Application and Event, and should have some logical meaning to the users. Including the Sequence Code (if an eCTD) and a simple description of the filing reason and a filing type can help in showing the logical progression of the Sequences when looking at the name. Examples of this are:

- <Sequence Code> <Filing Description> <Filing Type >

Examples:

- 0000 Safety Report – 6 months – Safety Filing
- 0003 New Manufacturer-label change – Vandelay Industries – Variation Filing
- New Manufacturer-label change – Vandelay Industries Supplement Filing
- Labeling – Storage Condition to 18 months – Variation Filing
- New Packaging – 24 count blister – Variation Filing
- New Packaging – 24 count blister – Reformat Filing
- Renewal – Renewal Filing
- New Strength – 500 mg – Extension Filing

14 Product Detail Set

It is considered best practice to create Product Detail Set Templates that can be used when first applying for a particular product in a selected country or region. The Product Detail Set Template Name must be unique within a Product. Defining the best practices for a Product Detail Set (PDS) in this section assumes that it is within the context of an Application. Typically, only 1 PDS is needed for each Product associated to an Application. Refer to the previous sections that provide best practices for creating a Product. The Product Detail Set level is where details about the Product are defined, so although the same Product may be approved in different countries, the PDS details may be different for different countries. Since typically only 1 PDS per Product will be created, best practice for the Product Detail Set Name is that it is the same as the Product Name. Where there is a need for more than one Product Detail Set per Product in any Application, the name should include an identifier to enable them to be differentiated, e.g. Flavour. The Product Detail Set Name must be unique within an Application.

14.1 Speciality Number

For MRP/DCP, the specialty number characterises the strength and/or pharmaceutical form of a medicinal product that is part of the MRP/DCP procedure number. Procedure number results from the concatenation of the Procedure Identifier field from Application and the Specialty Number from PDS.

Examples:

Procedure Identifier = FR/H/0450/

Specialty Number = 001

➔ MRP/DCP number will be: FR/H/0450/001

14.2 PDS Components

There are several sets of details that may be tracked for each component within a PDS. The following describes best practices in defining these details.

14.2.1 PDS Component Active Ingredient Pharmaceutical Products

It is considered best practice to include active ingredient Details in the PDS Components.

14.2.2 PDS Component Active Ingredient Flu Vaccine Products

It is considered best practice to include active ingredient Details in the PDS Components.

PDS Component Active Ingredient Flu Strain

It is considered best practice to assign the Flu strain and any derived strain information at the Flu Strain level in the active ingredient Detail. The Flu Strain node also captures the quantity of each flu strain in the finished product.

PDS Component Active Ingredient Manufacturing Details

It is up to each organization to decide what level of active ingredient Manufacturing Detail is important to track. Best practice would be to track the Manufacturer who supplies the active ingredient or to track the actual Manufacturing Processes used to create the active ingredient, but not both. Although it is important to be consistent, it is appropriate to

track the supplier for some Products and track the entire Manufacturing Processes for other Products all within the same system.

14.3 PDS Component Substances and Substance Manufacturers

The PDS Component Substance will capture the ingredient of a component that is not the active ingredient. The Substance will be defined with its substance type (e.g. Excipient, Adjuvant).

It is considered best practice to include Substances and Substance Manufacturers (suppliers) in the PDS Components. Doing this will enable the organization to perform impact analysis queries on Substances and Substance Suppliers across Products and Applications

It is best practice to enter the values (quantitative composition) for each Substance contained in each Component.

14.4 PDS Component Manufacturing Details

Just as with PDS Component active ingredient Manufacturing Details, it is up to each organization to decide what level of Component Manufacturing Detail is required. Best practice would be to either track the Manufacturing Functions and the Manufacturers who perform the Functions or to track the actual Manufacturing Processes used to create the Component. Although it is important to be consistent, it may be appropriate to track the Functions for some Products and track the entire Manufacturing Processes for other Products all within the same system.

14.5 PDS Country Details

It is considered best practice to include Country Details for the Product in the PDS, specifically the Country Trade Name field. The list of Trade Names is populated from the selection made in the Product Family.

Approved Trade Names defined on the Country Details will be displayed on the Product Family entity for each product.

14.6 PDS Indications/Intended Use Detail

It is considered best practice to include the Indications/Intended Use for the product in the PDS. Tracking should be done on Approved, Not Approved, and Withdrawn Indications. These details are rolled up in various places in the system and if the data are not entered, then this valuable information will be missing. For example, on the Product view, approved indications are listed.

14.7 PDS Manufacturing Details

It is considered best practice to include PDS level Manufacturing Functions and the Manufacturers performing the Functions in the PDS. Doing this will enable the organization to perform impact analysis queries on Functions and Function Manufacturers across Products and across Applications.

14.8 PDS Package Set Details

It is considered best practice to include Package Sets in the PDS. Package Sets define each presentation in which the Product is packaged and sold under the Application. Package Sets are also used in the Registration entity to support countries that provide authorization numbers by package (e.g. 28 tablet pack and 96 tablet pack). The Package Set Name should conform to a naming convention that can be applied across all Events/Applications and should have some logical meaning to the users. It is preferable that the Product Name is not included in the Package Set Name so that

queries of “like” Package Sets can be done easily. It is up to each organization to decide what fields should be tracked at this level, but as best practice the following fields should be tracked:

- Shelf Life
- Shelf Life Unit
- Storage Conditions

14.8.1 PDS Packaging Details

It is considered best practice to include Packaging Details in the Package Set. Doing this will enable the organization to perform impact analysis queries on specific pieces of Packaging across Products and across Applications.

14.9 Basic Considerations

The status values for the various details cannot be changed. However, the detail names can be changed to meet organizations’ terminology. In addition, complete nodes can be hidden if an organization chooses not to capture information at a particular level.

15 Registration Entities

Registrations are used to track the licensing aspects of products within countries and/or regions (EU, GCC, etc.). Even for countries who do not necessarily issue a “license” or for products that are not formally approved by an external body, there are data elements found on the registration entities that should be tracked. This allows for consistency across the data. The Registration entity is the record of approval to place a product on the market.

In the European Union, there is a Sunset Clause provision that requires organizations to send periodic updates about the marketing status of their products to the authorities. This document will not address all of the Sunset Clause data except to say that it is considered best practice to track all the data related to this provision. Please see Appendix 2 for a list of the Sunset Clause data attributes.

The Registration information spans across several entities. Each is addressed below.

15.1 Registration

It is considered best practice to create a Registration for products that have been approved to be marketed at one time in the lifecycle of the product in a particular country (or Region) and to populate the fields identified in this section. As stated above, even if the authority did not issue a specific license code, it is considered best practice to create a registration so that queries can be run to show the status of a product from an approval perspective and to provide consistency for all queries that return Registration Data.

15.1.1 License Code

The Registration, license code, or MA number, when issued by a country or region should be used to populate the License Code field on the Registration. In the case where a license code was not issued, a naming convention should be established to guide users on how to populate the field.

Examples of possible values when a license code is not provided:

- <Application Code > (some text may be useful for reporting purposes to ensure that this is not mistaken for an authority issued License code)

- <Product Name> <initial approval date>

15.1.2 Marketing Authorization Holder

The Marketing Authorization Holder (MAH) should be entered for each Registration/License that is issued.

15.1.3 License Issue Date

The date on which the License was first issued should be entered for each Registration/License that is issued. This is an important date to track, especially for key reports and for countries that will approve new presentations against an existing License.

15.1.4 Registration Valid Until

The date on which the registration will expire should be maintained. This facilitates performing queries on upcoming expirations to plan for renewals, annual reports, or possible license cancellations.

15.2 Full Product Presentation

The Full Product presentation attributes support XEVMPD requirements. This Full Product presentation is only available for an Application of type Package Set Registration.

Best practice is to always create at least 1 Full Product Presentation per Registration and associate one or more Package sets.

Example of Full Product presentation:

- Full Product Name: ABCD ® 60 mg solution for injection in a pre-filled syringe
- Full Product Short Name: ABCD

The entity also captures the EV Code associated with the Approved Product and any previous EV codes for that Product.

15.3 Registration FPP Attachment (XEVMPD)

The Registration FPP Attachment supports XEVMPD to link the Prescribing Information Label to the Full Product Presentation aligned with its version.

Best practice is to always create a Registration FPP Attachment and associate it to the Full Product Presentation. The Registration FPP Attachment contains a reference to the Printed Product Information (PPI) that is stored in the Registration Attachments table from the Home Page.

15.4 Registration Package Set

It is considered best practice to create the Registration Package Set entry for each Package Set (presentation) approved against the license. This allows for querying on all the presentations that have been approved at one time for the life of a product in a country or region. There is no status on this piece of data because the status is specific to the information at the next level in the Registration hierarchy.

15.5 Registration Package Set Country

The Registration Package Set Country entity tracks additional license information per country. Many of the data required for tracking of the Sunset Clause can be found on this entity. Please see Appendix 2 for more detail on Sunset Clause data.

15.5.1 Currently marketed in this country?

This field is a toggle used to identify whether a product is currently marketed in the country and should be tracked against each license. It enables users to quickly identify the marketing status of a particular presentation of a product. The default on creation is 'No'.

15.5.2 Marketed Date

This date is used to identify the date on which the presentation was released to the market. It should be tracked so users can quickly identify this information. When queried with the above field, a user can see not only if a presentation is currently marketed or not, but if it is no longer marketed, the marketed date when populated implies that it was marketed at one time.

16 Clinical Trial Submissions

Calyx RIM for Registrations functionality supports the 2 main methods of submitting data in support of a clinical trial authorization:

- One Application detailing all clinical trials in a rolling submission (like the US IND)
- Individual Applications each detailing one clinical trial in one or more (EU procedure) countries (like the European CTA)

16.1 Clinical Trial Comparators

Comparators are used to capture specific details about comparators used in clinical trials across the Calyx RIM for Registrations hierarchy. To that end the comparators are not assigned to an individual Product Family. Comparators can be any of 3 types: Comparator, Placebo, or IMP. As a best practice, minimally the suppliers for each Comparator should be tracked. Your primary investigation medicinal product should be created as a Product and associated with the Application.

16.1.1 Clinical Trial Comparator Names

Clinical Trial Comparators may be named to match the investigational product they represent or will be compared with, for example:

- Ibuprofen comparator
- Ibuprofen placebo matched capsule

16.2 Clinical Trial Shared Data

The Clinical Trial Shared Data entity captures information about a specific clinical trial protocol. Since the Clinical Trial Shared Data entity is assigned to an Application's Event, it captures information that is relevant across all Application types (IND –like or CTA-like). As a best practice, the following information should be tracked:

- Protocol Code Number
- Protocol Title
- EUDRACT number (if applicable)

16.3 Clinical Trial Application

Clinical Trial Applications are captured at the country or region (EU procedures) level. This level facilitates tracking the lifecycle of a Clinical Trial (or group of Clinical Trials as in the US IND) as it is approved by the regulatory authority. As a best practice, the following information should be captured at the Clinical Trial IND/CTA Application.

16.3.1 Application Code

Best practice for the Application Code is to use the code provided by the regulatory body or organization being applied to for Marketing Authorization. If the Application Code is not known at the creation of the Application entity, best practice would be to use the Application Name until such time as the Application Code is known.

Beginning in v7.0, a new uniqueness rule requires that the Application Code/Application Name combination be unique for all Applications.

16.3.2 Study Number (CTA only)

Best practice for the Study Number is to use the internal Clinical Protocol Number.

Beginning in v7.0, a new uniqueness rule requires that the Application Code/Study Number combination be unique for all Applications.

16.3.3 Application Name (IND only)

Best practice for the Application Name is to apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

Beginning in v7.0, a new uniqueness rule requires that the Application Code/Application Name combination be unique for all Applications

17 References

References are used to help clients link external documents to specific entities based on their individual processes. In the System Setup Workshop (not covered in this document), clients will determine the right place for their users to attach references. In the workshop, clients will also decide the appropriate values to be used in the various drop-down selections. From a best practice perspective, clients should keep in mind that standard naming conventions should be considered, and examples should be provided in their Operations Manual. This will allow for consistency in the creation and tracking of References throughout the system. Reference Name must be unique within its association.

18 Tasks

Tasks help users track activities that need to be completed. Tasks will track due dates and statuses as the activities are being completed. In the System Setup Workshop (not covered in this document), clients will determine the right place for their users to attach tasks. In the workshop, clients will decide the appropriate values to be used in the various drop-down selections. From a best practice perspective, clients should keep in mind that standard naming conventions should be considered, and examples should be provided in their Operations Manual. This will allow for consistency in the creation and tracking of Tasks throughout the system. Task Name must be unique within its association.

19 Appendices

19.1 Appendix 1: Product Family Scenarios

Scenario 1

- Active ingredient: Liquentamycin
- 2 different Manufacturers (one to support EU one for US) each with its own manufacturing site
- 2 different Products: Liquentamycin tablets and Liquentamycin liquid
- Products may be sold as competitors by the same company (e.g. Liquentamycin tablet made in US is marketed in UK)

1 Product Family, 2 Products, 2 PDSs

Scenario 2

- Active ingredients: Brown Spider venom, Black Spider venom, Yellow spider venom
- 3 different products: One for each spider venom product, never included in same MAA

3 Product Families (Black Spider Venom, Brown Spider Venom and Yellow Spider Venom), 1 Product per Product Family, 1 PDS per Product

Scenario 3

- 1 active ingredient
- 3 different flavors
- Separate Registrations for each flavor

1 Product Family, 3 Products (each flavor), 3 PDSs

Scenario 4

- Active ingredient: Liquentamycin
- Registered in humans and horses

2 Product Families (1 Veterinary, 1 Pharmaceutical), 2 Products, 2 PDSs

19.2 Appendix 2: Sunset Clause

The following information is tracked specifically for the Sunset Clause. For more detail please refer to the Calyx RIM for Registrations User Guides.

- Currently Marketed – yes or no
- Marketed Date – the date the PDS is released into the distribution chain
- Marketing Cessation Date – the date when the PDS was last released in the distribution chain
- Temporary Cessation Date – date when the PDS “temporarily” ceased to be marketed
- Reason for temporary Cessation
- Estimated return-to-market date
- Restart Marketed Date – date when the PDS was returned to the market